Digital Image Receptor

The PaxScan 4336R is a radiographic digital x-ray imaging sub-system

Abstract The Operating Instructions (P/N 35858-000) covers safety, setup, operation, and maintenance of the PaxScan 4336Rv1 / 4336Rv2 / 4336R DRZ+ digital radiography image receptor. The imager 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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Chapter Summary

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Introduction

The PaxScan 4336R model family of radiographic digital image receptors is commonly referred to as a flat panel detector (FPD). The detector together with image processing and command software called Virtual Command Processor (VCP) is designed for integration into a complete X-ray system. The imaging system has two main system components: The 38.3 x 42.7cm 139µm-pixel amorphous silicon FPD that houses the solid-state, flat panel sensor and the VCP software, and the External Power Supply (I/O Box) that provides power supply. The PaxScan 4336R model family will also be referred to as 4336R throughout this manual.

Shipment Contents

Flat Panel Receptor Assembly (includes an attached receptor cable)

PaxScan Receptor Install CD

(Files specific to the receptor in the shipment)

PaxScan Software CD

Virtual CP/ViVA System Software L.04 (or higher)

External Power Supply (I/O Interface Box)

PaxScan 4336R Operating Instructions

Optional Parts

Main Power Cable for I/O Box -

Cover, Enclosure, 4336R, Molded

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 4336R model family is designed for general radiography applications.

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

Safety Warnings, Precautions and Contraindications

Warning:

This device is only for use on adult patients with healthy skin; for example, free of blemishes, scars, skin rashes, irritants, disorders, discoloring and abnormal moles.

Warning:

For hand held applications, the operator and end-user must take precautions to protect themselves against dangerous X-ray exposure when using the flat panel imager in the X-ray beam path of an X-ray source.

Warning:

The 4336R is not intended to be used as a primary barrier to X-rays. The user is responsible for insuring the safety of the operator, bystanders, and the subjects being radiographed.

Warning:

To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.

The metal enclosure of the 4336R must be connected to earth ground.

Warning:

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

Warning:

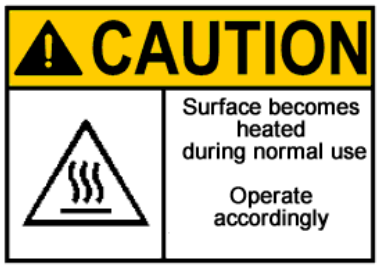
The equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide.

Warning:

Do not exceed maximum load weight of 100kg over a diameter of 40mm and 150kg distributed around the entire surface of the panel.

This device is not intended to supply heat to a patient. However, during normal use surfaces will become heated due to power dissipation in the imager.

Temperature increases based on frequency of image acquisitions taken. Patient contact surfaces will not exceed 8 degrees C above ambient under normal use conditions – ***not to exceed 150 image acquisitions per hour.*** See Figure 1-0 for the view of patient contact surfaces. Internal temperature sensor data is provided in the diagnostic data attached to each image. These temperature measurements are well correlated with the panel external surface temperature. It is advisable to monitor this diagnostic data as an additional safety precaution.



The operator should monitor and evaluate how much and how long the patient is in contact with these surfaces. Exposure beyond limitations may result in, but not limited to, the surface layer of the skin to become reddened, welted, and swollen with pain.

Limitations for patient contact are listed in the "Patient Contact Limitation" section of this manual. It is important that the operator understand and follow these instructions to avoid possible adverse effect to patient.

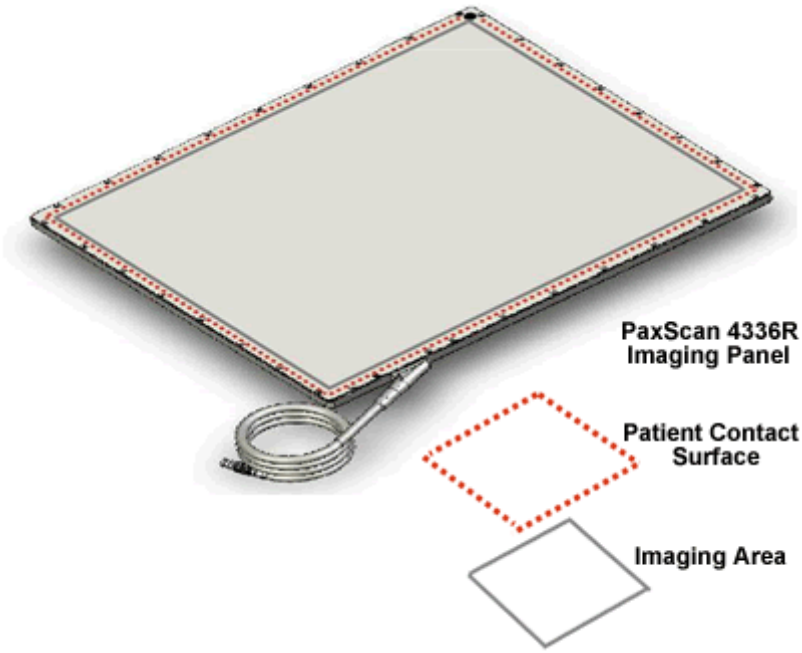
Note:

System Integrators: At a system level, it is possible to apply for UL approval without the patient contact limitations discussed below. If the imaging system monitors the internal temperature data supplied by the panel, mechanisms can be put in place at the OEM system level to control panel surface temperature so that it does not exceed 41^{o}C.

Patient Contact Limitations

1. Patient contact time between 1 and 10 minutes.
2. No more than 10% of a patient's body area should be in direct contact with surfaces.
3. No more than 10% of patient's head area should be in direct contact with the surfaces.
4. The device is intended for use on adult patients with healthy skin only.
5. No additional pressure should be applied when patient is in contact with surfaces.
6. Number of image acquisitions not to exceed 150 per hour.

Figure 1-0 Patient Contact Surfaces



Explanation of Symbols

	On (power: connection to the mains)		Caution / Warning / Important: Describes action or conditions that could result in equipment damage, data loss, or personal injury		Protective Earth Ground
	Alternating Current		Off (power: disconnection from the mains)		Direct Current
	Handle With Care		Indicates step-by-step description of the respective function follows		Useful / Important information
	Authorized Representative in the European Community/European Union		Manufacturer		Consult Instruction for Use
IPX1	Moisture Resistance Level Tested – minimal water exposure		Heated Surface		Type B Applied Part
	Load Weight Restriction		Temperature Limits		

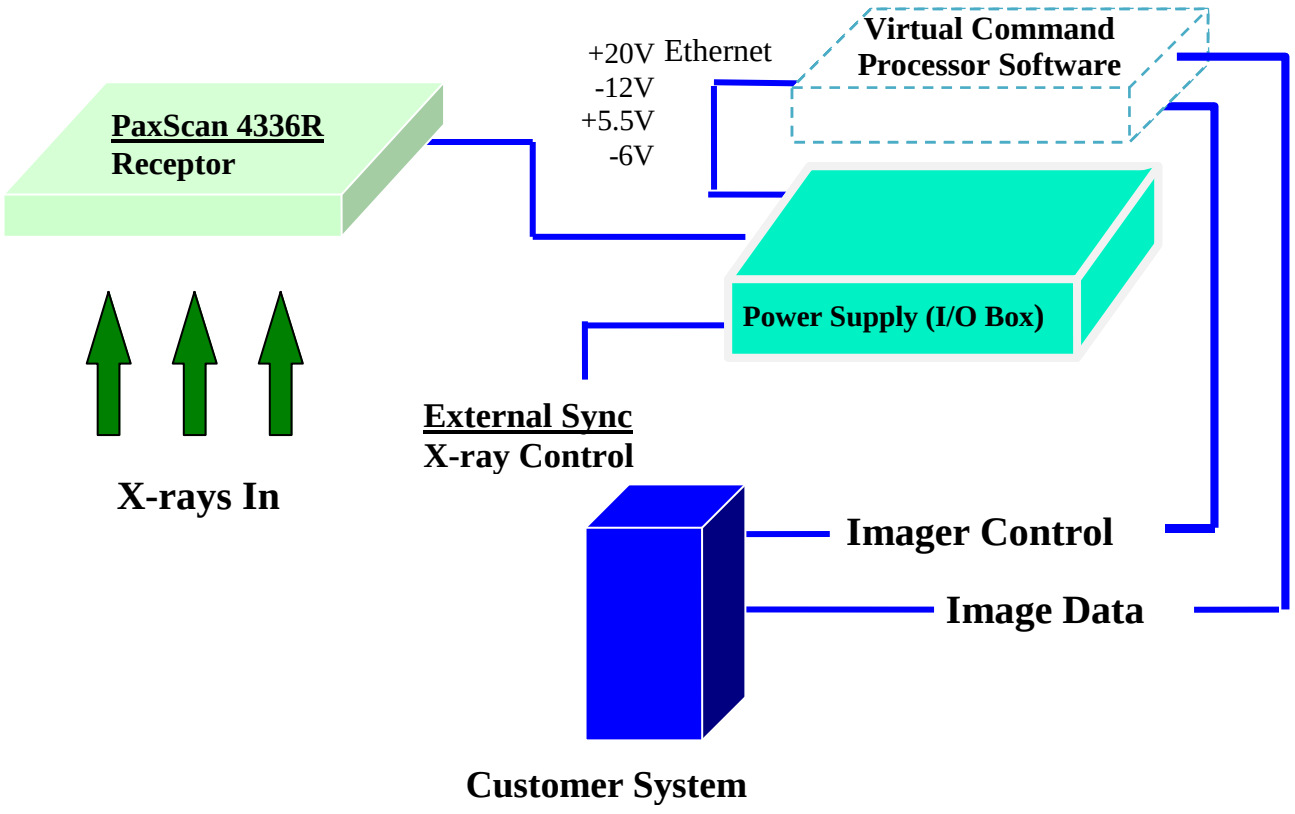
Getting Started

System Overview

In medical application, the function of the 4336R FPD is to absorb the x-rays that pass through the patient's anatomy, and to convert those X-rays into a digital image. The I/O Box is the interface between the FPD and the imaging system will typically be mounted in an equipment enclosure and will not be in view or reach of the operator or patient. The Receptor is intended to be patient contact and is provide with a software application package Virtual Command Processor (VCP) which performs all the interface functions with the receptor; such as, communication and respective calibration. During operation, the Receptor is often draped or bagged to ensure cleanliness and sterilization, and is manipulated such that the Receptor's input window is located near, but on the opposite side of the patient, from the X-ray source.

Figure 2-0 shows the configuration of the Receptor in the context of the overall imaging system. The dimensions for receptor only is 15.098 ±0.039 x 18.091 ±0.039 x .596 +0.04 /- 0.08 and with enclosure is 19.370 ±0.040 x18.697 ±0.040 x .906 ±0.039 inches.

Figure 2-0 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.

The I/O Box (power supply) provides all hardware interfaces for the PaxScan 4336R. It consists of an external hardware interface connection and a power supply. The I/O Box also provides all the DC power necessary for the Receptor through an integrated, internal 24V power supply. The I/O Box connects to an standard wall outlet and has a footprint of 11.13 x 7.13 inches and a height of 1.97 inches.

WARNING: All regulatory approvals, including UL and CE mark, are contingent on the use of the I/O Box with the internal power supply provided by the Varian Medical Systems. If substitutions are made, these approvals are void and the image quality cannot be guaranteed.

Connecting the Cables

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

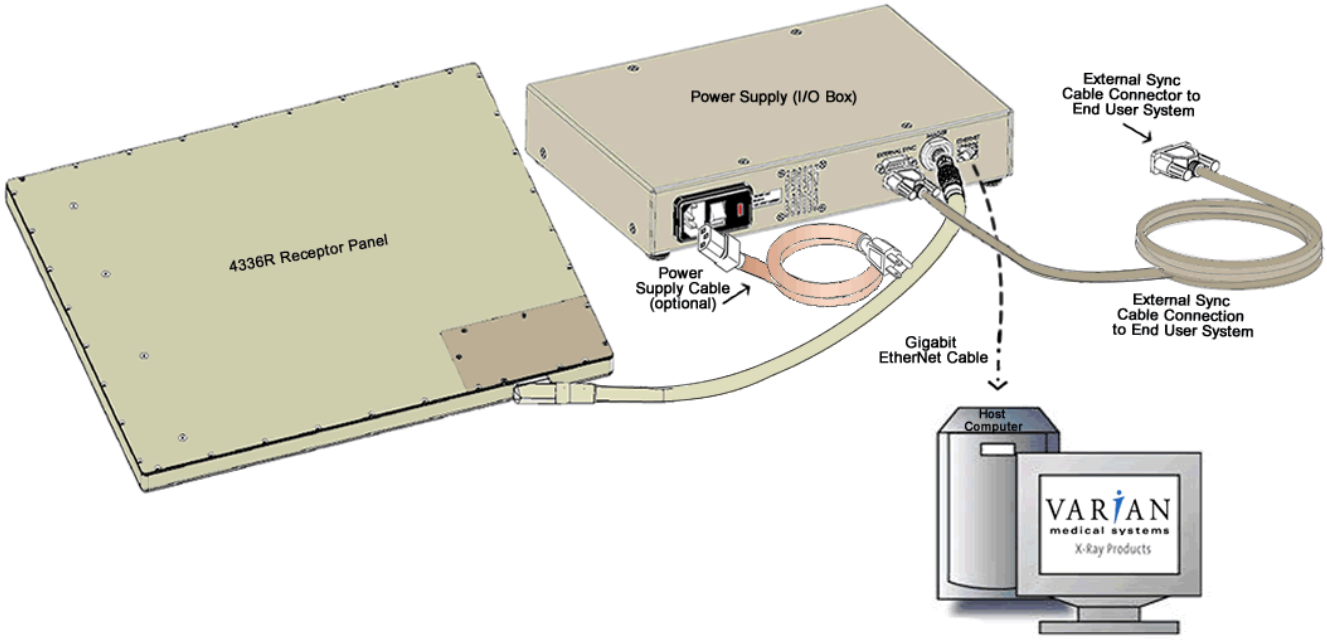
Table 1-0 Cable Connection Details

Step	Action / Description
There are three (3) cable connections for the 4336R Flat Panel Receptor: (a) The external power supply (I/O Box) cable - (optional), (b) Category 5 or better Ethernet cable, and (c) external sync cable. The Flat Panel Receptor includes an attached cable. The cable connections are described below.	
1.	**Power Supply (I/O Box)** This functions as interface between the receptor and the customer system by provides power to the receptor and an RJ-45 Ethernet. It is also an interface for the external synchronization. Connect the receptor cable to the imager connector on the power supply. Plug the power supply into the main AC supply. *Panel should be installed / operated as far as possible from power supply.*
2.	**Gigabit Ethernet Connection** Connect the Ethernet cable to the power supply (I/O Box) connector and to a gigabit capable interface in the user's host computer.
3.	**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 power supply.
4.	**Ground Lug** Connect chassis ground lug to acceptable ground connection

Note: The External Sync Cable Connection is user supplied equipment.

This connection shall only be handled by the service personnel.

Figure 3-0 Cable Connection



Powering On The Receptor

Plug in the AC power cord going to the I/O box (Power Supply). There are 5 (five) LEDs located in the front of the I/O box. The "POWER" LED is green when power is supplied to the receptor. The other LEDs indicate when external signal are asserted at the time acquisition is taking place.

Note: The average lifetime of the panel can be improved by turning it off when not in use. Recommended warm up time for proper image quality is 15 minutes.

Warning: Moisture Resistance Level Tested – minimal water exposure

IPX1

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: When using this product with enclosure, you must avoid excessive bending and twisting of the power cable. Regular inspection of the power cable for any damage is required – immediately replacing the cable if any damage is observed.

Additional Features

Power Down Algorithm

The PaxScan *4336R version 2* model provides an alternative option to allow customer to power down major voltages in the receptor as soon as undesirable higher temperature is reached. This new algorithm will prevent the receptor to work in such conditions thereby lowering the power consumption of it.

Implementation

The algorithm will TURN ON/OFF based in customer desire. As soon as it is ON the receptor will continuously check the temperature reported by sensor 2 and 4.

If either one of the temperature sensors go above the threshold established for T2 and T4 respectively, the receptor will finish any current acquisition and will TURN OFF most of the power on it to reduce power consumption in the system. Once the receptor is in power down, it will report it status to VCP and will not allow any further acquisition.

If the temperature of both sensors is below the threshold temperature minus the cold temperature, for the next 4.4 seconds after the power is back, the user will not be allow to acquire any additional images (initialization).

After this time pass, the receptor will come back to a normal operation. Please consult your Varian representatives to set up this feature.

Hot Swappable

This new feature implemented in *4336R version 2* allows the customer to disconnect the primary cable from the I/O Box to the receptor without power down the unit. After the disconnection occurred, the user shall reestablish the link for future acquisitions. Even though, the Hot Swappable feature allows the panel not to get damage in the event of power is off (primary cable disconnection), any previous acquisition will be lost because the panel does not have either battery or flash memory to keep previous data stored. This feature is supported by the *Paxscan Virtual CP revision L06* system software and available upon request.

Paxscan System Software

There are two CDs supplied with this product. The Software CD 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 CD 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® XP compatible. A Software Developer Kit (SDK) including sample code notes are located in the directory:

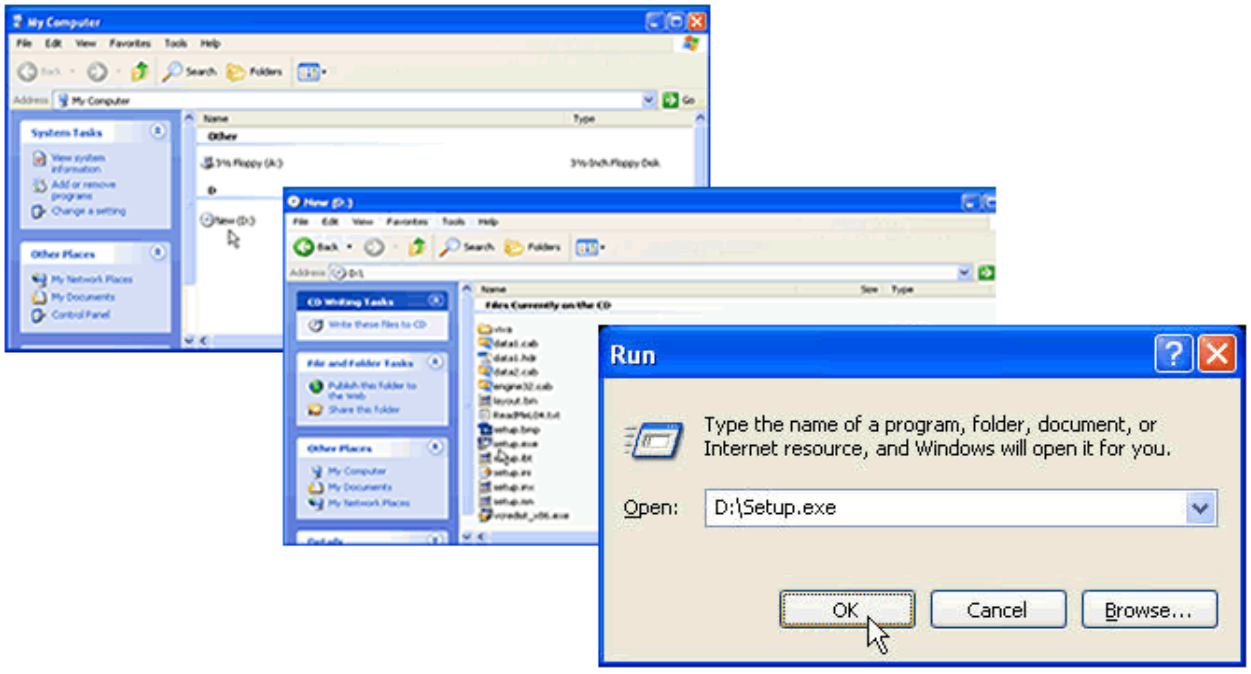
PaxscanL04\DeveloperFiles\SampleCode

The Receptor software CD 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 4336R model family is compatible with the Paxscan System Software version L04 or higher depending on the model. Please consult your Varian representative.

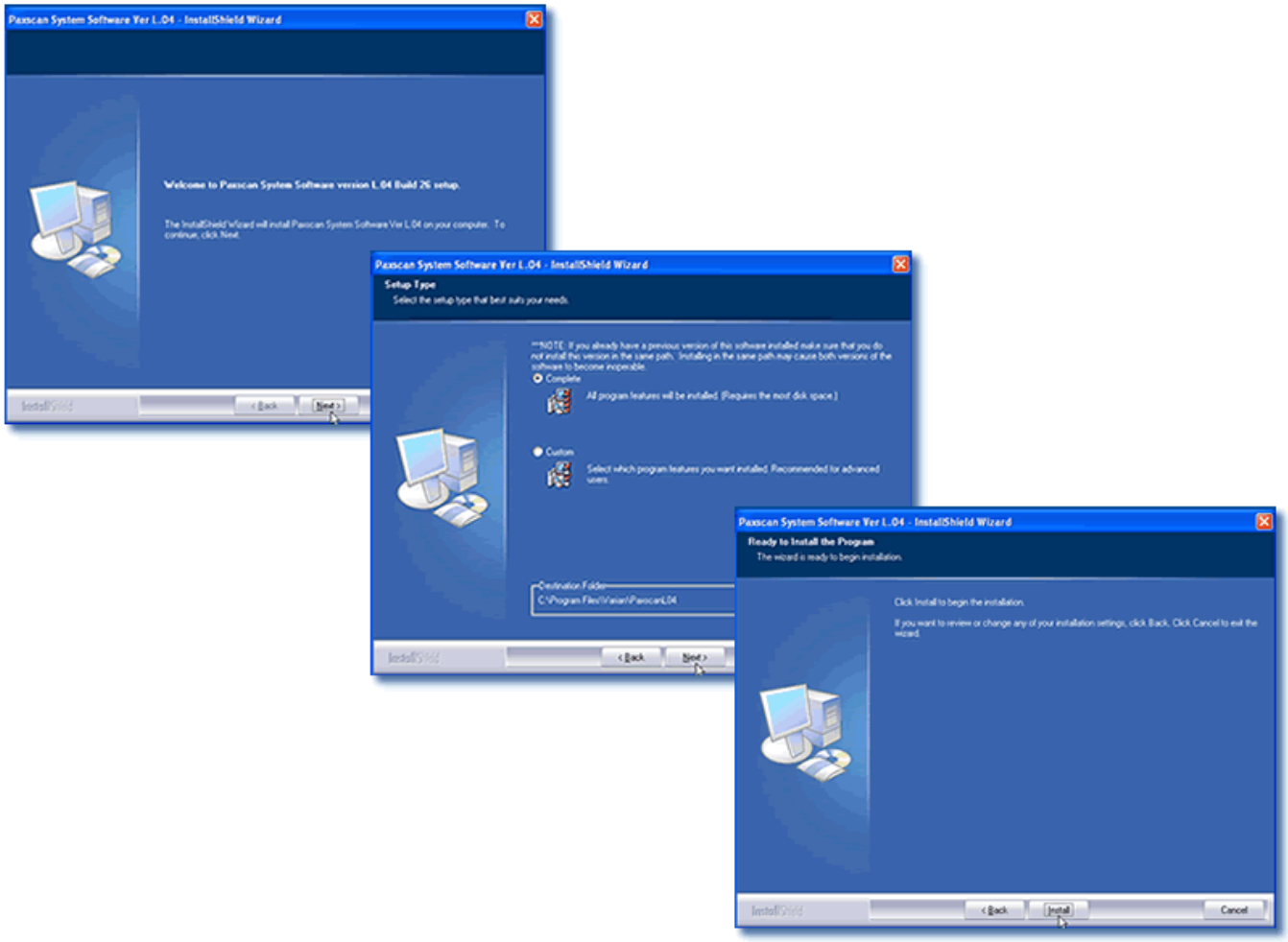
Software Installation

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 CD. 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. ▶



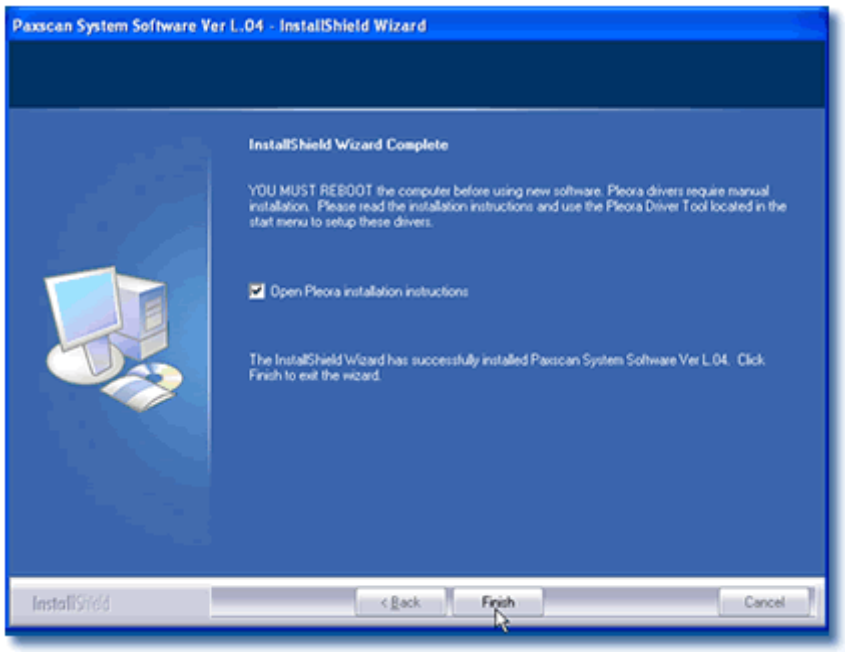
Step	Action / Results

1. For a normal install, you may simply accept all the defaults in progressing to the *Install Shield Wizard Complete* screen.



Step	Action / Results

2. Ensure the Open Pleora Installation Instructions is *"checked"* and select the finish button at the *Install Shield Wizard Complete* screen will automatically launches a README file instruction to complete the Pleora driver installation. You may only install the iPORT™ High-Performance IP Device Driver if you have the Intel Pro/1000 adapter; this is the recommended configuration. An alternative which gives lower overall data handling capability is the filter driver which may be installed to almost any Ethernet adapter on the computer. If the filter driver is installed, make sure to disable it on any adapters NOT used for connection to the Pleora. *See Note below regarding drivers.*

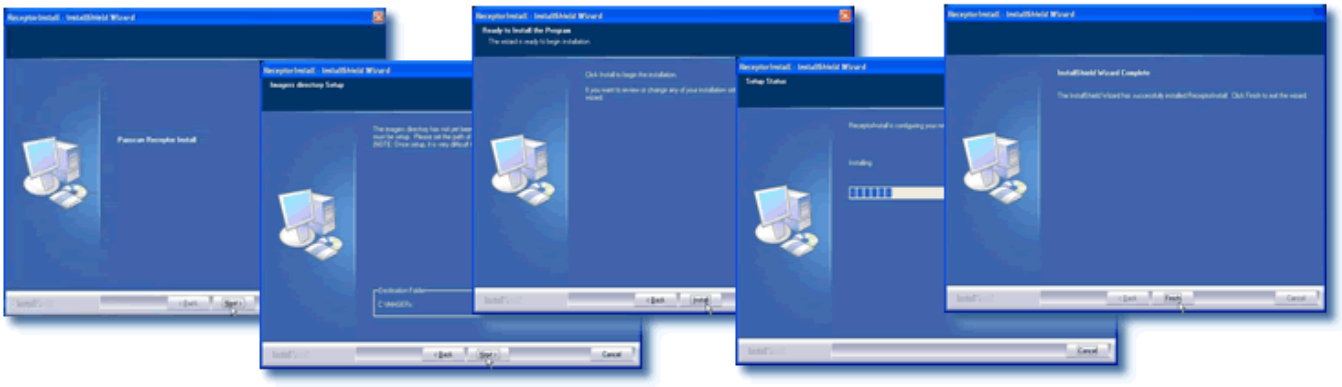


Note:

Pleora provides three options for the Ethernet driver. For fastest possible operation install the Pleora Performance driver onto the Ethernet adapter of the host computer; but, – this is only possible with specific Ethernet adapter – namely, the Intel Pro/1000. Other gigabit Ethernet adapters may be used without noticeable loss of speed for radiography (single shot) modes. Operation is possible with the native Windows driver which requires no additional installation, however, performance will vary depending upon the computer system. The Pleora Filter driver provides a third option that gives performance intermediate between the other two. The filter driver solution is better than the Windows driver though still not nearly as good as the performance driver. We strongly recommend using only the Performance driver for medical applications. The user must validate that any configuration used is suitable for the intended application.

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. ▶



Modes of Operation

The PaxScan 4336R supports the radiography mode of operation as defined in Table 2-0. 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 4336R 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	600ms	547 ms	Full Field	2,560 x 3,072	Accumulation
Radiography – Full Resolution SCT	10 sec	1 x 1	600ms	547 ms	Full Field	2,560 x 3,072	Accumulation

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 4336R will acquire one frame with its respective offset.

Multiple Receptor

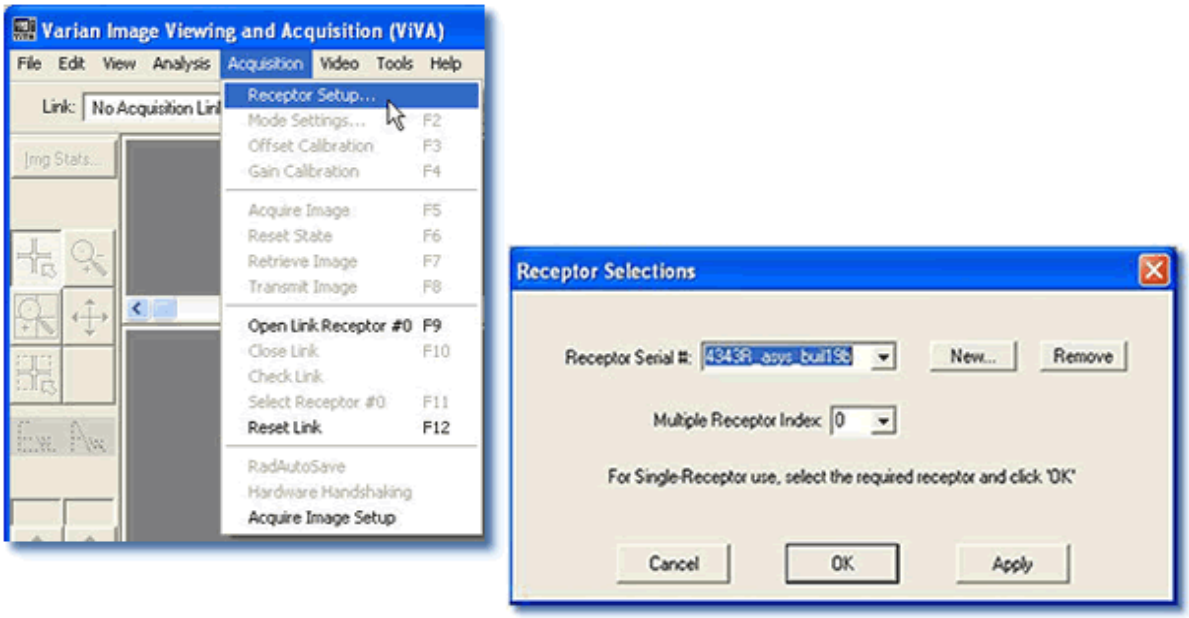
The Virtual Command Processor software supports multiple connections to two or more receptors of the same type; however, ViVA controls one receptor at a time. The receptor selection is changed from the *Acquisition* drop down menu. This feature is typically useful in a testing environment. ▶

UL 60601-1 Equipment Mode

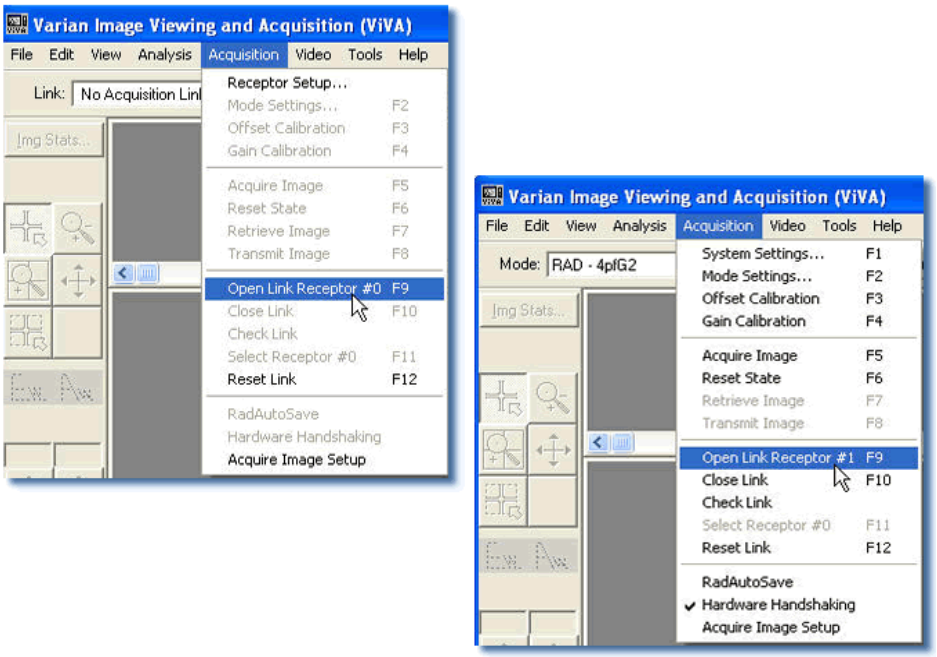
The UL defined operation of **equipment mode**, UL60601-1 Clause 2.10.3 is “continuous operation with intermittent loading”. The panel is intended to run up to a maximum of 150 cycles per hour.

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

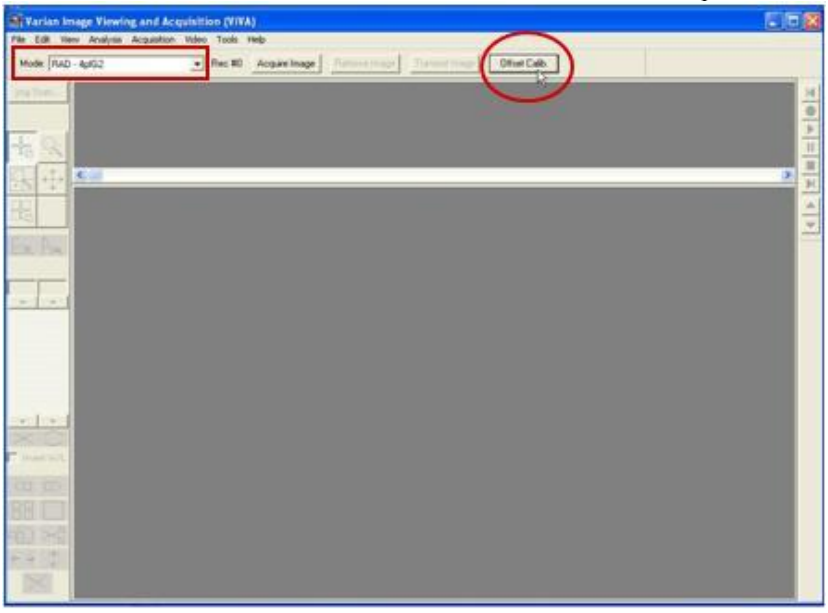
Offset calibration compensates for fixed pattern pixel intensity variations in the image associated with the dark current and electronic offsets. The Offset reference image is an average of a series of frames acquired without X-ray illumination and referred to as dark fields. ▶

- 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

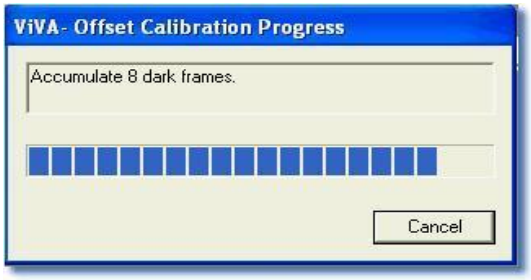
There are two types of offset calibration; one is used for the preview image and the other to calibrate the final image. Prior to acquiring images, an offset calibration must be performed in each mode. This offset calibration is used for the preview image. In addition, an offset calibration is automatically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

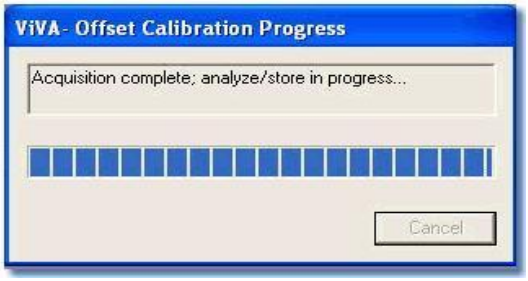
Step	Action / Results
1.	To perform offset calibration, click the *ViVA* icon  launches the application
2.	Ensure required receptor appears in the *Mode* drop down. The 4336R currently supports Rad 1x1 4pf. Click Offset Calib. button or select from the menu bar under Acquisition.



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 1,600 – 3,000. 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: 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.

The general procedure for Gain calibration for all modes is as follows in Table 3-0 and described below. Detailed instructions on performing gain calibrations are covered in the ViVA Online help documentation.

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

Table 3-0 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.

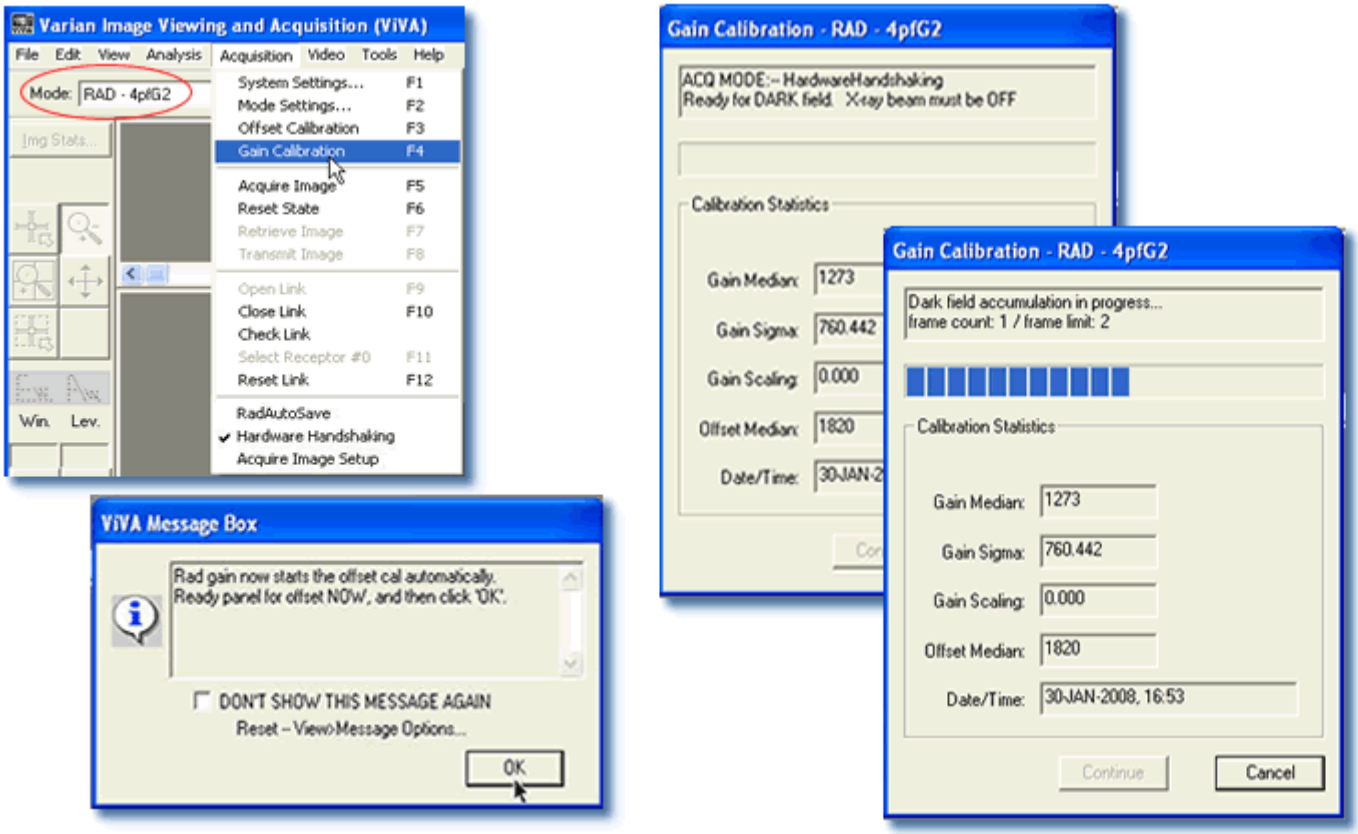
A series of accumulated frames equals one radiographic X-ray exposure. Exposures are averaged to obtain the Flat Field image used by the VCP correction module. The number of exposures acquired can be varied by clicking the **Finish** button after collecting the desired number of exposures.

Take the following steps to complete radiographic gain calibration. ▶

Step	Action / Results

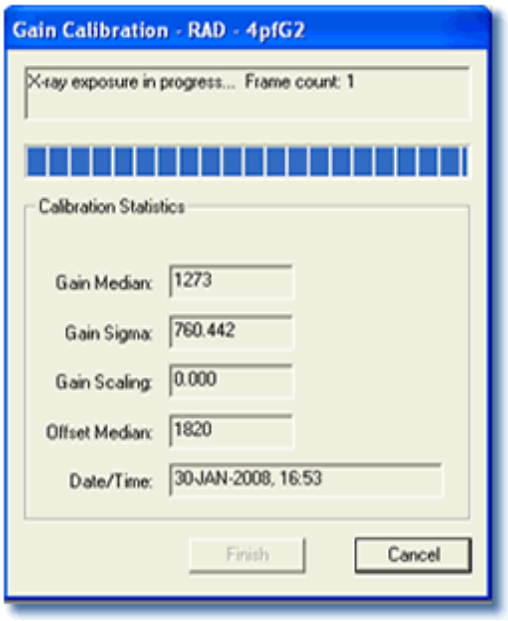
1. Ensure the desire receptor and imaging mode appears in the *Mode* drop down.

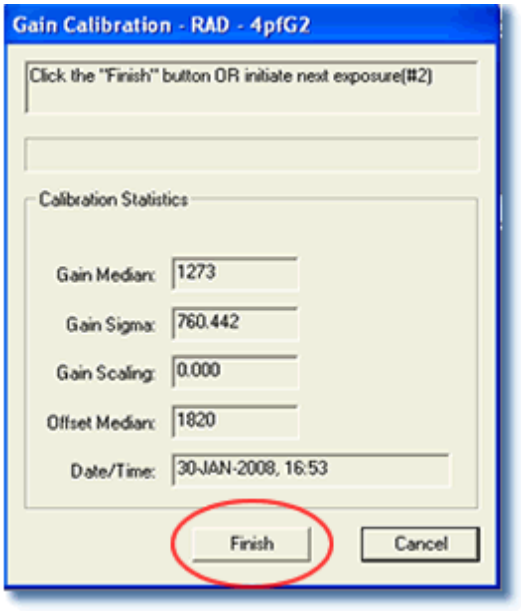
2. Click Gain Calibration from the menu bar under *Acquisition* invokes hardware handshaking for dark field calibration.



Step	Action / Results

3. Use *operator control* to perform an exposure. Click Finish to Complete calibration.





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: We recommend 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.

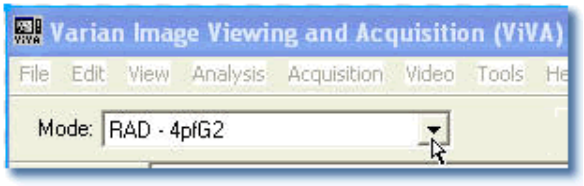
Note: For additional assistance operating ViVA™, use the ViVA Online help documentation.

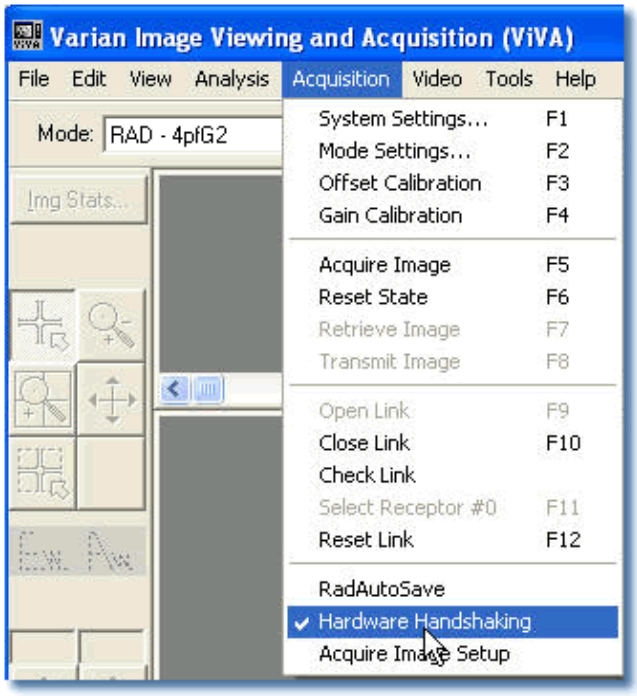
ViVA Mode Settings

The calibration and system settings are verified as follows. ►

Step	Action / Results

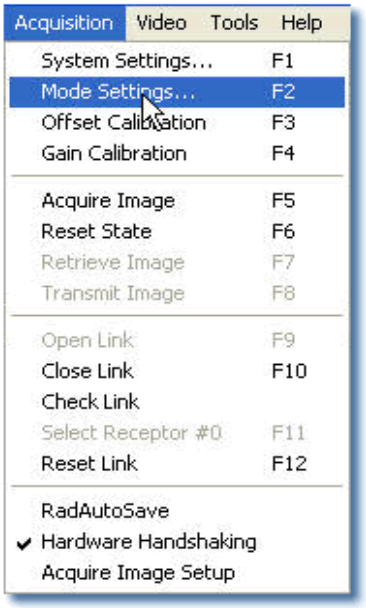
1. Make sure the desired receptor is selected from the *Mode* drop down menu; and, that **"Hardware Handshaking"** is *"checked"* from the menu bar under *Acquisition*. ViVA will remember your preference for future launches

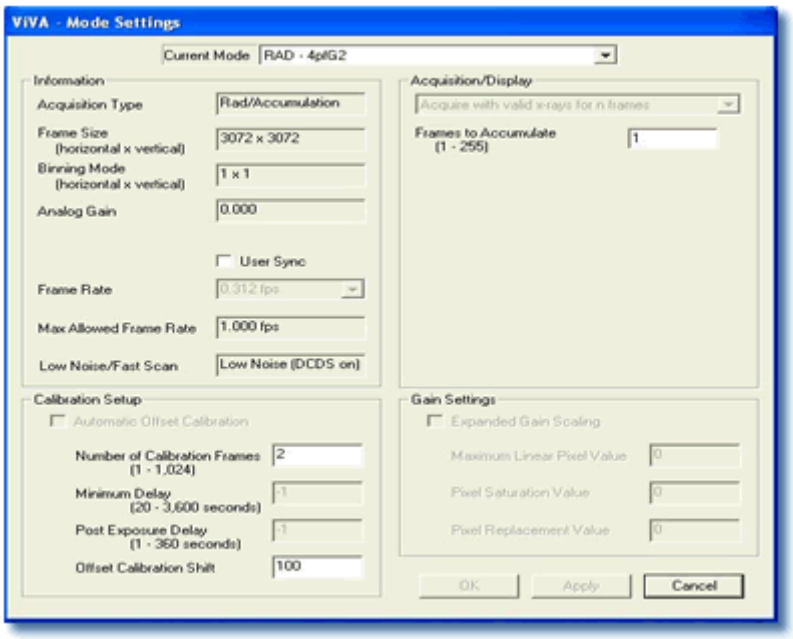




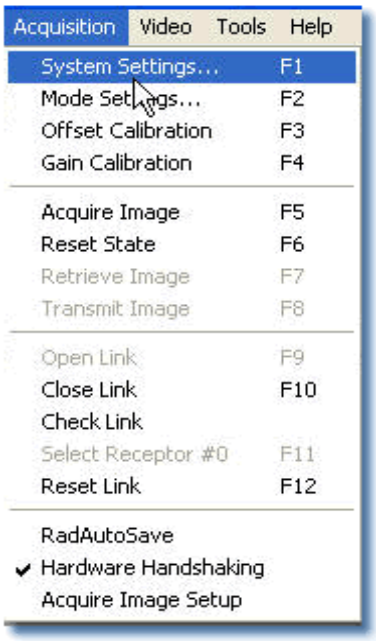
Step	Action / Results

2. Select *Mode Settings* from the menu bar under *Acquisition* for Calibration and Frame Rate settings. Frame rate settings are fixed. However, calibration frames can be adjusted**.**





3. System settings are verified as follows. **.**



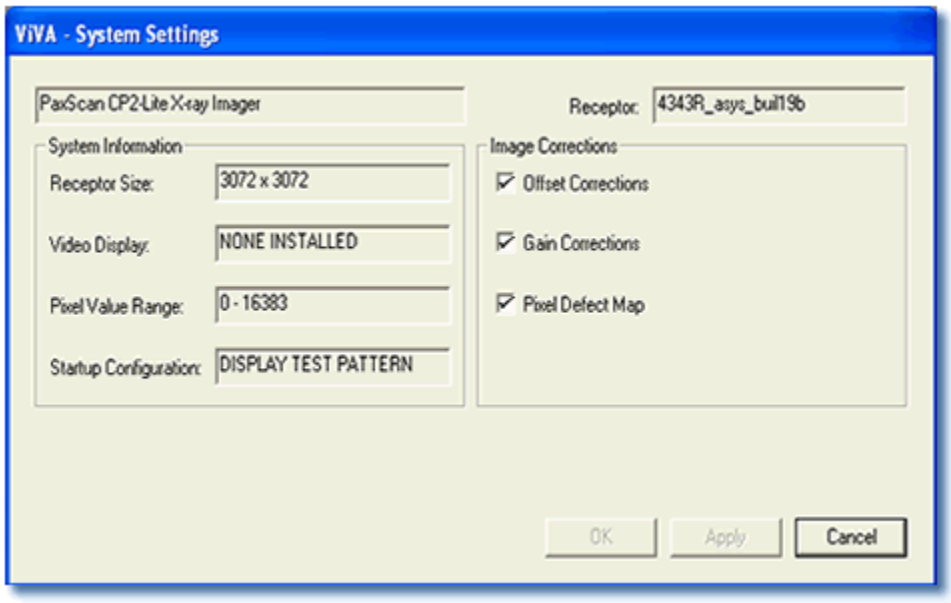


Image Acquisition

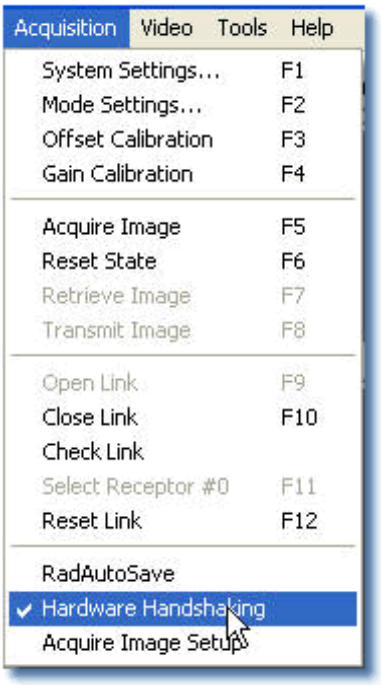
Once Offset and Gain Calibration is performed, you are ready to acquire images.

Radiography Mode

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

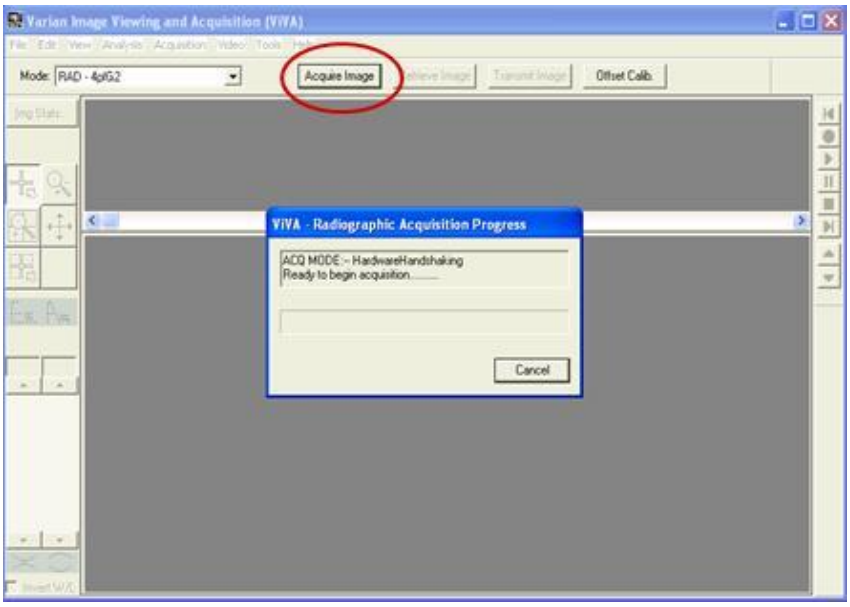
Step	Action / Results

1. Select required receptor from *Mode* drop down menu. The 4336R currently supports Rad 1x1 4pf.
2. Make sure hardware handshaking is checked.

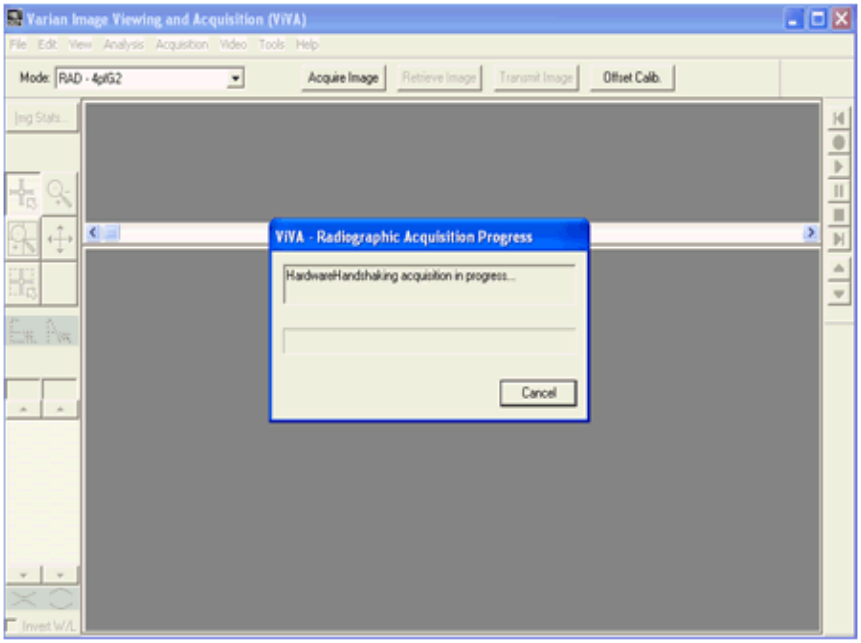


Step	Action / Results

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

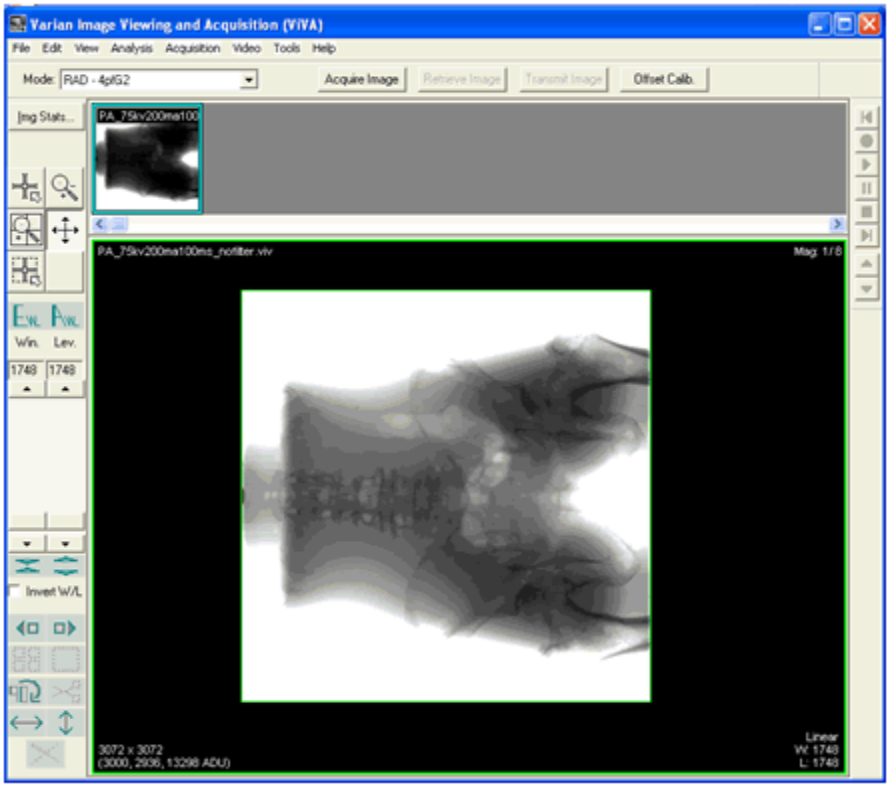


4. Depress *operator control* fully to "Expose" position to complete image capture and retrieval.



Step	Action / Results

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



Note: *Operator Control* is user supplied equipment.

Safety

Electro-Magnetic 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 in the vicinity. In any all circumstance; however, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, 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 the **Troubleshooting** section.

Electrical Shock Protection

- Electrical Ratings for Model 4336R: Input Voltage 100 – 240VAC, Input Frequency 50 to 60 Hz, Input Current 1.5A. FUSE: T3.2 AL 250VAC

Environment Limits

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

Temperature & Humidity

Category	Limits
Storage & Transport (ambient)	-20º C to +70º C
Storage Humidity (non-condensing)	10% to 90%
Normal Operation Temperature (measured at the center of the back cover)	10º C to 35º C
Operation Humidity (non condensing)	10% to 90%

Altitude Limits

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

Regulatory

- The PaxScan® 4336R model family is a Type B component sub-system per Standard or Medical Electrical Equipment. The PaxScan® 4336R model family is an associated equipment x-ray medical equipment 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

  CSA-C22.2 No 60601-1 Medical Electrical Equipment, Part 1 General Requirements for Basic Safety and Essential Performance 3rd ed.

  EN/IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility 3rd ed.

- Type B Applied Part 
- CE Mark - Varian Medical Systems' imaging products are designed and manufactured to meet the Low Voltage Directive 2006/95/EC, MDD 93/42/EEC.
- MDD Class IIa
- A Declaration of Conformity has been filed for this product and available upon request by contacting Varian Medical Systems - 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 aluminum 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.

Repairs

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

The least replaceable units (LRU) are:

- Receptor Assembly
- Power Supply (I/O Box)

Proper Disposal

The 4336R receptor should be returned to Varian Medical Systems for disposal. We request that you obtain an RMA number using the same procedure for warranty/returns of products.

Contact: PAXSCAN.RMA@VARIAN.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 4336R Problem Report. 2. Email the error log file generated to: paxscan.rma@varian.com. This log file is normally found at C:\users\{username}\AppData\Local\crashdumps\viva.log

How To Reach Us

In order to provide you with the most comprehensive technical support, (hardware or software), please complete the problem report on following page before contacting your Varian representative.

To speak with our technical support personnel:

- Call (800) 432-4422 dial 8.

For Warranty and Returns please refer to:

- http://www.varian.com/us/xray/services_support.html

For other problem reporting:

- Complete the form on following page
- E-mail: PAXSCAN.RMA@varian.com

PaxScan 4336R 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: PAXSCAN.RMA@varian.com

Appendix A

Interfacing Information

All the interfacing connections for the Paxscan 4343R 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 ("B") is a 9-pin D-sub type. Power for the panel is supplied by a medical-grade "laptop" style supply whose dc supply cable "C" can be up to 3 meters in length.

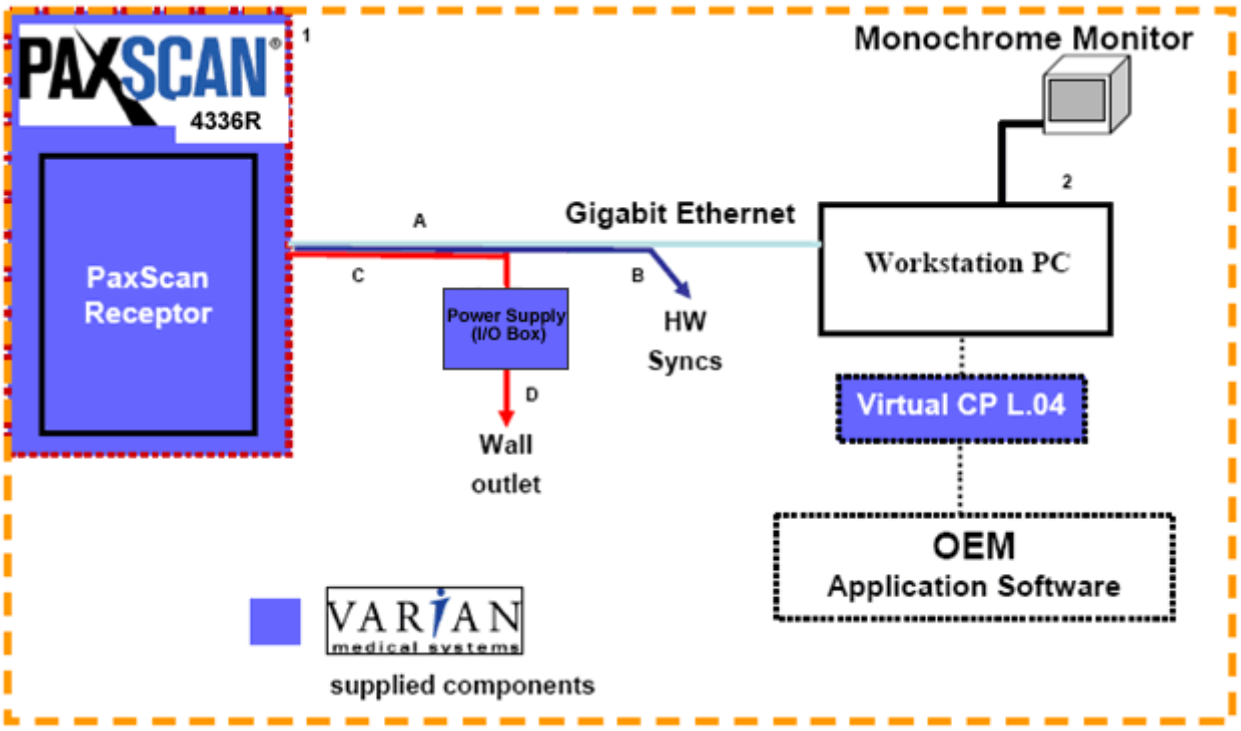


Figure A.1 Block Diagram of the 4336R Imager

The synchronization interface to the panel consists of two inputs and one output, all through opto-couplers. The expected inputs to the panel are Prepare and 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 4336R panel currently ignores Prepare and responds only to Exposure_Request. 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 4336R is 5V. Refer to the TSM0505S datasheet for additional information.

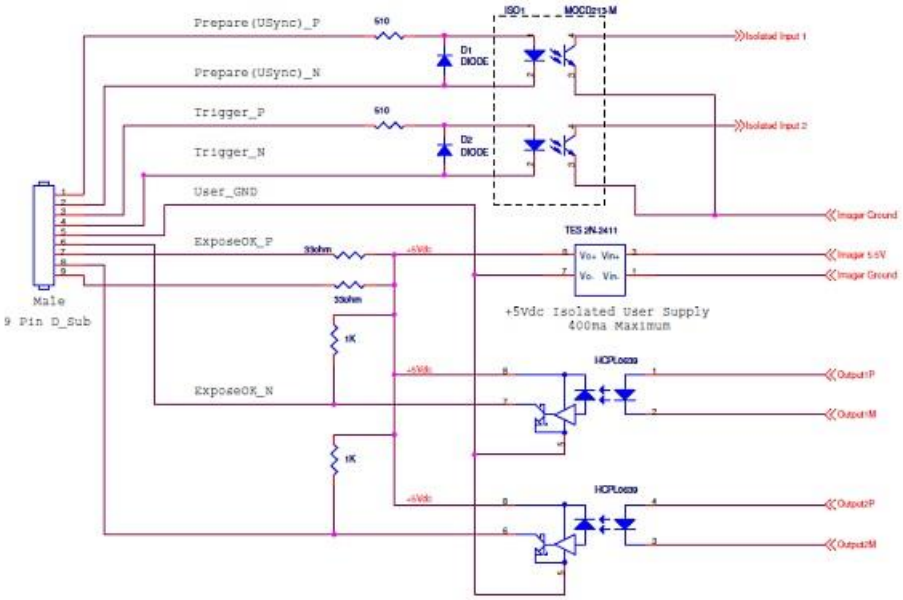


Figure A.2 Schematic for "Expose Ok" and "Expose Request" Signal

The typical timing of the synchronization interface is shown below. The panel is maintained in an idle state, until the asynchronous Expose_Request is received. The Expose_Request signal is detected as a level and so the signal must be maintained for a minimum of 360 msecs. When the panel receives the Expose_Request, the assumption is that the generator is ready to make an exposure when Expose_OK is issued.

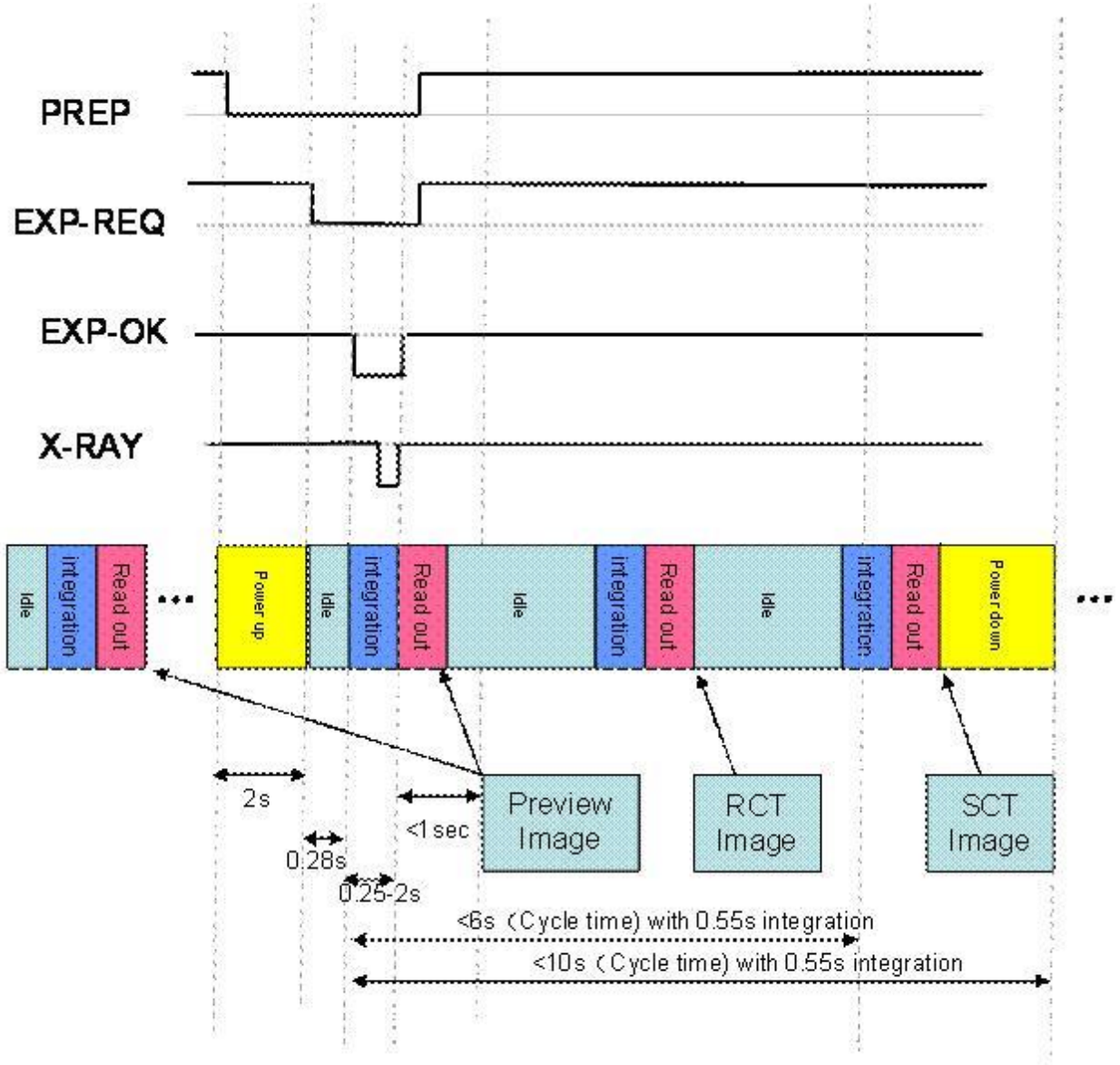


Figure A.3 Example Timing for 4336R Synchronization Interface