

Digital Image Receptor



The PaxScan 4343R v1 / 4343R v2 is a radiographic digital x-ray imaging sub-system

Abstract The Operating Instructions (P/N 135156-000) covers safety, setup, operation, and maintenance of the PaxScan 4343R v1 and 4343R v2 product family of digital radiography image receptors. The receptor is a component sub-system intended for integration by a qualified systems integrator.



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Updates For updates to these instructions, please refer to the *Release Notes*.

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How To Reach Us

Technical Support In order to provide the most comprehensive hardware and software technical support, please send an email to flatpanelwarranty@vareximaging.com before contacting a Varex representative.

To speak with our technical support personnel, please call (800) 432-4422.

For warranty and returns, please visit <https://www.vareximaging.com/flat-panel-service-report>.

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General Safety Information



PLEASE READ THIS ENTIRE MANUAL BEFORE USING. PRIOR TO USING PLEASE ENSURE UNDERSTANDING OF THE WARNING, PRECAUTIONS AND ADVERSE EFFECTS RELATING TO THIS DEVICE.

Safety Warnings, Precautions and Contraindications

The Paxscan 4343R v1 and 4343R v2 are designed to be integrated into a complete X-ray system by qualified system integrator. The system integrator is responsible for obtaining FDA clearance for medical use.



Important:

No part of the Receptor is intended to be attached to a patient and/or to contact the patient.

The closeness of the Receptor to the patient is dependent upon the application by the system integrator.

All parts of the PaxScan Product Family are suitable for use within the patient environment.



Warning:

The Receptor 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 metal enclosure of the Receptor must be connected to earth ground.



Warning:

To reduce the potential of electrical shock, the operator should not simultaneously touch the patient, cable connections, ex-sync serial connector, fuse holders, and the power supply.



Warning:

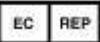
The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.



Note:

There are no contraindication situations.

Explanation of Symbols

	<p>On (power: connection to the mains)</p>		<p>Caution / Warning / Important: Describes action or conditions that could result in equipment damage, data loss, or personal injury</p>		<p>Protective Earth Ground</p>
	<p>Alternating Current</p>		<p>Off (power: disconnection from the mains)</p>		<p>Direct Current</p>
	<p>Handle With Care</p>		<p>Indicates step-by-step description of the respective function follows</p>		<p>Useful / Important information</p>
	<p>Authorized Representative in the European Community/European Union</p>		<p>Manufacturer</p>		<p>Consult Instruction for Use</p>
	<p>Temperature Limits</p>				

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Introduction

The PaxScan 4343R v1 and 4343R v2 is a radiographic digital X-ray device commonly referred to as flat panel detector (FPD) or receptor. The detector together with image processing and command software, called Virtual Command Processor (VCP) or Virtual CP, is designed for integration into a complete X-ray system. The imaging system has two main components: The 43 x 43cm 139 μ m-pixel amorphous silicon FPD which houses the solid-state flat panel sensor and VCP software, and universal power supply. The universal power supply is optional.

For convenience, PaxScan 4343R product family and/or 4343R is used throughout this manual to refer to 4343R v1 and 4343R v2 models *unless otherwise indicated*

Shipment Contents

Flat Panel Receptor Assembly

PaxScan Receptor Install DVD

(Files specific to the receptor in the shipment)

PaxScan Software DVD

Virtual CP/ViVA System Software

PaxScan 4343R Operating Instruction (for 4343R v1 / 4343R v2)

Optional Parts

External Power Supply AC/DC switching mode – (OEM)

Immediately 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, please call the PaxScan Service Center at (800) 432-4422 or (801) 972-5000.

Intended Use

The PaxScan 4343R product family is specifically designed for fixed applications where the receptor is installed in tables, chest stands or other holding fixture. In medical application the FPD is mounted into the OEM's mounting structure, such as a C-Arm and typically is completely covered by the mounting and contrast-enhancing screen.

The PaxScan 4343R v2 incorporates Gigabit Ethernet data communication and operates at lower power levels with improved cycle time.

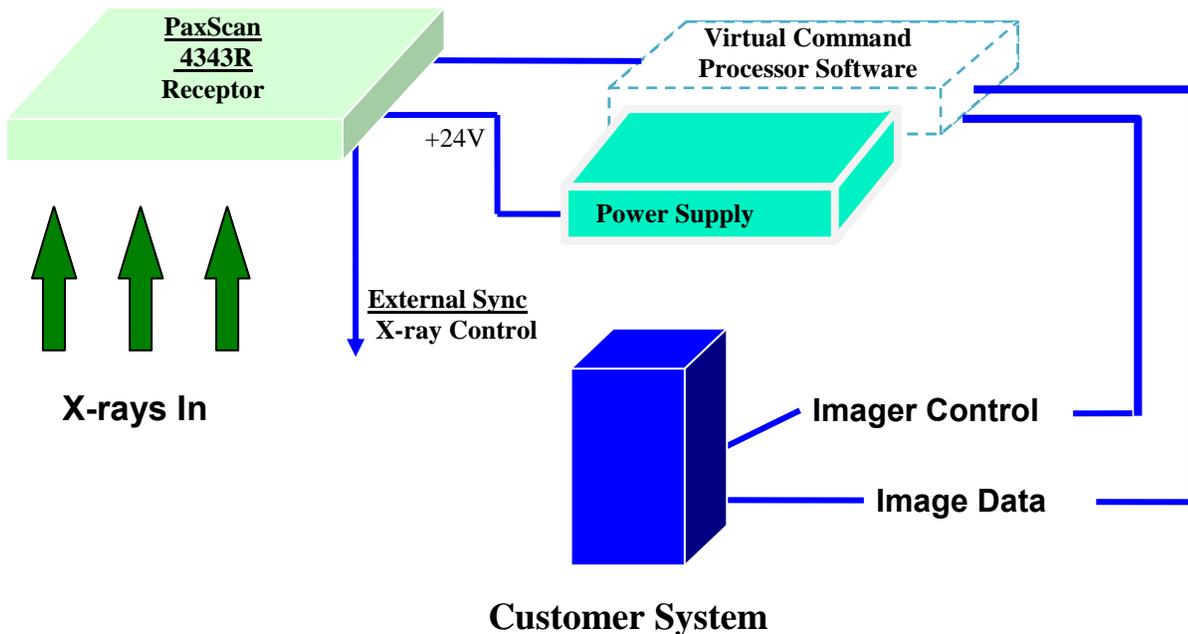
Getting Started

System Overview

In medical applications, the function of the 4343R FPD is to absorb the x-rays that pass through the patient’s anatomy, and to convert those X-rays into a digital image. X-rays are absorbed by the Receptor and converted to raw digital data. The raw data is normalized for offset and gain variations pixel-by-pixel in the Virtual Command Processor (VCP) software application packaged provided with the FPD. The VCP performs all the interface functions with the FPD; such as, communication and respective calibration. The VCP also interpolates the value of any pixels identified as defective. These corrections are accomplished in “real-time” and there is no frame delay in the data stream from the Receptor through the VCP. A multi-output power supply provides all the power required for the FPD.

Figure 1-0 shows the configuration of the Receptor in the context of the overall imaging system. The dimension for receptor is: 469mm(±0.5mm) x 469mm(±0.5mm) X 37.6(±.5mm) mm..

Figure 1-0 Imager Configuration



The Receptor operation is controlled using software commands via UART which use an Ethernet's link as physical layer. The set of possible Receptor control operations is supplied to systems integrators in a C++ library of callable functions, in the form of a Win32 DLL. The control of the Receptor is platform-independent.

Connecting the Cables

Connect the cables as described below in Table 1-0 and shown in Figure 2-0. ►

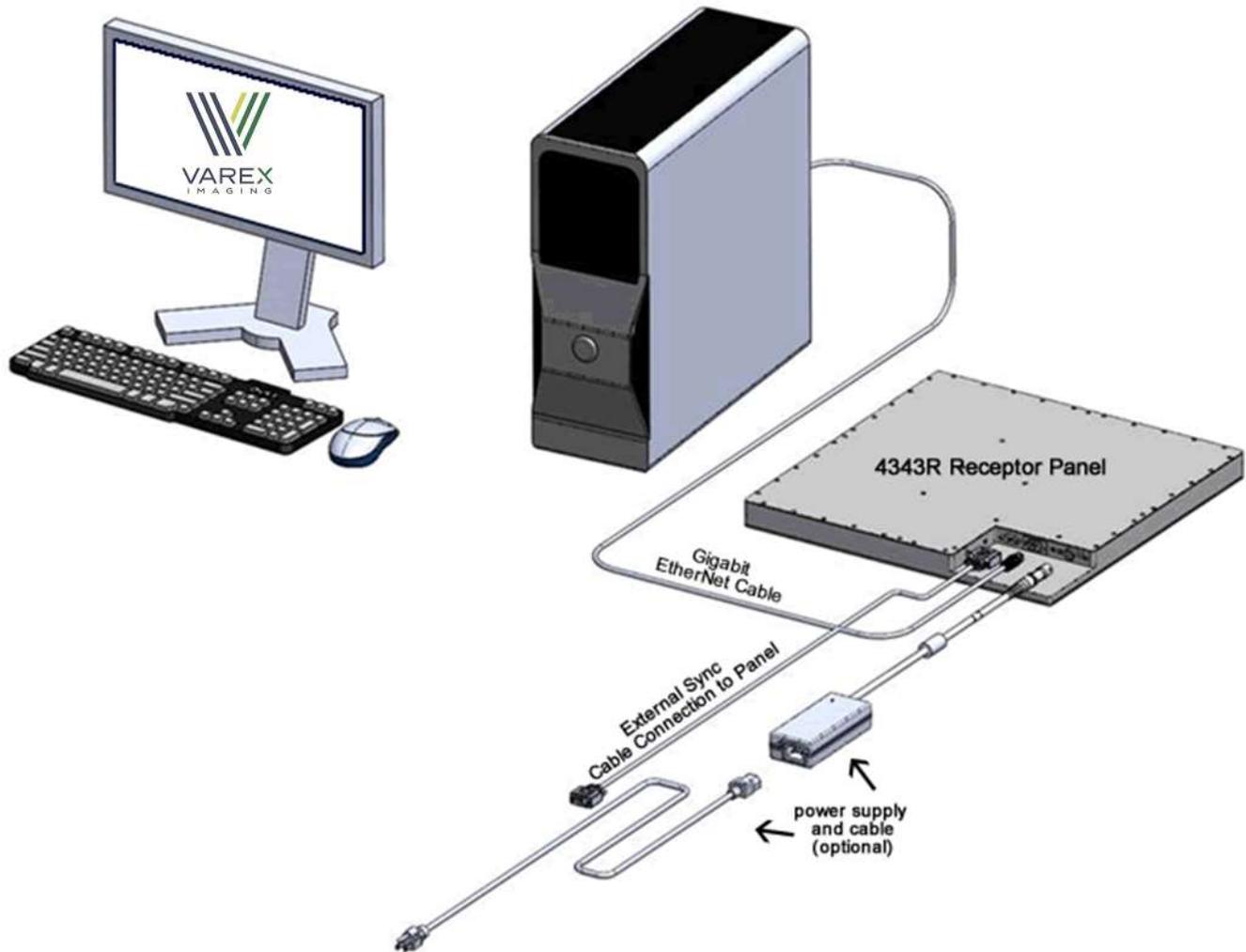
Table 1-0 Cable Connection Details

Step	Action / Description
<p>There are three (3) cable connections for the 4343R Flat Panel Receptor: (a) External Sync Cable, (b) Power Supply Cable which is permanently connected to the power supply (optional), and (c) Category 5 or better Ethernet cable. The connections are described below.</p>	
1.	<p>External Sync Cable Connection This connector is intended to provide the user with a means to synchronize the end-user system-level application with the imager. This connector provides the connections for four opto-isolated signals, (two outputs, and two inputs). The one output signal named "Expose OK" is intended to signal that the receptor is ready for the generator to produce X-rays and the input named "Expose Req" allows the user to trigger the panel readout. See Appendix A, diagram 1.0 for "Expose OK" and "Expose Req" signal schematic. Connect this cable to the external sync connector on the receptor.</p>
2.	<p>Power Supply - (optional) This connection provides power to the receptor. Connect the power supply connector to receptor then plug into the main AC supply.</p>
3.	<p>Gigabit Ethernet Connection Connect the Ethernet connector to a gigabit capable interface in the user's host computer.</p>
4.	<p>Ground Lug Chassis ground lug to acceptable ground connection.</p>



Note: The X-Ray Generator Interface is user supplied equipment

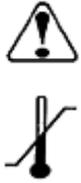
Figure 2-0 Cable Connection

**Important:**

The Receptor should be mounted onto user supplied equipment using the holes provided in the integral flange.

**Warning:**

The receptor is not sealed against dripping moisture.

**Important:**

The temperature at the back surface of the receptor should not exceed 35°C when the unit is installed. This may necessitate air flow over the back surface of the receptor. Humidity levels should be between 10-90% with higher limits for storage

**Caution:**

Accessory or optional equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e., IEC 60950-1 for data processing equipment and 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 our technical support personnel

**Warning:**

Precautions should be taken to not open the receptor module. Depending upon the type of scintillator used, opening the receptor module may expose the user to potentially toxic materials.

**Warning:**

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

Paxscan System Software

There are two DVDs supplied with this product. The Software DVD allows installation of the Virtual Command Processor (VCP) that provides the API to the receptor, allowing control and image transfer functionality; see the Virtual CP Interface Specification for more information. The Software DVD also includes ViVA™ software which is the viewing application used to perform detector calibration, detector set-up, image acquisition, and image corrections in a Windows PC environment. NOTE: ViVA™ is intended to be used for development, testing, and maintenance purposes only. ViVA™ includes file translators for saving image files in .viv, .raw, .jpg, .bmp file formats and is Windows 7 and Windows 8.1 compatible. A Software Developer Kit (SDK) including sample code notes are located in the directory, where X is the version of software used:

PaxscanL0X\DeveloperFiles\SampleCode

The Receptor software DVD is specific to the panel providing calibration and configuration files. Installation of the *Software* and *Receptor* files is briefly discussed in the following sections. Refer to the ViVA Online help documentation for complete details on installation and assistance operating ViVA™.

The 4343R model family is compatible with the multiple Paxscan System Software versions. Please consult your Varex representative.

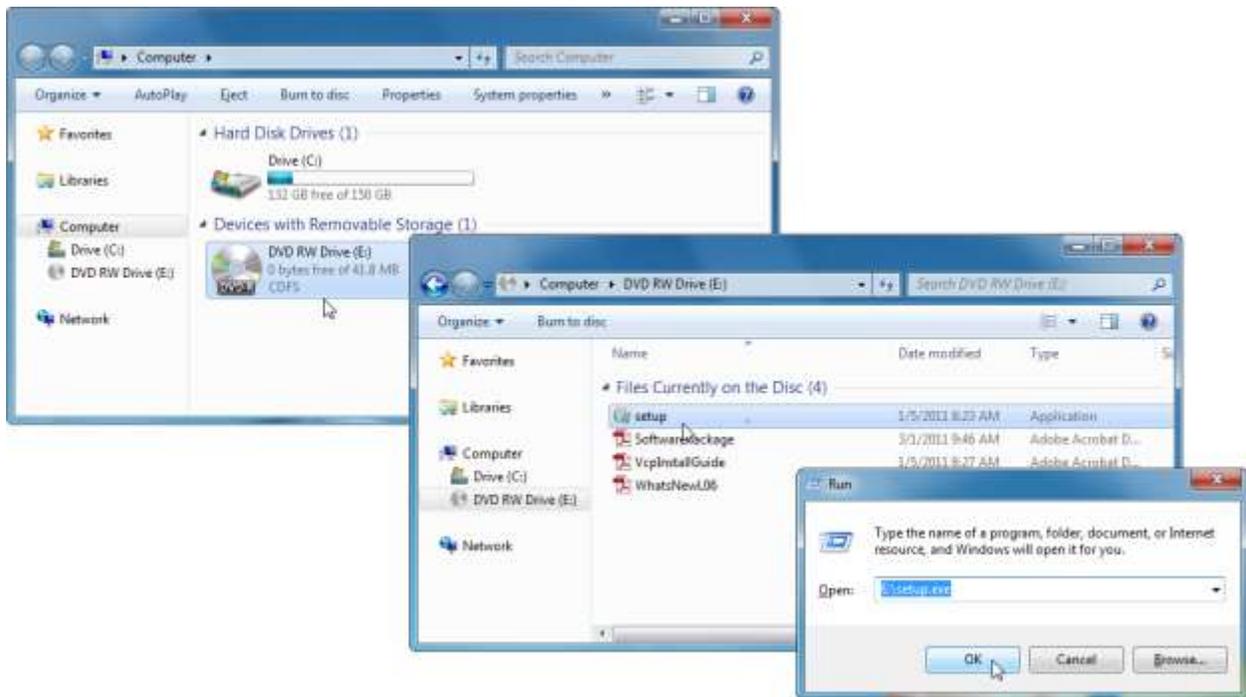
Software Installation

Begin software installation by using the run command under the Windows Start button, select Browse, My Computer, and your DVD/CD ROM Drive that contains the PaxScan DVD. Select the icon  Setup.exe *or* alternatively at the run command window enter drive location and file name, select *OK* – will launch the PaxScan ViVA System Software Install Shield Wizard. ►

Step

Action / Results

1. For a normal install, follow example shown in below screenshots.



2. Install Ebus driver as follows:

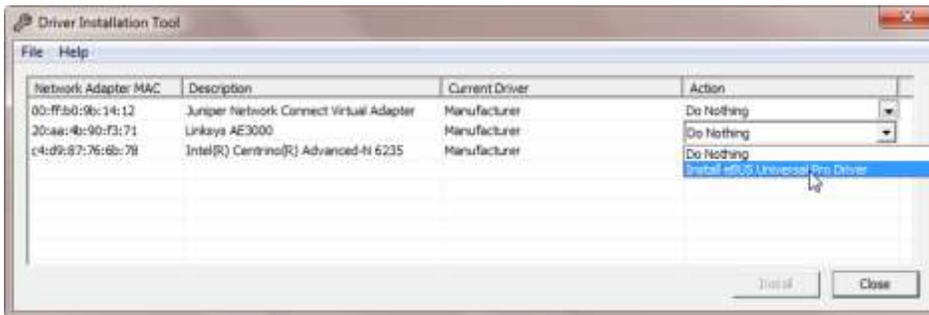
- a. For 64 bit installation use the following path:

C:\Program Files\Common Files\Pleora\eBUS SDK\ EBusDriverInstallationTool64.exe

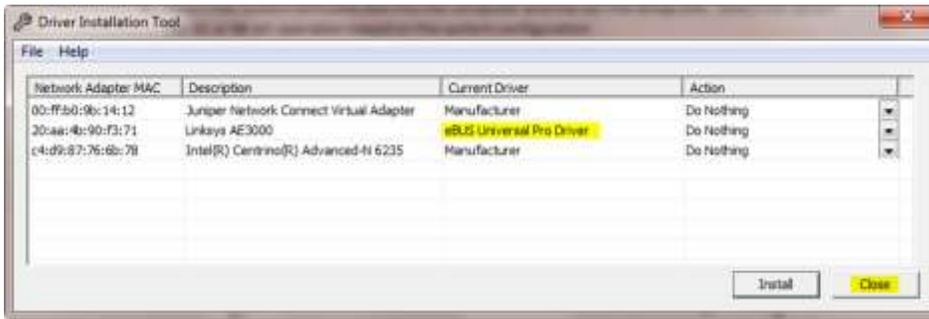
- b. For 32 bit installation use the following path:.

C:\Program Files (x86)\Common Files\Pleora\eBUS SDK\EbusDriverInstallationTool.exe

3. After running the executable the following window will display.

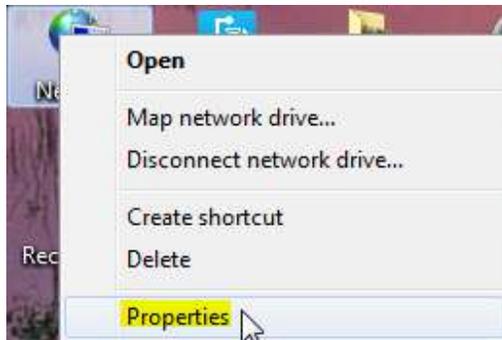


4. Select the install eBUS Universal Driver and click *install button*, verify that the eBUS Universal Pro Driver is installed and click Close



Note: It is critical to turn OFF any firewall on the workstation otherwise the system will not connect.

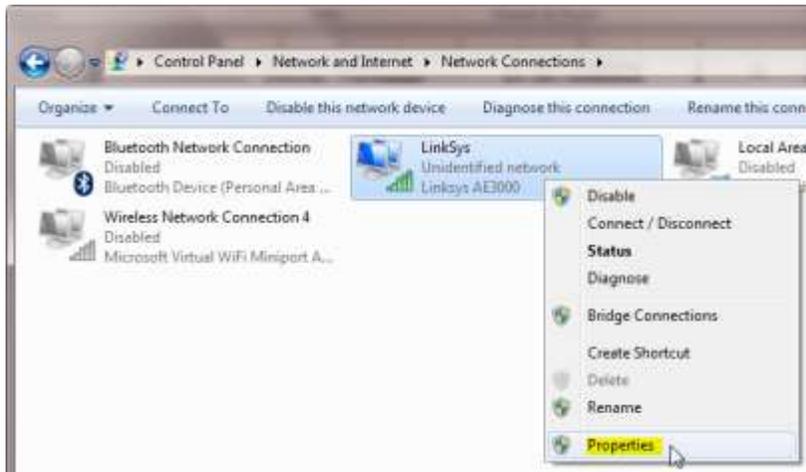
5. Set Network card IP address as follows:
 - a. Right click on Network Icon and Select Properties



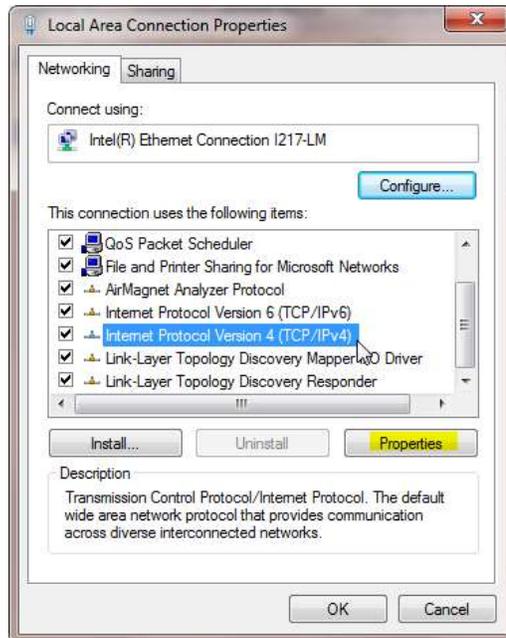
- b. Select “Change adapter settings”



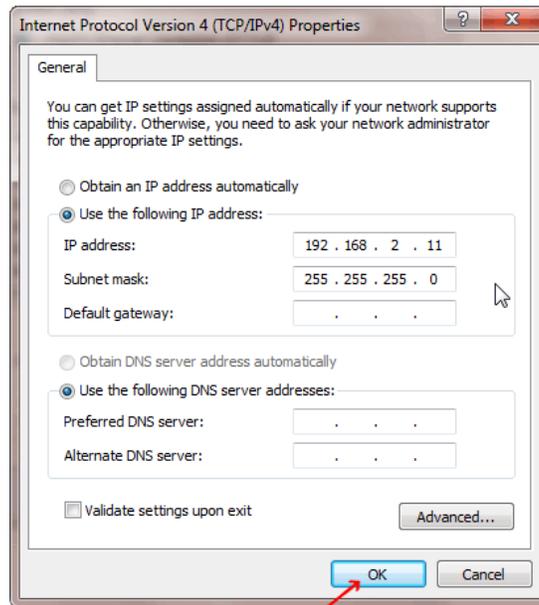
- c. Select “Properties”



- d. Click on “Internet Protocol Version 4 (TCP/IPv4)” and click “Properties”



6. The subnet mask will automatically be set to the one described below. Click “Ok”.
 If a network interface card is already using 192.168.2.0/255.255.255.0, contact your Varex representative for instructions.



Click "Ok"

Receptor Files Installation

Follow through the Install Shield Wizard screens to complete the PaxScan Receptor installation. You must restart your computer for installation to take effect.

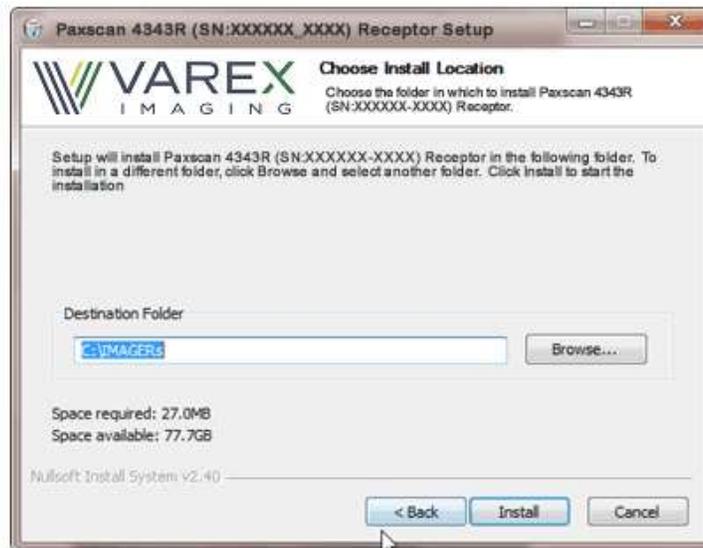
Step	Action / Results
------	------------------

- 4343R – follow the prompt sequence

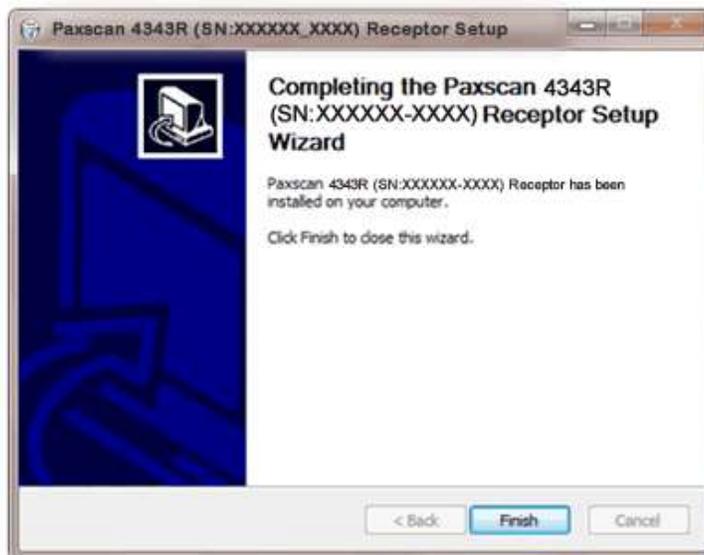
1. Install Receptor installation Disk



2. Run Setup.exec and follow the instructions. When you get the prompt to verify where the receptor data is located, use the default shown below or specify the file location; then click install.



3. Select "Finish"



Modes of Operation

The PaxScan 4343R product family supports the radiography mode of operation as defined in the below Tables. In general, there is a trade off between varying operation modes of resolution, or field of view, or cycle time, or noise. The sensitivity of the imager is optimized to match the X-ray dose used in each mode.

The purpose of each mode is to configure the detector to achieve optimal performance during specific imaging procedures. Modes are defined by a combination of factors, such as pixel binning, cycle time, analog gain, and continuous versus single acquisition. Each mode requires a unique set of calibration files. Refer to the ViVA Online help documentation for complete details.

The user can select the mode of operation based on image performance and cycle time. The following two (2) modes are available:

- **Reduce Cycle Time (RCT)**
- **Standard Cycle Time (SCT)**

For either RCT or SCT the user has the option to retrieve a preview image – which has the benefit of having preliminary view of the target object in reduced time.



Note:

The system may be in only one mode at a given moment.

Not every mode will be available with every system. The OEM should work with PaxScan technical support for configuration of the mode(s) which best suit the customers intended application

Table 2-0 PaxScan 4343R v1 Operational Modes

Mode	Cycle Time	Pixel Binning	Panel Scan Time	X-Ray Window Time	Image Area	Frame Size	Acquisition Type
Radiography – Full Resolution RCT	6 sec	1 x 1	720ms	547 ms	Full Field	3,072 x 3,072	Radiography
Radiography – Full Resolution SCT	10 sec	1 x 1	720ms	547 ms	Full Field	3,072 x 3,072	Radiography

Table 3-0 PaxScan 4343R v2 Operational Modes

Mode	Cycle Time	Pixel Binning	Panel Scan Time	X-Ray Window Time	Image Area	Frame Size	Acquisition Type
Radiography – Full Resolution MSR2 4pf	4 sec	1 x 1	720ms	550 to 2000 ms	Full Field	3,072 x 3,072	Radiography

Default Mode

Mode 0 is the default. The default mode will be invoked automatically upon system power-up when a link is opened or receipt of a reset state command. ViVA will normally remember the last mode used and select it for future launches.

Operation States

The operational states of the imager can be categorized as follows:

- **Radiography acquisition:** (Radiography-type)
- **Offset Calibration:** (OEM-initiated)
- **Gain calibration:** (always-OEM initiated)
- **Analog offset calibration:** (always OEM-initiated)

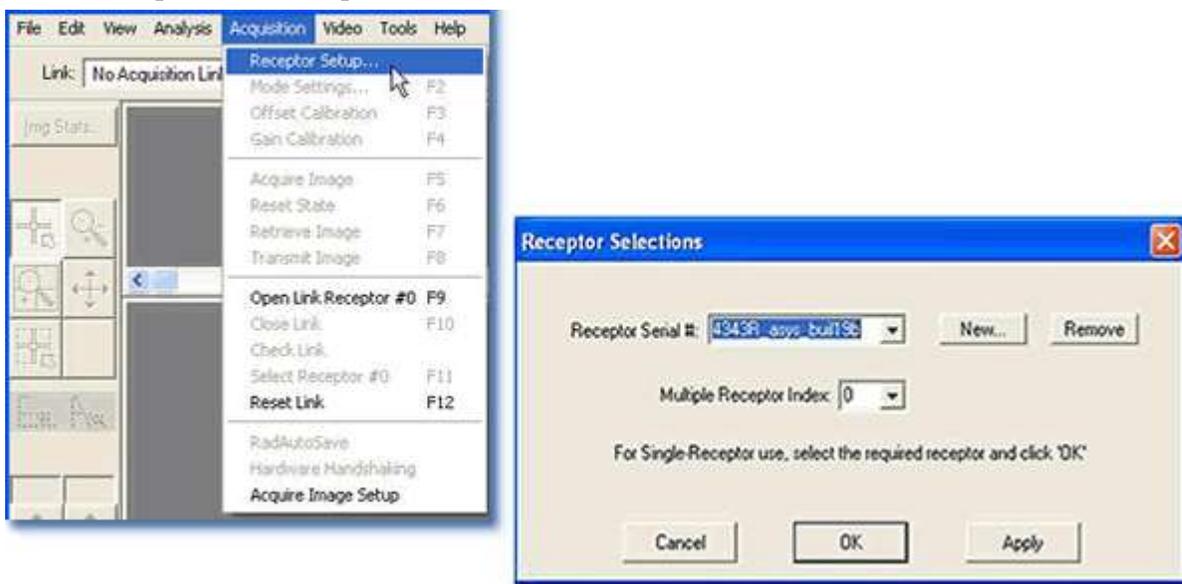
Each operating mode employs all types of calibration. In radiography-type acquisitions, the PaxScan 4343R will acquire one frame with its respective offset.

Multiple Receptor

The Virtual Command Processor software supports multiple connections to two or more receptors of the same type; however, ViVA controls one receptor at a time. The receptor selection is changed from the *Acquisition* drop down menu. This feature is typically useful in a testing environment. ►

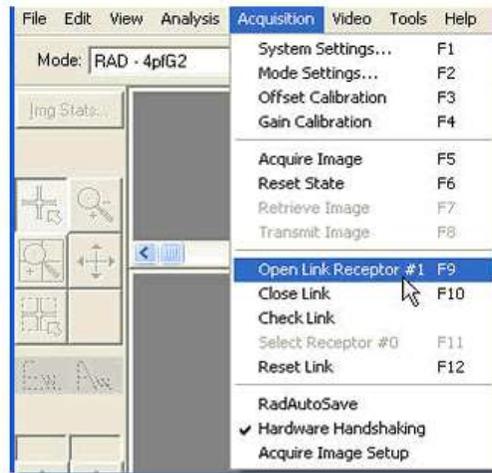
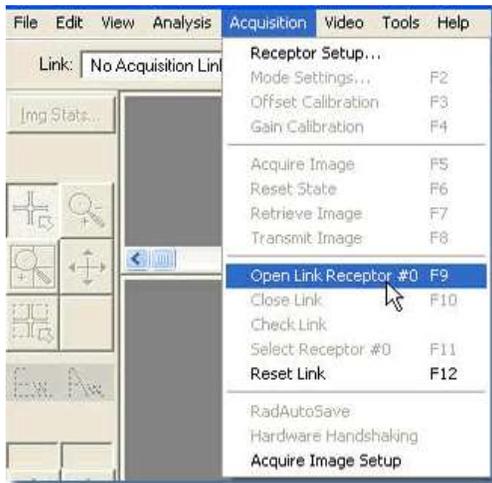
Step	Action / Results
------	------------------

1. Select receptor setup from the menu bar under Acquisition. Then select the specific receptor from the receptor serial # drop down and click ok.



2. Select *Open link Receptor* under the Acquisition drop down menu bar to establish connection to the

PaxScan imaging system. For multiple receptors, completion of the single receptor setup is required before additional receptors are available for setup in the serial # drop down.



Calibration Procedures

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 illumination and referred to as dark fields. ▶

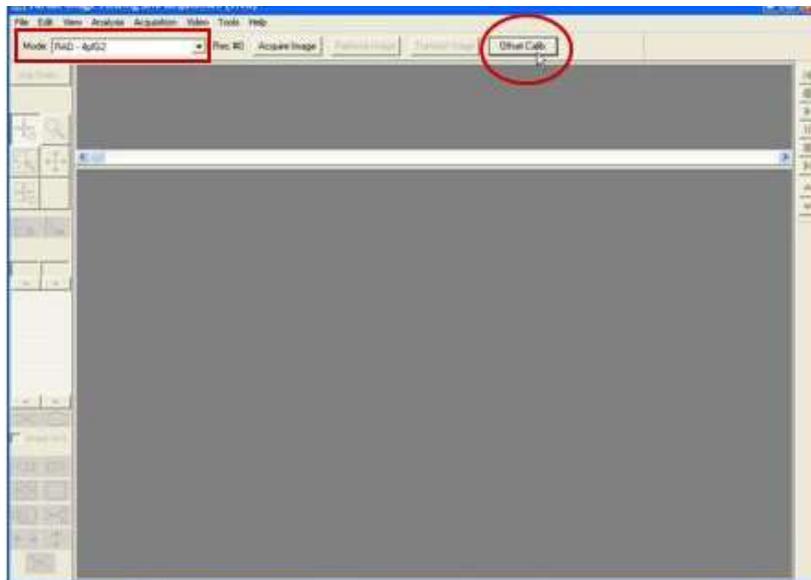
- Offset calibration should not be performed during X-ray.
- The X-ray-to-digital conversion factor does not change as a result of calibration.

Preview Offset Calibration

There are two types of offset calibration; one is used for the preview image and the other to calibrate the final image. Prior to acquiring images, an offset calibration must be performed in each mode. This offset calibration is used for the preview image. In addition, an offset calibration is automatically performed after each single acquisition. The number of frames used for this offset calibration is based on the mode selected – either RCT or SCT.

Step	Action / Results
------	------------------

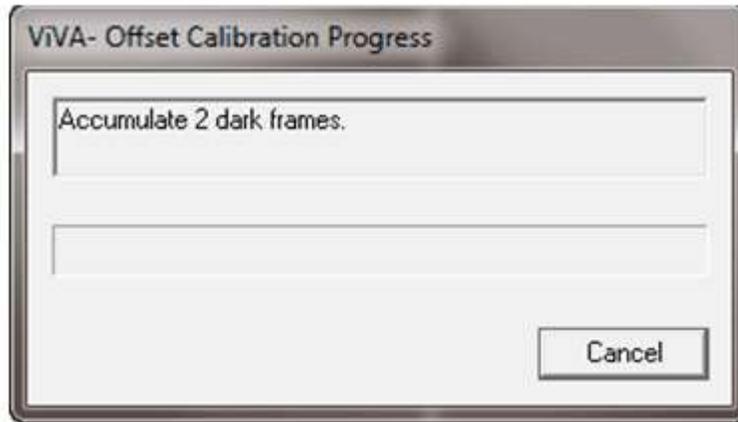
1. To perform offset calibration, click the ViVA icon  launches the application
2. Ensure required receptor appears in the *Mode* drop down. The 4343R currently supports Rad 1x1 4pf. Then, click Offset Calib. button or select from the menu bar under Acquisition.



Step	Action / Results
------	------------------

3. An accumulating Dark Frames window appears followed by an offset calibration acquisition

completion.



Gain Calibration

To compensate for non-uniformities in the Receptor, a gain reference image (flat field) is used by the Corrections module as required to correct all images. The flat field image must be captured by the Virtual Command Processor (VCP) prior to acquiring images. The process of capturing the flat field image is known as Gain Calibration.

Gain calibration is based upon the linear response of the Receptor to dose. Normalization is achieved by applying the flat field image acquired during the Gain calibration to all images corrected by the VCP. Normalization will fail with pixels that are responding to dose in a non-linear manner. Pixels responding to dose in a non-linear manner are usually caused by the saturation of the Receptor, or a low signal-to-noise ratio.



Note:

It is critical to acquire the flat field image within a range that is large enough to be higher than the background noise created by the X-ray source and readout electronics of the Receptor, but lower than the saturation point of the imager.

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. We recommend that flat field images be acquired with a median count of approximately 9000 +/- 1000. This range will ensure that Gain calibration will meet both the upper and lower dose requirements under all modes of operation

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:

Using larger numbers of calibration frames to capture the flat field image will result in more accurate calibration.

The number of calibration frames used during Gain and Offset calibrations can be adjusted under the *Mode Settings* pull down menu. We recommend accumulating 32 frames for gain calibration and 8 frames for offset calibration for optimal image quality. However, the actual number of calibration frames used must be determined solely by the system integrator depending upon their specific performance requirements.



Important:

Gain calibration requires the production of X-rays and therefore certain precautions must be taken by the human operator.

The general procedure for Gain calibration for all modes is as follows in Table 4-0 and described below. Detailed instructions on performing gain calibrations are covered in the ViVA Online help documentation.

Table 4-0 Gain Calibration - All Modes

Step	Action	Results
1.	Warm Up	To ensure proper warm up, the PaxScan 4343R Receptor must be operational for a least two (2) hours prior to Gain calibration.
2.	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.
3.	X-Ray Radiation	A uniform flat field with no obstructions in the path of the

X-Ray beam. The radiation should ideally be at a level and technique representative of the typical radiation dose for the Receptor during typical procedures, keeping in mind the general consideration outlined above.

4. Repeat

The above procedure must be repeated for each of the stored imaging modes.

Radiographic Mode Gain Calibration

Radiography Gain calibration requires an Offset calibration performed prior to collecting the Flat Field image. X-Ray illuminated frames are then offset-corrected and accumulated in the VCP internal buffer.

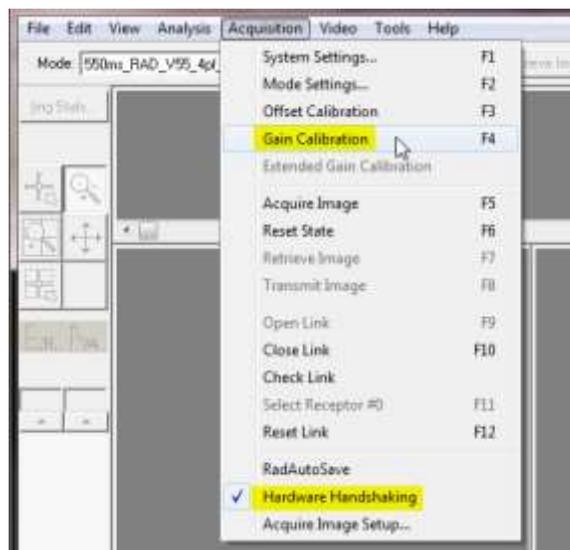
A series of accumulated frames equals one radiographic X-ray exposure. Exposures are averaged to obtain the Flat Field image used by the VCP correction module. The number of exposures acquired can be varied by clicking the **Finish** button after collecting the desired number of exposures.

Take the following steps to complete radiographic gain calibration. ►

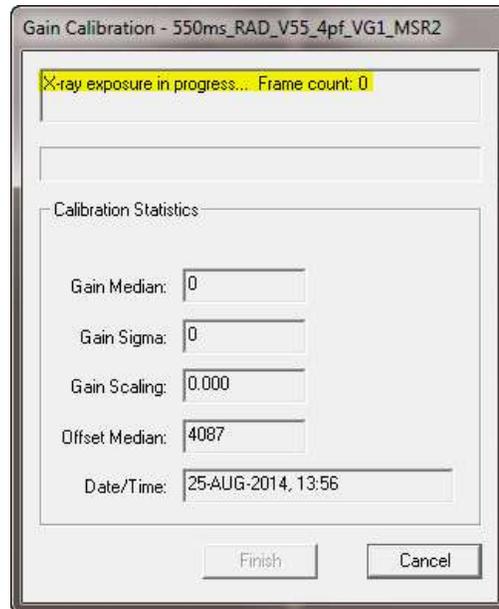
Step

Action / Results

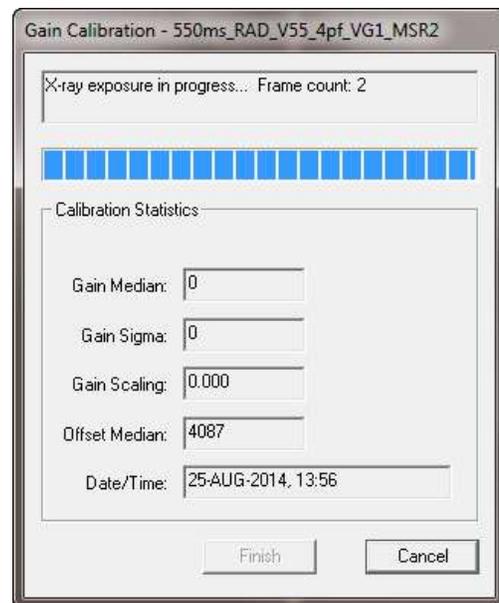
1. Ensure the desired receptor and imaging mode appears in the *Mode* drop down.
2. Click Gain Calibration from the menu bar under *Acquisition* invokes hardware handshaking for dark field calibration.



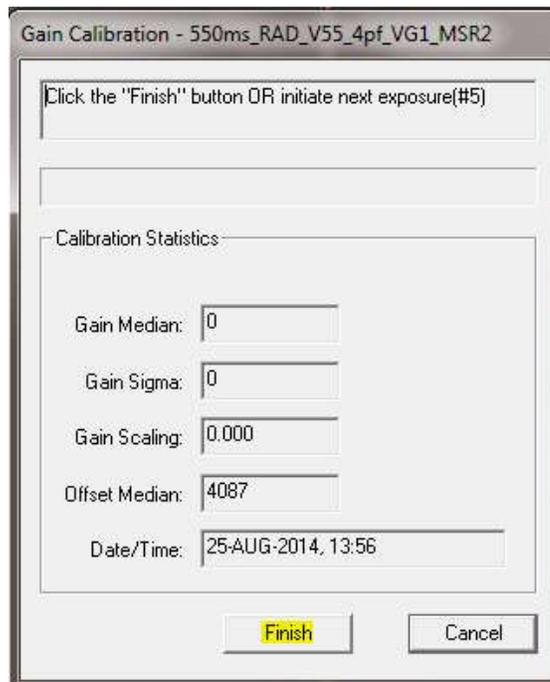
3. Start an Exposure when the Gain Calibration windows display “X-ray exposure in progress... Frame count: 0”.



The software will accumulate 2 frames right after the panel is exposed to an X-ray, when the current image process is completed the “Gain Calibration” window will display “X-ray exposure in progress... Frame count: 0”:



4. Once all X-ray frames have been acquired, click “Finish” to complete the calibration.



Gain Calibration - 550ms_RAD_V55_4pf_VG1_MSR2

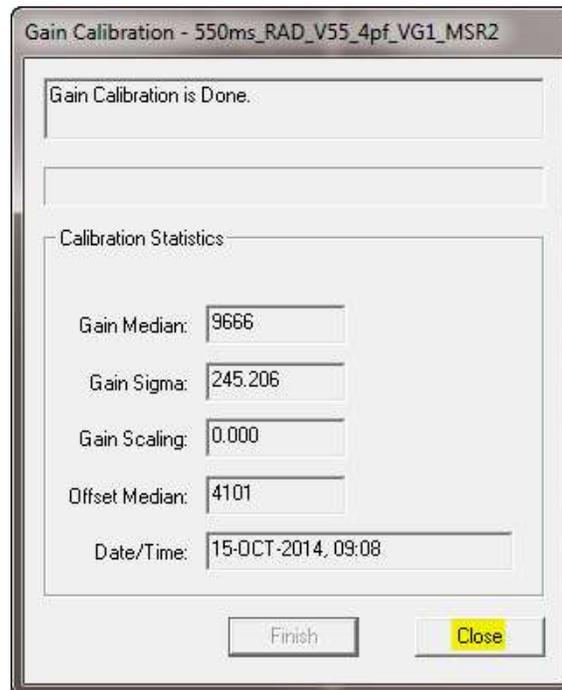
Click the "Finish" button OR initiate next exposure(#5)

Calibration Statistics:

Gain Median:	0
Gain Sigma:	0
Gain Scaling:	0.000
Offset Median:	4087
Date/Time:	25-AUG-2014, 13:56

Finish Cancel

The Gain Media should be 9000 +/- 1000 counts, click “Close” to complete gain calibration.



Gain Calibration - 550ms_RAD_V55_4pf_VG1_MSR2

Gain Calibration is Done.

Calibration Statistics:

Gain Median:	9666
Gain Sigma:	245.206
Gain Scaling:	0.000
Offset Median:	4101
Date/Time:	15-OCT-2014, 09:08

Finish Close



Note: *Operator Control* is user supplied equipment.

**Note:**

Gain calibration should be performed at regular intervals, typically once every three (3) months, or whenever the central beam of the X-ray source has been moved relative to the Receptor.

Replacement of the X-ray tube will require a new gain calibration to be performed.

**Note:**

Varex recommends accumulating 32 frames for gain calibration for optimal image quality. However, the actual number of calibration frames used must be determined solely by the system integrator depending upon their specific performance requirements.

**Note:**

For additional assistance operating ViVA™, use the ViVA Online help documentation.

Image Acquisition

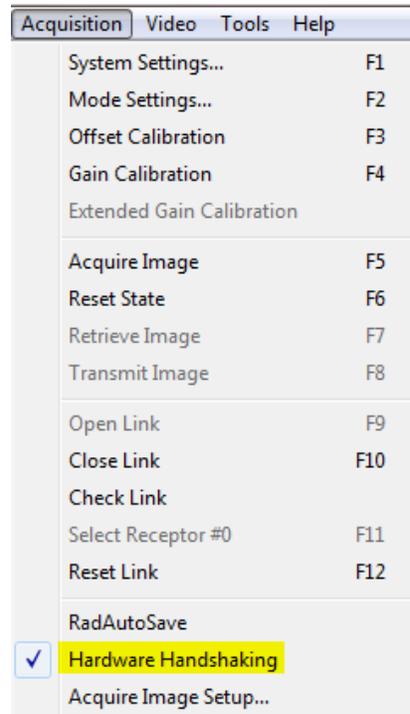
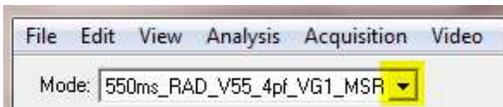
Once Offset and Gain Calibration is performed, you are ready to acquire images.

Radiography Mode

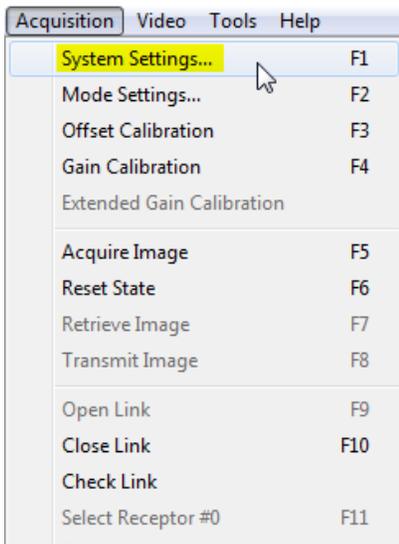
The Radiography mode provides the technician with superior single-shot, higher resolution images, for diagnosis. ▶

Step	Action / Results
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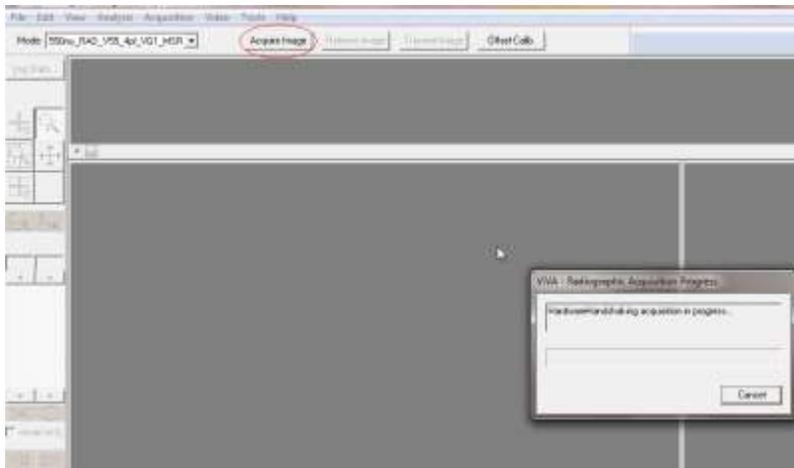
1. Select required receptor from *Mode* drop down menu.



2. Select “*System Settings*” from the menu bar under *Acquisition* to turn ON corrections for a calibrated image. Only select “Offset Corrections”, “Gain Corrections”, and “Pixel Corrections”



- Select the Acquire Image button invokes imager to begin acquiring images.



- When “Viva – Radiograph Acquisition Progress” windows appears Depress *operator control* fully to “Expose” position to complete image capture and retrieval.



- Acquired image can be saved in the desired file format by selecting File / Save As.

Safety

Electro-Magnetic Compatibility

PaxScan flat panel detectors (FPDs) generate, use, and radiate radio frequency (RF) energy. If not installed and used in accordance with the instructions, they may cause harmful interference to other devices or may be affected by other equipment in the vicinity. There are no guarantees that installation does not cause interference, regardless of whether everything was installed and is being used in accordance with all instructions.

If the equipment causes harmful interference to other devices or is affected by other equipment, attempt to correct the interference by one or more of the measures listed in the **Troubleshooting** section. Because it is designed for incorporation into a complete x-ray system with various mountings, cabling, etc., overall emissions and immunity of the FPD are linked to the electromagnetic compatibility (EMC) of the system into which it is installed.

Varex PaxScan FPDs are suitable for use in the electromagnetic environments specified in Appendix B. The user of the x-ray system should assure that it is used in an electromagnetic environment as described.

Electrical Rating

4343R v1

<ul style="list-style-type: none"> ● <u>External Power Supply Specification - (optional):</u> – type: MPU50-336-B, ratings: Input Voltage 100– 240 VAC, Input Frequency 47 to 63 Hz, Input Current 1.35-0.53A, DC Output V1: +6V / 4.5A, V2: +24V / 0.5A, V3: -13V / 0.3A or – type: MPU50-336-3-B, ratings: Input Voltage 100– 240 VAC, Input Frequency 47 to 63 Hz, Input Current 1.35-0.53A, DC Output V1: +6V / 4.6A, V2: +24V / 0.36A, V3: -13V / 0.5A
<ul style="list-style-type: none"> ● <u>Electrical rating if the power supply is not provided with the unit:</u> – Continuous power rating is: 24 Watts – Input voltage is: 100 – 240V

4343R v2

<ul style="list-style-type: none"> ● <u>External Power Supply Specification - (optional):</u> – type: XP Power model AHM85PS24 , ratings: Input Voltage 100 – 240V, Input Frequency 50/60Hz, Input Current 1.0 A, DC Output 24V
<ul style="list-style-type: none"> ● <u>Electrical rating if the power supply is not provided with the unit:</u> – Continuous power rating is: 18 Watts – Input voltage is: 100 – 240V

Environment Limits

Rigorous environmental testing is conducted on an engineering basis using a sample receptor.

Temperature, Humidity & Atmospheric Pressure

Category	Limits
----------	--------

Storage & Transport (ambient)	Receptor: -20° C to +70° C Battery: -20° C to +60° C
Storage Humidity Range (non-condensing)	10% to 90%
Normal Operation Temperature (measured at the center of the back cover)	10° C to 35° C
Operation Humidity (non-condensing)	10% to 90%
Atmospheric Pressure Range	700hPa to 1060hPa

Altitude Limits

The Paxscan Digital Imager Receptor is rated to operate at an altitude \leq 3000m.

Regulatory

- The PaxScan® 4343R is a X-Ray subassembly which has been classified with respect to electrical shock, fire and mechanical hazards only in accordance with:
 - 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.
 - IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance 3rd ed.
 - 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.
- CE Mark - Varex Imaging's imaging products are designed and manufactured to meet the Low Voltage Directive 2006/95/EC, MDD 93/42/EEC, and R&TTE Directive 99/5/EC
- MDD Class IIa
- A Declaration of Conformity has been filed for this product and available upon request by contacting Varex Imaging - X-Ray Products.

Maintenance

Cleaning and Disinfection

The flat panel receptor and connected cables are likely to be soiled during use. The specific material most likely to become soiled is the X-ray grade carbon fiber input window and magnesium housing.

Cleaning and disinfecting of the input window should be performed as needed. Wiping the surfaces with a soft cloth dampened with soap and water will generally clean the surfaces.

Proper disinfection requires that a disinfectant solution be used; such as Sani-Cloth® Plus, a hospital grade, EPA registered low to intermediate-level product for hard, non-porous surfaces and equipment. Use disinfectants in accordance with the manufacturer's instructions.

**Caution:**

Do not use flowing liquid or immersion on the receptor.
Do not sterilize

Repairs

**Note:**

No user serviceable parts. If repairs are necessary, please see *How To Reach Us*.

The least replaceable units (LRU) are:

- Receptor Assembly

Proper Disposal

The receptor should be returned to Varex Imaging for disposal. We request that you obtain an RMA number using the same procedure for warranty/returns of products.

Contact: FLATPANEL.WARRANTY@VAREXIMAGING.COM

**Warning:**

Precautions should be taken to not open the receptor module. Depending upon the type of scintillator used, opening the receptor module may expose the user to potentially toxic materials.

Troubleshooting

Problem	Solution
Imager fails to respond.	1. Check cables.
Imager causes Electro-Magnetic Interference.	1. Reorient or relocate the receiving device. 2. Increase the separation between the equipment. 3. Connect the other device(s) into an outlet on a different circuit. 4. Consult the manufacturer or field service technician for help.
Poor Image Quality.	1. Confirm that image corrections are all selected in the Systems Settings dialog box in ViVA . 2. Re-acquire gain and offset images. 3. Assure that the exposures are appropriate for gain calibration images (not saturated).
Software hangs up.	Restart ViVA.
Acquired image is completely dark.	Increase the exposure and acquire a new image. If the image is still dark, verify that all cables are properly connected. Turn the power “OFF” and “ON”. Acquire a new image.
Out of virtual memory.	Close some of the windows that are currently open.
Residual x-ray image from previous exposure shows in current image.	Charge on the sensor pixels from a super saturated exposure may cause a residual image. It can be erased by taking another image or multiple images without X-rays until the residual image is gone.
ViVA error message.	1. Please complete PaxScan Problem Report. 2. Email the error log file generated to: FlatPanel.Warranty@vareximaging.com. This log file is normally found at C:\users\{username}\AppData\Local\crashdumps\viva.log

PaxScan Problem Report Customer Information

Date:	Your Name	Company/Unit Name:
Email:	Phone Number:	Fax Number:
Product Information.		
PaxScan Part Number: Imager Serial Number: Software Revision #:		
Operation I was trying to perform (be as specific as possible:		
What happened (use additional sheets as necessary):		

E-mail: FlatPanel.Warranty@vareximaging.com

Appendix A

Interfacing Information

All the interfacing connections for the receptor are at the panel itself. The Gigabit Ethernet connection carries control information to the panel and supplies image data with diagnostic information to the customer supplied workstation. The Hardware Synchronization connection is a 9-pin D-sub type. Power for the panel is supplied by a medical-grade “laptop” style supply whose dc supply cable can be up to 3 meters in length.

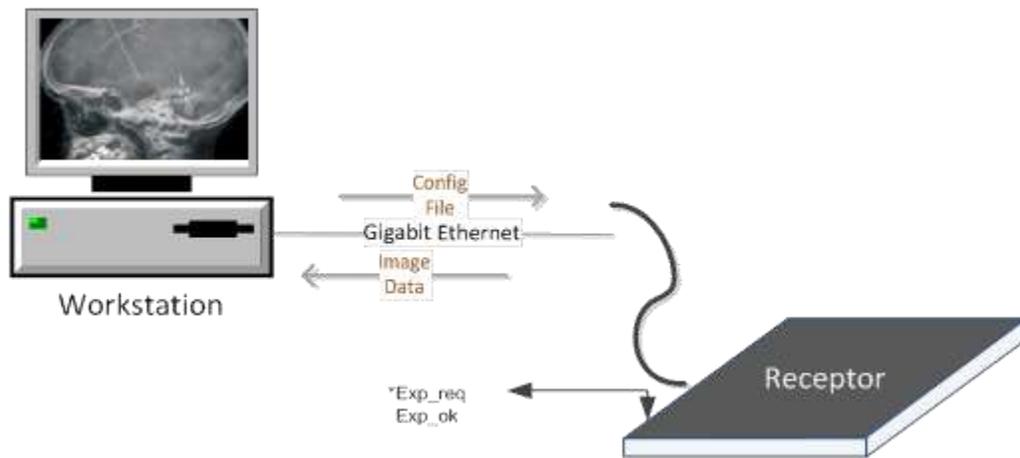


Figure A.1 Block Diagram of the 4343R Imager

The synchronization interface to the panel consists of one input and one output, all through opto-couplers. The expected input to the panel is Exposure_Request. The output from the panel is Expose_OK, which can be used to trigger the generator. This active low signal is used to identify when the panel is ready for exposure. The exposure delay is defined as the worst case time between Exposure_Request and Expose_OK. The interface circuit is shown below.

NOTE: The maximum input voltage on the opto-couplers used in the 4343R is 5V.

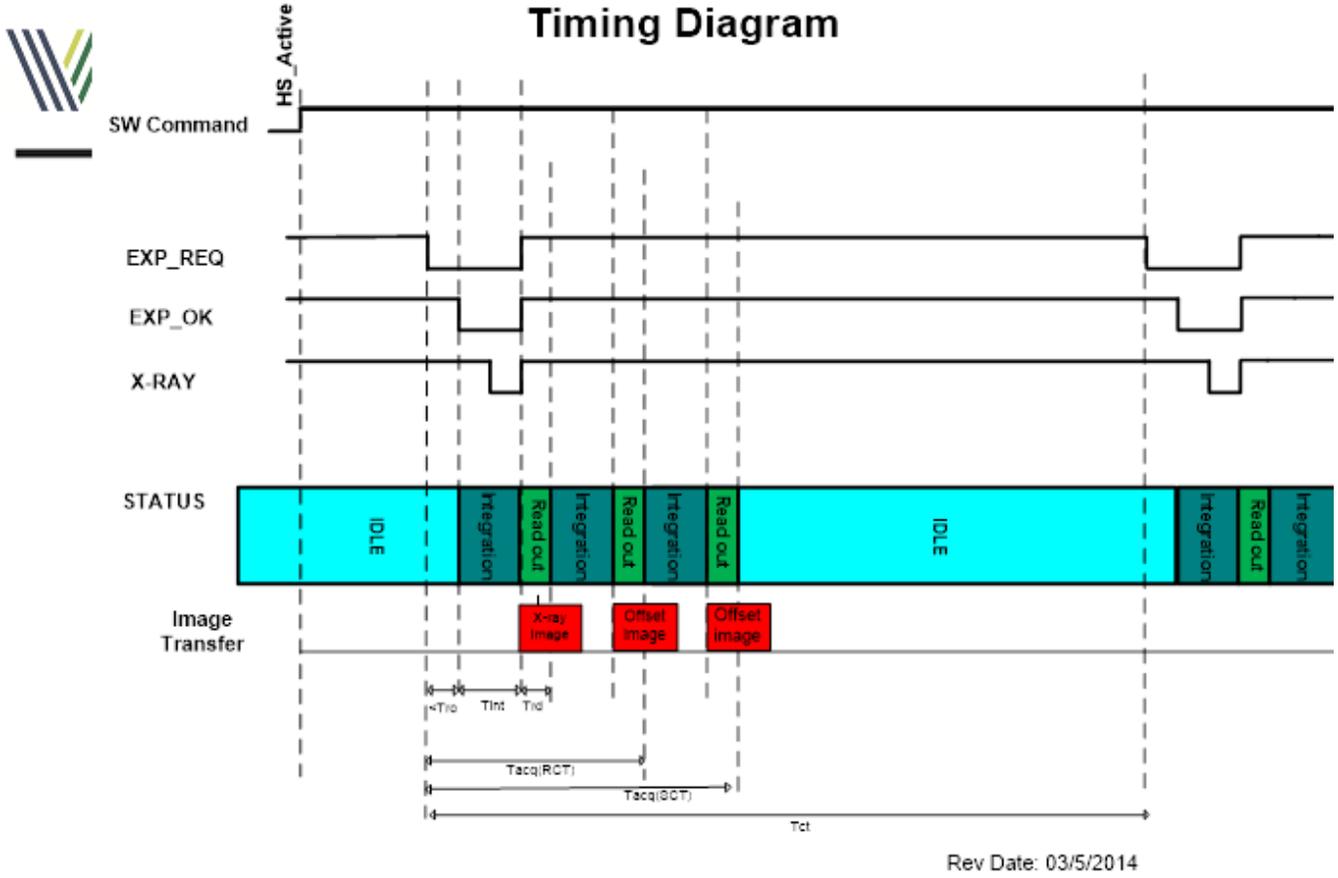


Figure A.3 Example Timing for 4343R Synchronization Interface

Timing MSR1

Name	Description	Time 4343R	Time 4343RvDX	Unit
Tro	Time between "Exp_Req" to "Exp_Ok"	<0.25	<0.25	s
Tint	Integration Time	n/a	0.5 to 6	s
Trd	Readout Time	n/a	<.25	s
Tacq	Acquisition time (550ms RCT)	<3.45	<3.5	s
Tacq	Acquisition time (550ms SCT)	<6.2S	N/A	S
Tct	Cycle time (550ms RCT)	<8.4	<7	s

Times are based in typical values

Figure A.4 Timing MSR1

Appendix B

Electromagnetic Emissions

Table B-1. 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 B, 150 kHz – 30 MHz	Group 1, Class B, 150 kHz – 30 MHz	The FPD uses RF energy for its internal function. Nearby electronic equipment may be affected.
RF radiated emissions EN55011/CISPR 11	Group 1, Class B, 30 MHz – 1 GHz	Group 1, Class B, 30 MHz – 1 GHz	The FPD uses RF energy for its internal function. Nearby electronic equipment may be affected.
Harmonic emissions EN/IEC 61000-3-2	Class A	Class A	The FPD 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	Limits defined clause 5 of standard	The FPD 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.

Electromagnetic Immunity

Table B-2. 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	±2 kV AC Mains ±2 kV I/O Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV Line to Line ±0.5 kV, ±1 kV, ±2 kV Line to Ground	±0.5 kV, ±1 kV Line to Line ±0.5 kV, ±1 kV, ±2 kV Line to Ground	Mains power quality should be that of a typical commercial or hospital 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	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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FPD requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
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 commercial or hospital environment.

RF Immunity

Table B-3. Conducted / Radiated RF

Immunity test	IEC 60601-1-2 test level	Compliance	Electromagnetic environment
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the FPD than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	$d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol:  Some degradation of video & increase in video noise possible.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
 NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
 a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [EQUIPMENT or SYSTEM] is used exceeds the applicable RF compliance level above, the [EQUIPMENT or SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the [EQUIPMENT or SYSTEM].
 b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

**Warning:****Degraded electromagnetic compatibility**

The use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

**Warning:****Use of equipment in the vicinity of other equipment**

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

**Warning:****Use around portable RF communication equipment**

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the FPD, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.