Digital Image Receptor

The PaxScan 4336W / 4336X is a radiographic digital x-ray imaging sub-system

Abstract The Operating Instructions (P/N 42449) covers safety, setup, operation, and maintenance of the PaxScan 4336W / 4326X 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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Introduction

The PaxScan 4336W/4336X 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 three main system components: The flat panel sensor , VCP software, and the External Power Supply (I/O Box) that provides the wireless communication and power to recharge the receptor battery. The PaxScan 4336W/4336X model family will also be referred to as 4336W throughout this manual.

Shipment Contents

Flat Panel Receptor Assembly (includes a detachable receptor cable for wired operation or battery recharging)

PaxScan Receptor Install CD

(Files specific to the receptor in the shipment)

PaxScan Software CD

Virtual CP/ViVA System Software L.06 Release 5

I/O Interface Box

Laptop Style Power Supply (P/N AHM85US24-XB0273A) with Power Cable

PaxScan 4336W/X Operating Instructions

Optional Parts

Laptop Style Power Supply (P/N AHM85US24-XB0273A) with Power Cable

Battery Charger

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 4336W/ 4336X model family are designed to meet the needs of general radiography diagnostic for medical and veterinary use in portable applications utilizing multiple sensitive and extend dynamic range modes. This family model will acquire image over a wide range of dosage, while providing maximum access to the patient, with a minimum possible border on the active imaging area. This device is designed to communicate either wirelessly or tethered, using the optional combination cable.

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 portable 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 4336W 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: To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth when not in wireless configuration.

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.

WARNING: 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.

WARNING: Do not exceed maximum load weight of 100kg distributed around the overall surface of the panel

Patient Contact Limitations

Figure 1-0 Patient Contact Surfaces – 4336W

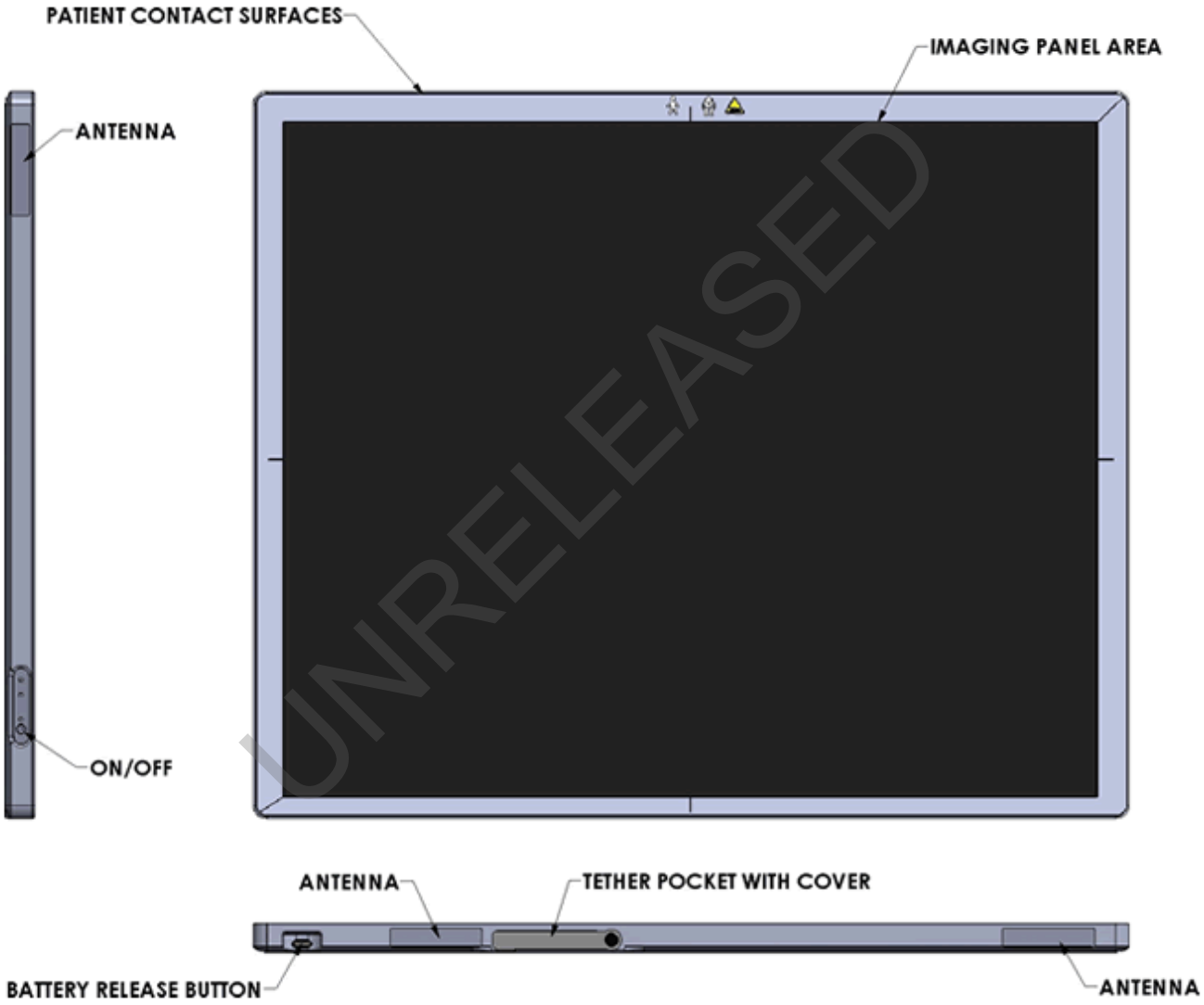
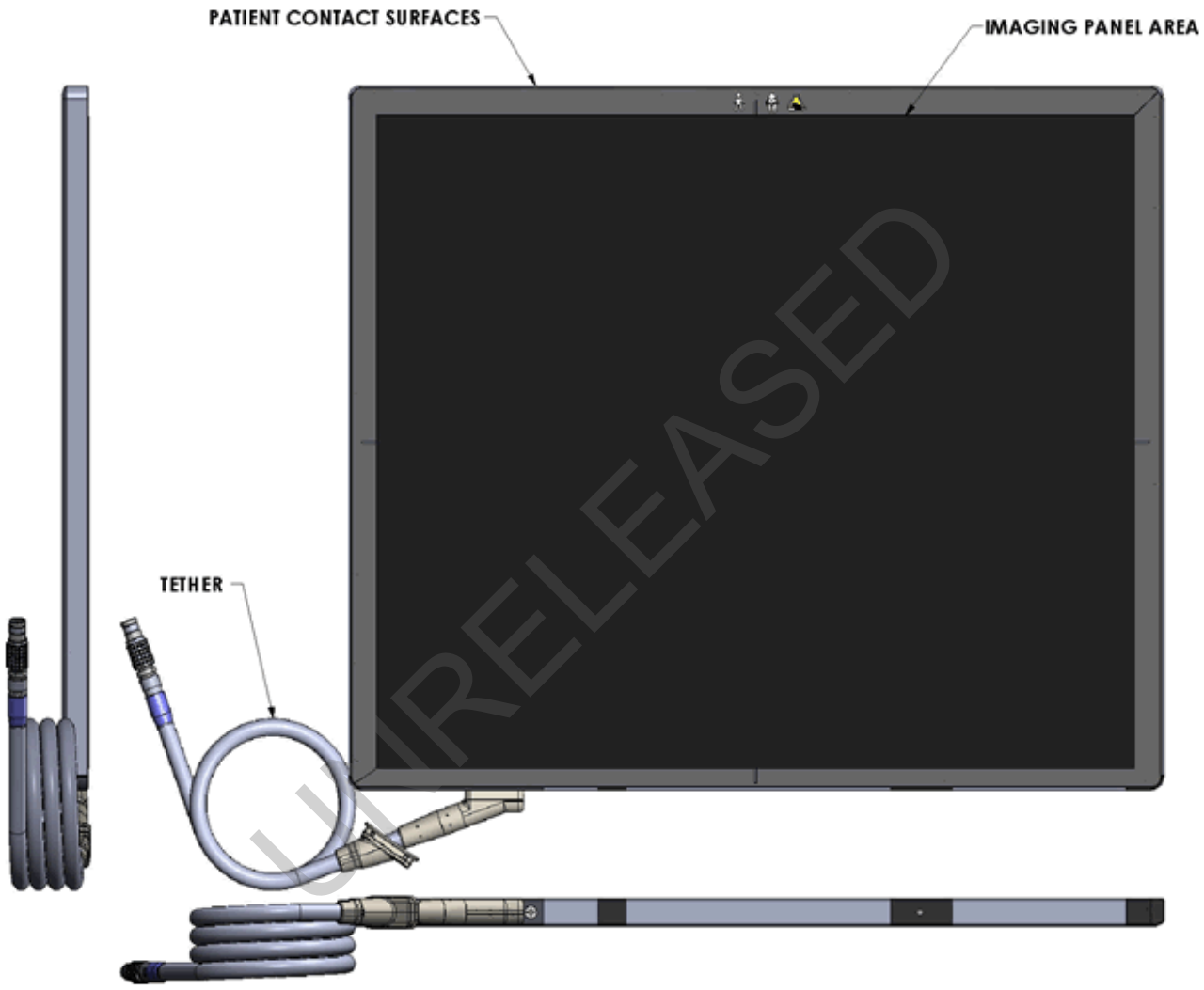
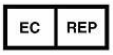


Figure 2-0 Patient Contact Surfaces – 4336X



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
	Heated Surface		Type B Applied Part		Load Weight Restriction
	Temperature Limits		Non-ionizing radiation		

Getting Started

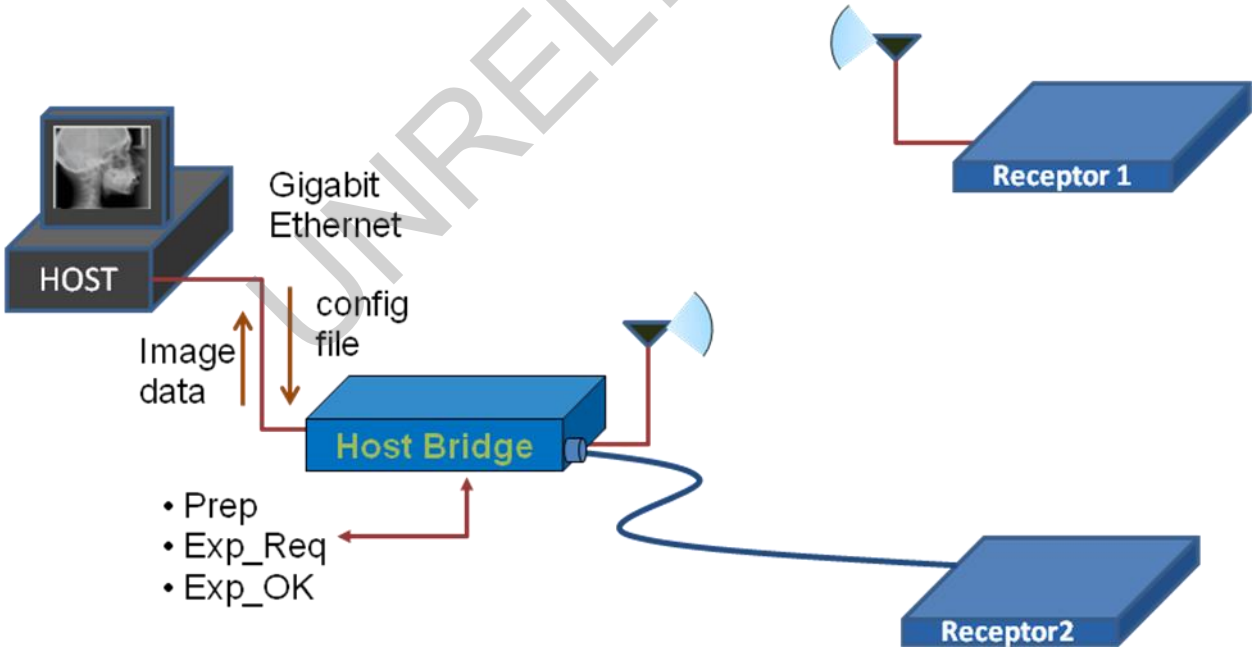
System Overview

In medical applications, the function of the 4336W FPD is to absorb the X-rays that pass through the patient's anatomy and convert them into a digital image. The I/O Box is the interface between the FPD 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. The Receptor is intended to be in patient contact and is provided 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 3-0 shows the configuration of the Receptor in the context of the overall imaging system. The dimensions for receptor are 459.5mm x 383.5 x 15.13mm.

Figure 3-0 Imager Configuration

(Receptor 1 – Wireless, Receptor 2 – Wired)



The Receptor operation is controlled using software commands via UART which use an Ethernet link as a physical layer. The set of possible Receptor control operations are supplied to system 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 provides all hardware interfaces for the PaxScan 4336W using an external hardware interface connection. The laptop style power supply, which is optional equipment, provides the I/O Box with +24V DC power. The receptor is battery powered but can operate in wired mode through the tether, which can also be used to recharge the battery. The I/O Box has a footprint of 182mm x 167mm and a height of 192mm.

WARNING: All regulatory approvals, including UL and CE mark, are contingent on the use of the I/O Box with the external 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 4-0 and 5.0. ▶

Table 1-0 Cable Connection Details

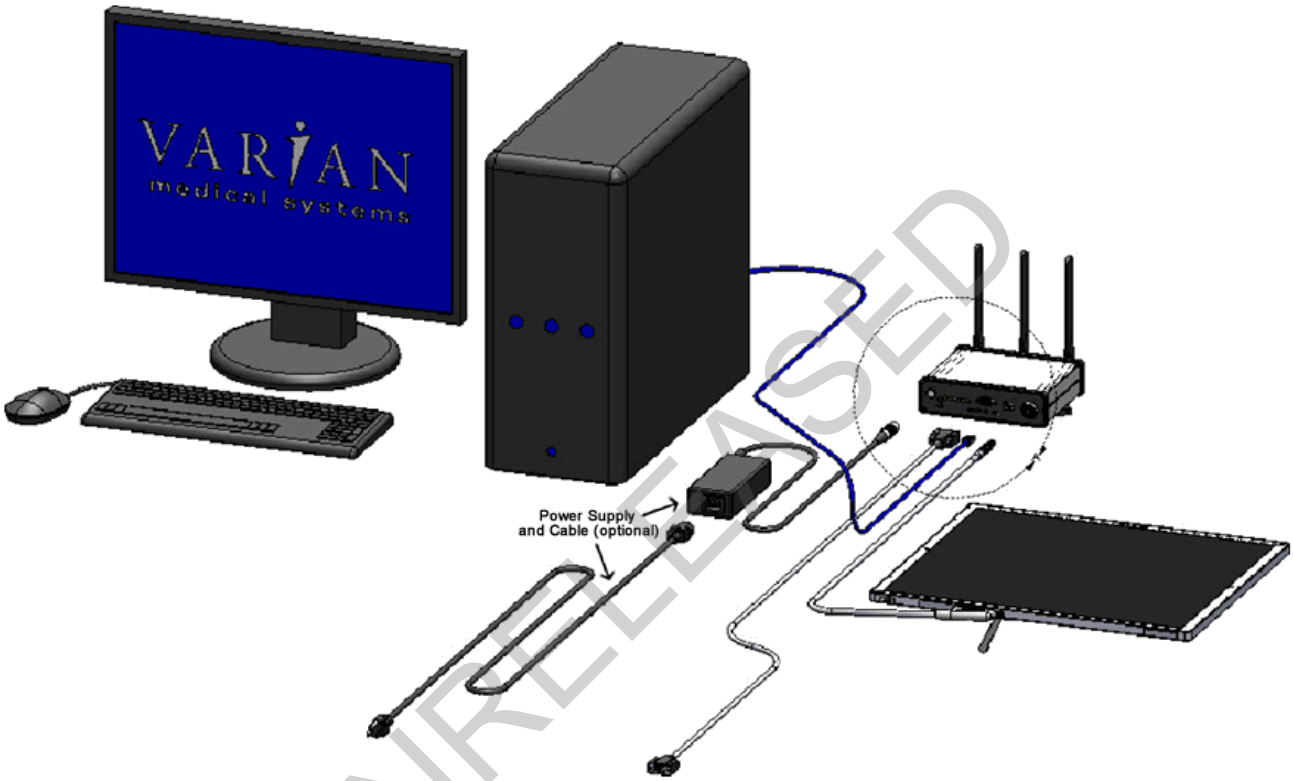
Step	Action / Description
There are four (4) cable connections for the 4336W Flat Panel Receptor: (a) The laptop style power supply cable - (optional), (b) external sync cable, (c) Category 5 or better Ethernet cable, and (d) tether cable. The cable connections are described below.	
1.	**Laptop Style Power Supply - (optional)** This provides +24V to the I/O box. Connect the laptop style power supply to the I/O box at the +24V input. Plug the laptop style power supply into the main AC supply.
2.	**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.
3.	**Gigabit Ethernet Connection** Connect the Ethernet cable to the I/O Box connector and to a gigabit capable interface in the user's host computer.
4.	**Tether Cable** This cable functions as an interface between the receptor and the I/O Box by providing power and synchronization signals to the receptor (X model and tethered W configuration). Connect the tether cable between the imager and I/O box. Plug the Laptop Style Power Supply into the +24V outlet on the I/O Box. *When using the X model or tethered W configuration, the panel should be installed and operated as far as possible from the Laptop Power Supply.*
5.	**Ground Lug** Connect I/O box chassis ground lug to acceptable ground connection

Important:

The External Sync Cable Connection is user supplied equipment.

This connection shall only be handled by the service personnel.

Figure 4-0 Cable Connection - Overview



Important: Use minimum 18 AWG wire for connection to the external PE terminal on the I/O Box

Figure 5-0 Cable Connection - Detail

Powering On The Receptor

Plug in the LEMO connector from the external power supply to the I/O box. There are 6 (six) LEDs located on the front of the I/O box. The "POWER" LED is lit when power is supplied to the I/O box. The other LEDs indicate when external signals are asserted at the time image acquisitions are taking place. Wait at least 2 minute after powering up the I/O box before any operations.

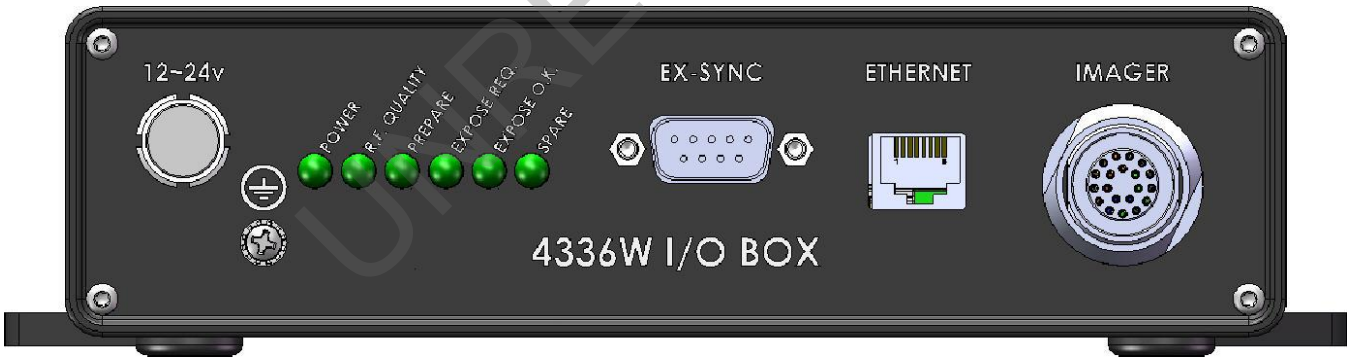
Wireless mode (W):

Hold the power button down on the receptor for 1 second to turn the receptor on (blue LED on the receptor will turn on). The panel will power on and immediately attempt to connect to the I/O box. The green LED on the receptor will turn on when there is a wireless connection and will also detail connection strength. See Appendix C for additional information about connections.

Tethered mode (W/X):

The receptor will turn on as soon as power is present by either connecting the tether cable to a powered I/O box or by powering on the I/O box after the tether connection is made. The power button on the W model may still be used to turn the panel on and off after this initial power-up.

Figure 6-0 Power On Connection



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.

Additional Features

Power Down Algorithm

The PaxScan *4336W/X* provides an alternative option to allow customer to power down major voltages in the receptor as soon as an undesirable higher temperature is reached. This algorithm will prevent the receptor from working in such conditions thereby lowering its power consumption.

Implementation

The algorithm will TURN ON/OFF based on 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 its power in order to reduce its power consumption. Once the receptor is in power down, it will report its status to VCP and will not allow any further acquisition.

After the temperature of both sensors drops below a lower threshold the power will return and the user will not be allowed to acquire images for the next 4.4 seconds (initialization).

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

Hot Swappable

This feature allows the customer to disconnect the primary cable from the I/O Box to the receptor without powering down the unit. After this disconnection occurs, the user shall re-establish the link for future acquisitions by either re-connecting the tether or through a wireless connection, depending on desired acquisition type or receptor version being used. 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 CP that provides the API to the receptor, allowing control and image transfer functionality; see the Virtual CP Communications Manual 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™.

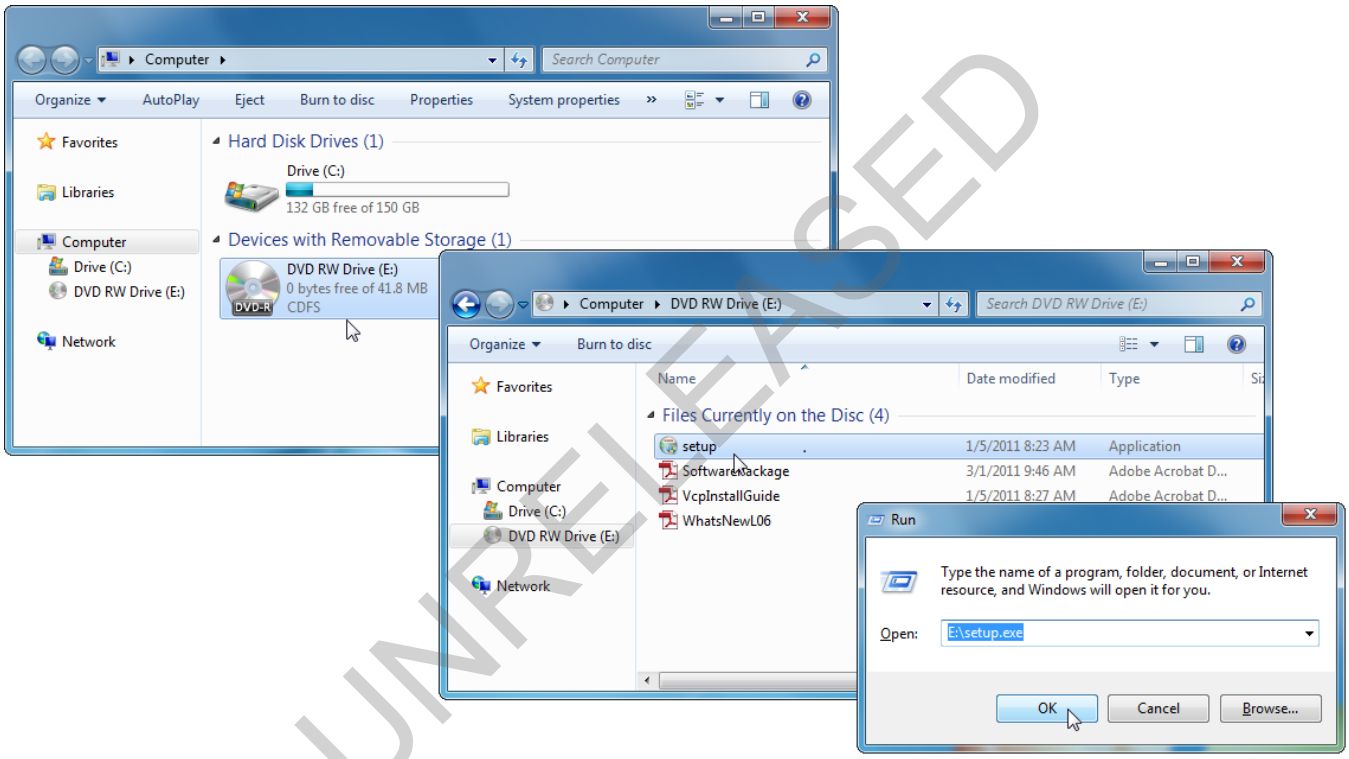
The 4336W/X model family is compatible with the Paxscan System Software version L06 or higher depending on the model. Please consult your Varian representative.

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. ▶

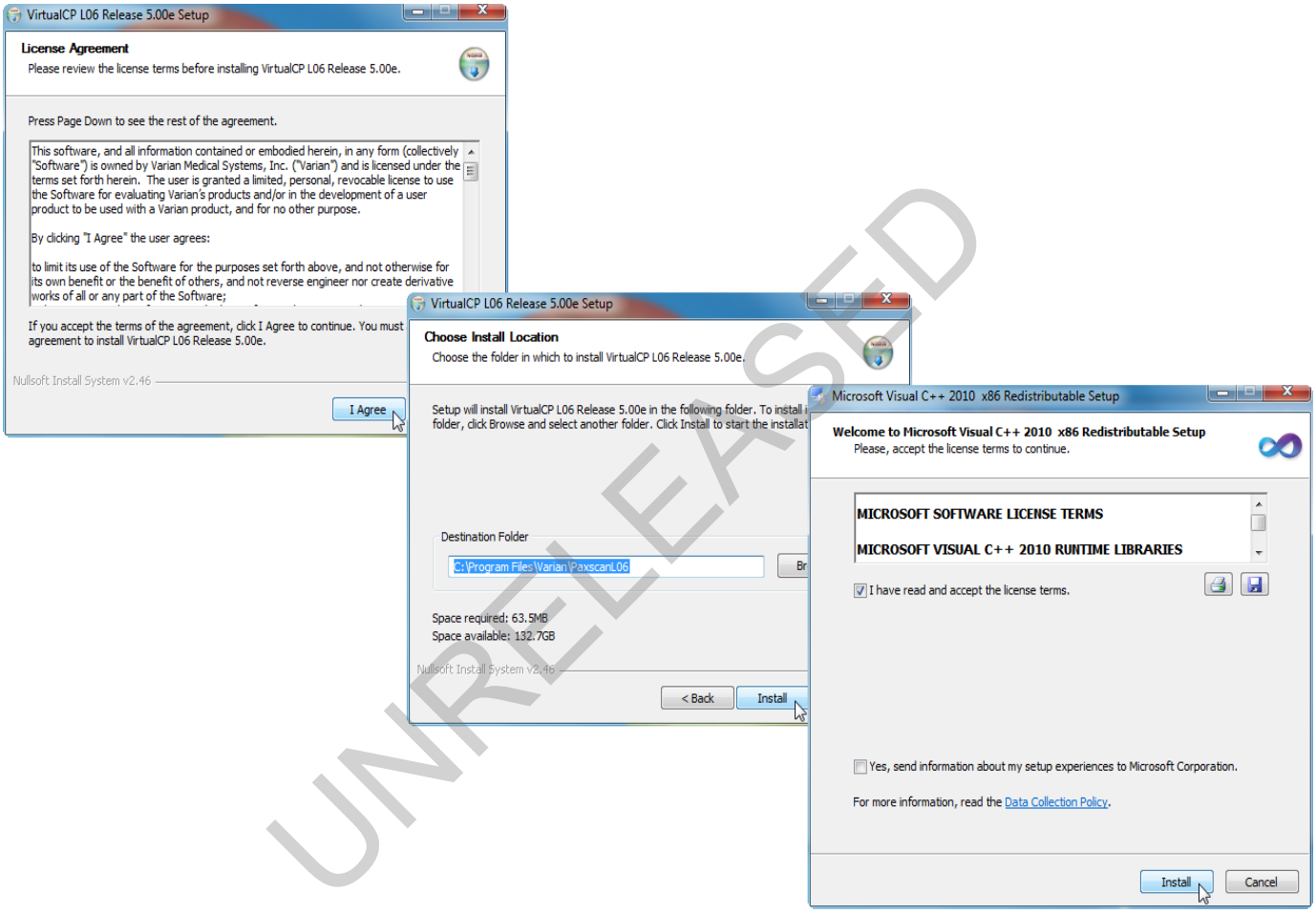
Step	Action / Results

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



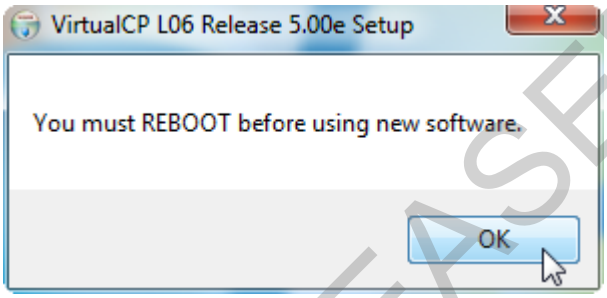
Step	Action / Results

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.*



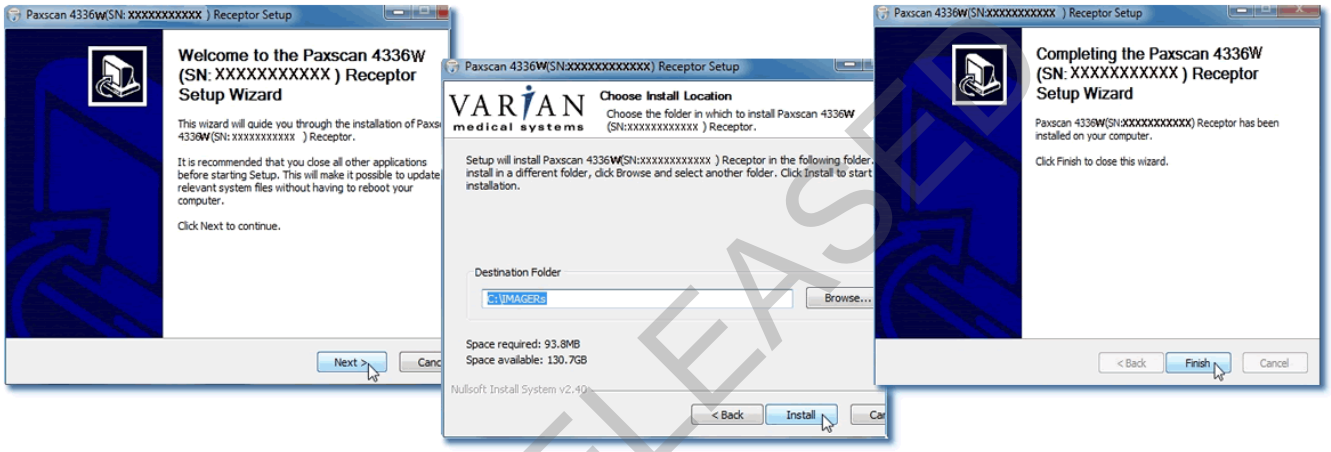
Note:

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.

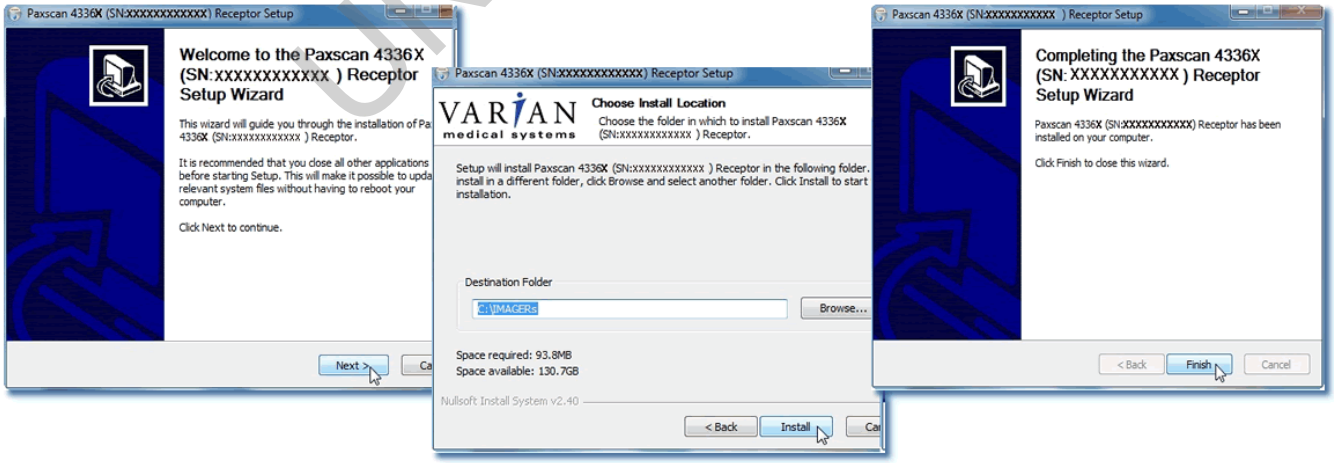
Receptor Files Installation

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

- **4336W – follow the prompt sequence**



- **4336X – follow the prompt sequence**



Modes of Operation

The PaxScan 4336W/X supports the radiography mode of operation as defined in Table 2-0. In general, there is a tradeoff 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.

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

Note: 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 4336W/X 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)

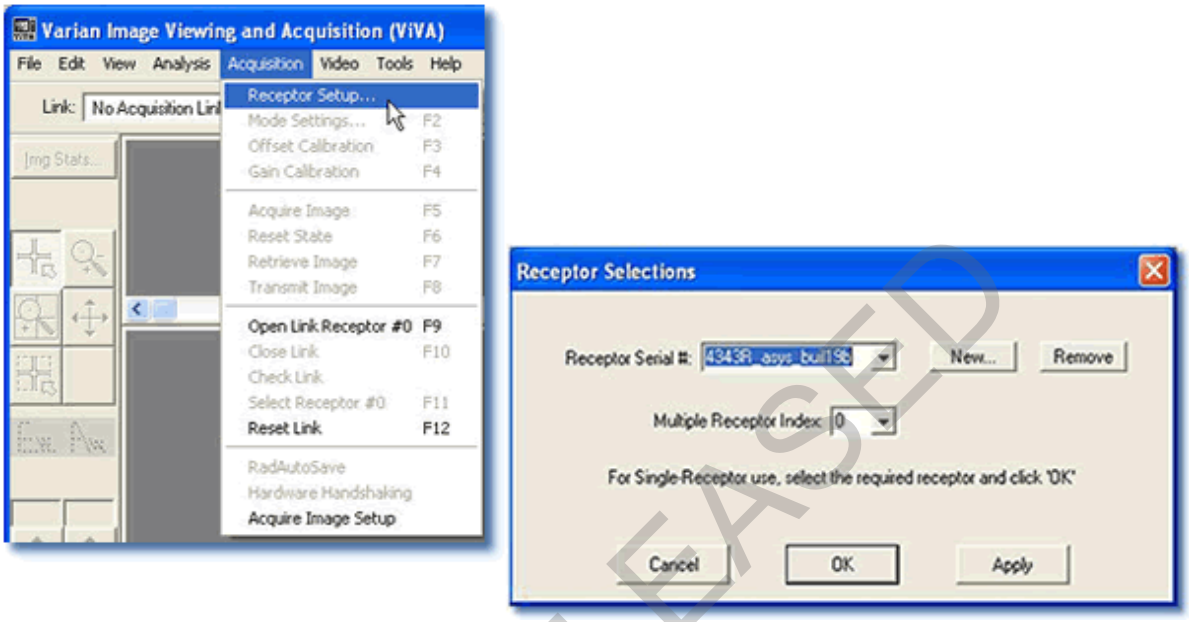
Each operating mode employs all types of calibration. In radiography-type acquisitions, the PaxScan 4336W/X will acquire one frame with its respective offset.

Multiple Receptor

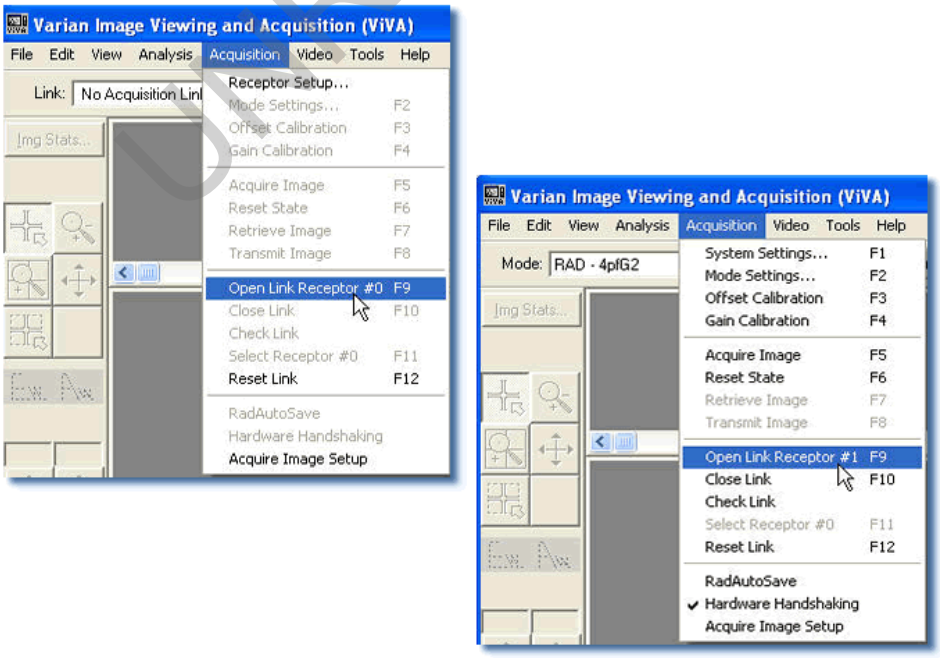
The Virtual Command Processor software supports multiple connections to two or more receptors of the same type; however, ViVA controls one receptor at a time. The receptor selection is changed from the *Acquisition* drop down menu. This feature is typically useful in a testing environment. ▶

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.

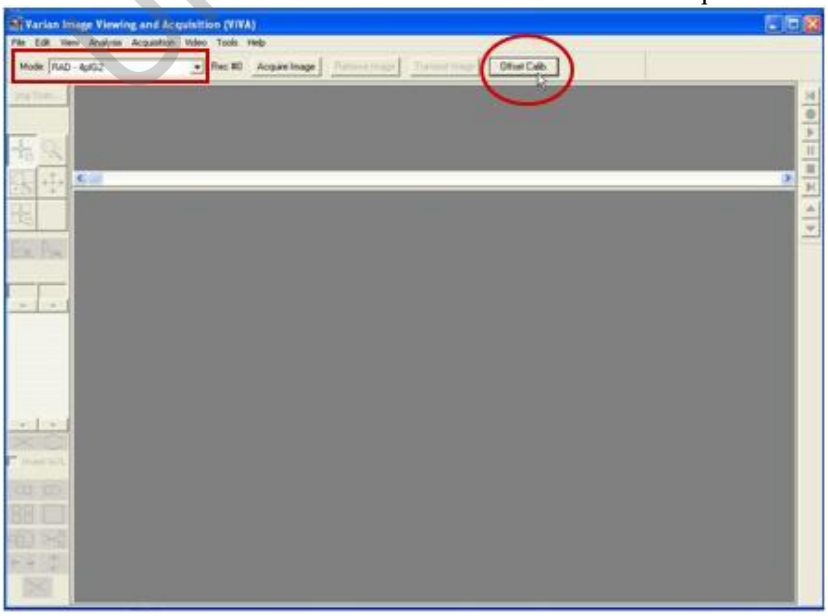
Preview Offset Calibration

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

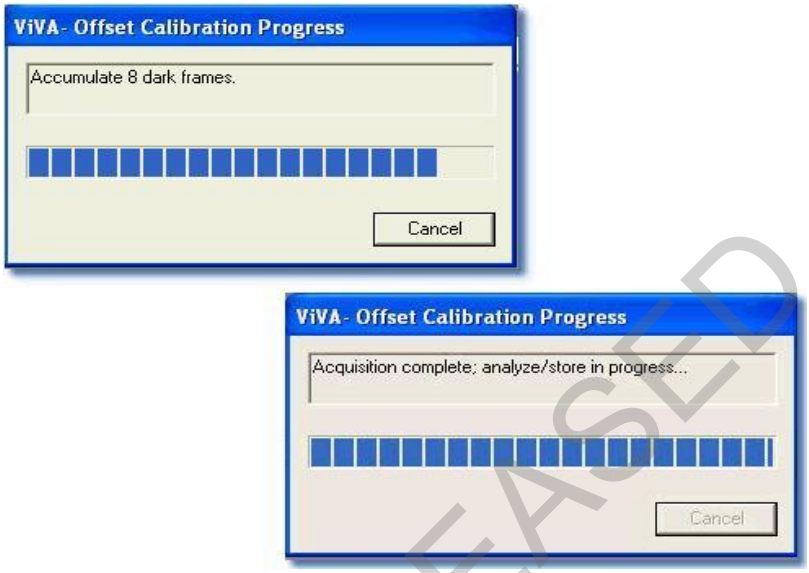
1. To perform offset calibration, click the *ViVA* icon  launches the application

2. Ensure required receptor appears in the *Mode* drop down. The 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 4336W/X 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.

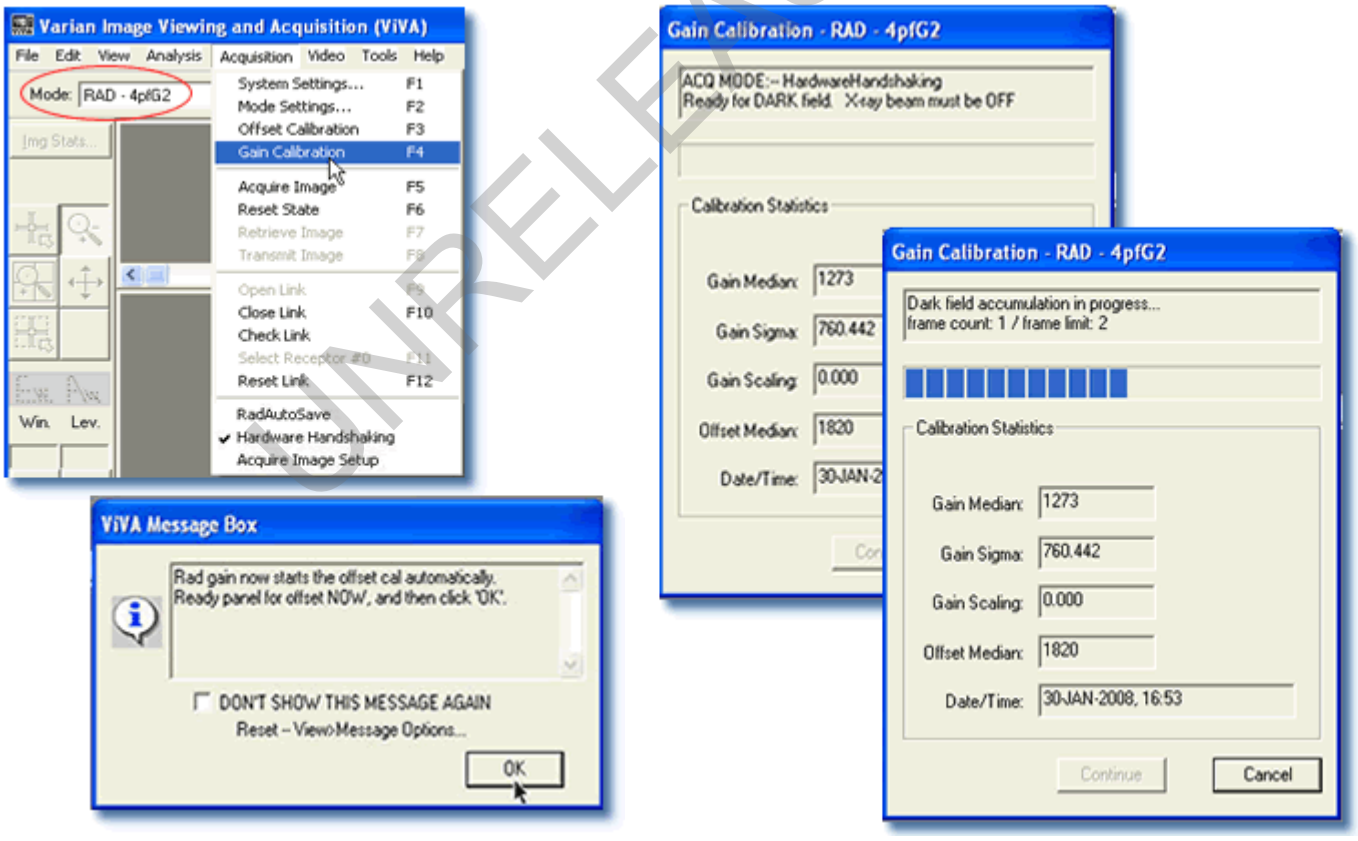
A series of accumulated frames equals one radiographic X-ray exposure. Exposures are averaged to obtain the Flat Field image used by the VCP correction module. The number of exposures acquired can be varied by clicking the **Finish** button after collecting the desired number of exposures.

Take the following steps to complete radiographic gain calibration. ▶

Step	Action / Results

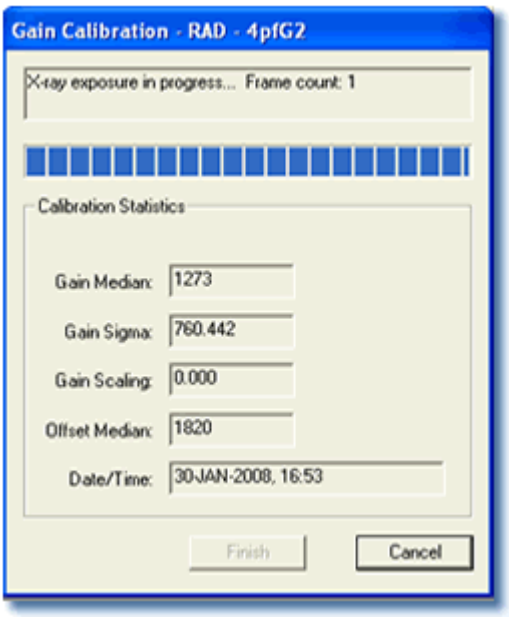
1. Ensure the desired receptor and imaging mode appears in the *Mode* drop down.

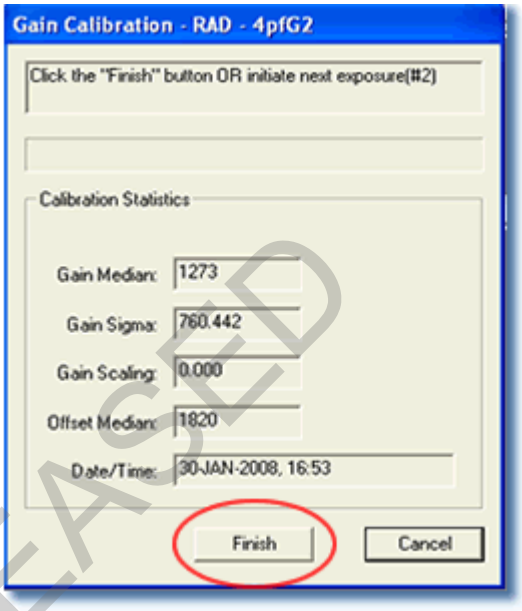
2. Click Gain Calibration from the menu bar under *Acquisition* invokes hardware handshaking for dark field calibration.



Step	Action / Results

3. Use *operator control* to perform an exposure. Once all x-ray frames have been acquired click Finish to Complete the 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: Varian 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.

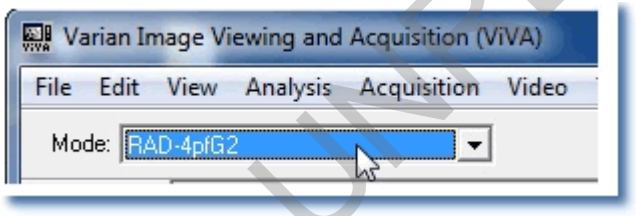
Note: For additional assistance operating ViVA™, use the ViVA Online help documentation.

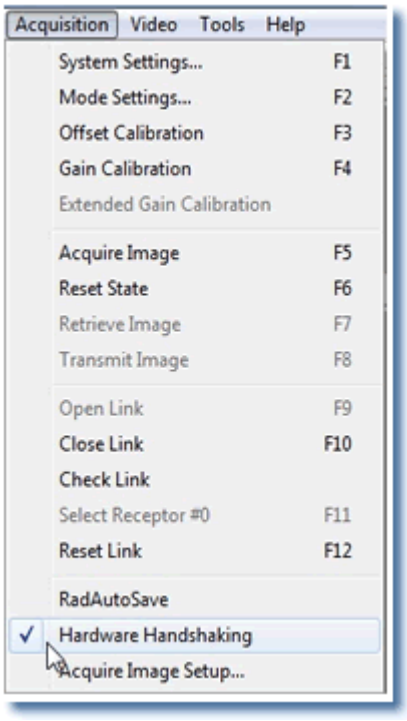
ViVA Mode Settings

The calibration and system settings are verified as follows. ►

Step	Action / Results

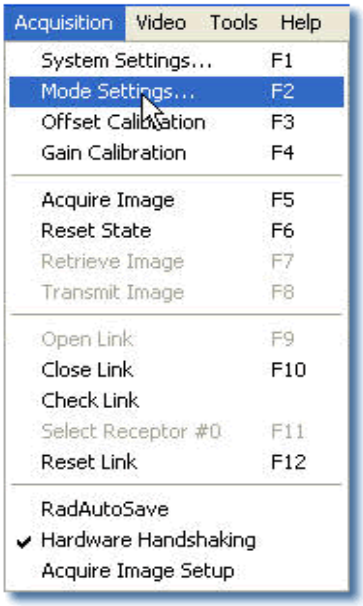
1. Make sure the desired receptor is selected from the *Mode* drop down menu; and, that **"Hardware Handshaking"** is *"checked"* from the menu bar under *Acquisition*. ViVA will remember your preference for future launches

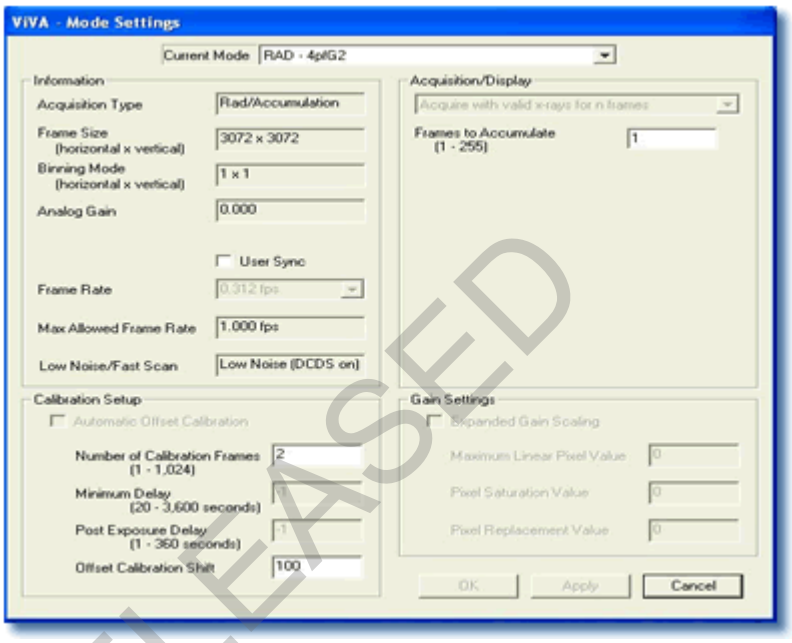




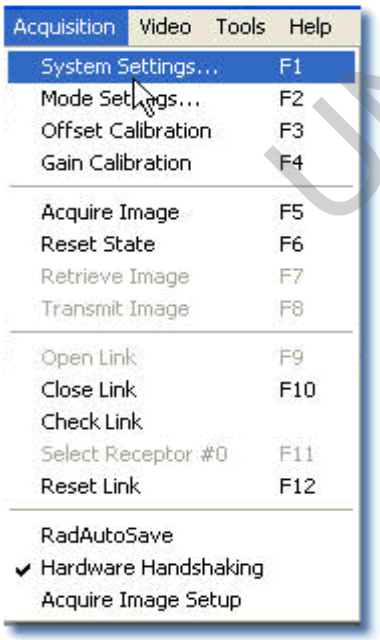
Step **Action / Results**

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.



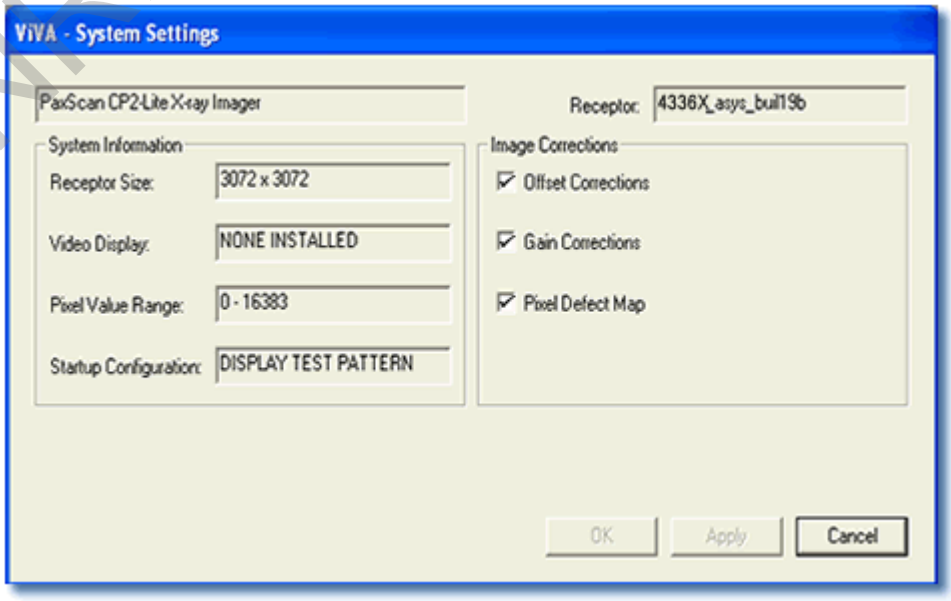


Image Acquisition

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

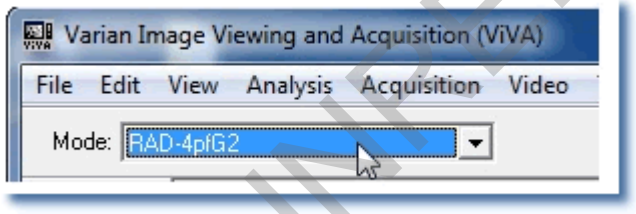
Radiography Mode

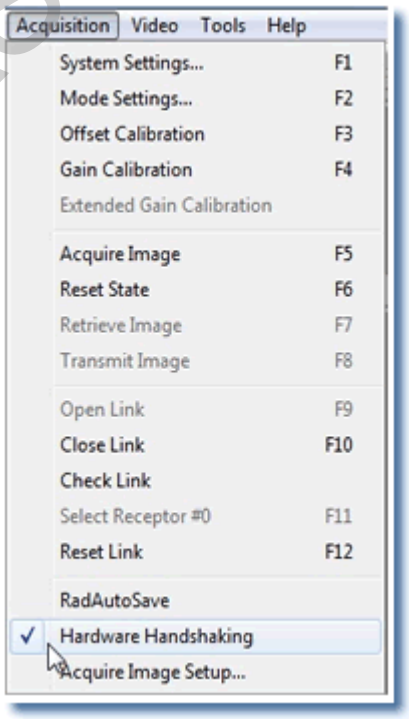
The Radiography mode provides the technician with superior single-shot, higher resolution images, for diagnosis. ▶

Step	Action / Results

1. Select required receptor from *Mode* drop down menu. The 4336W/X currently supports Rad 1x1 4pf.

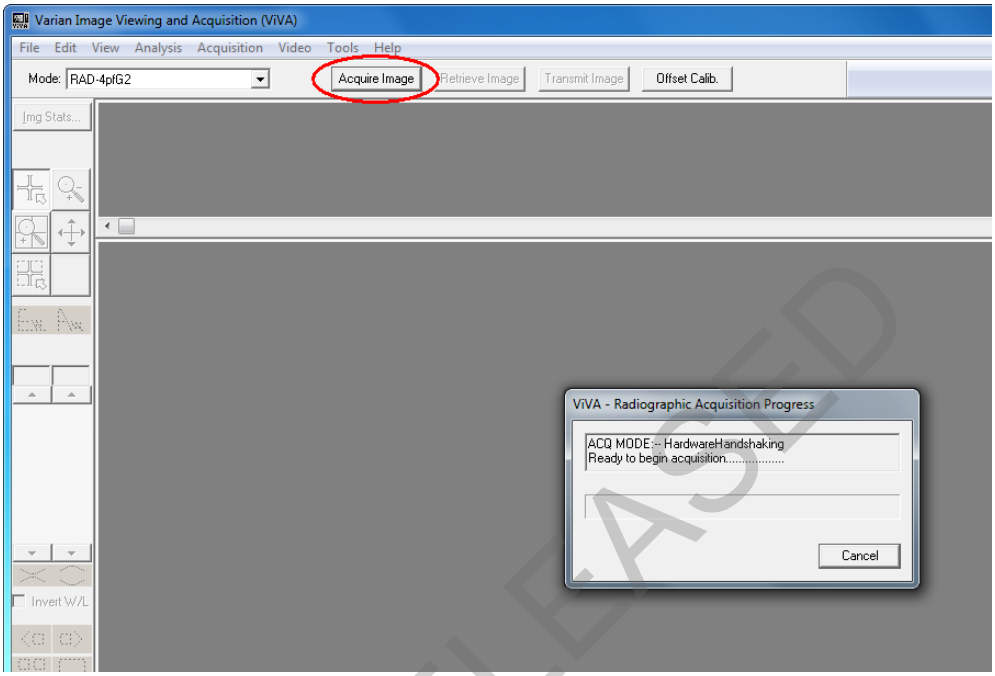
2. Make sure hardware handshaking is checked.



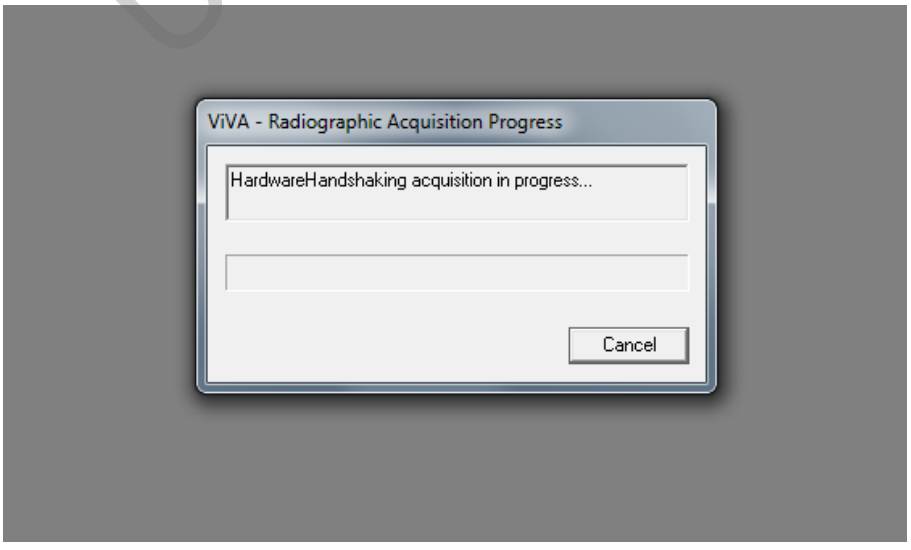


Step	Action / Results

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

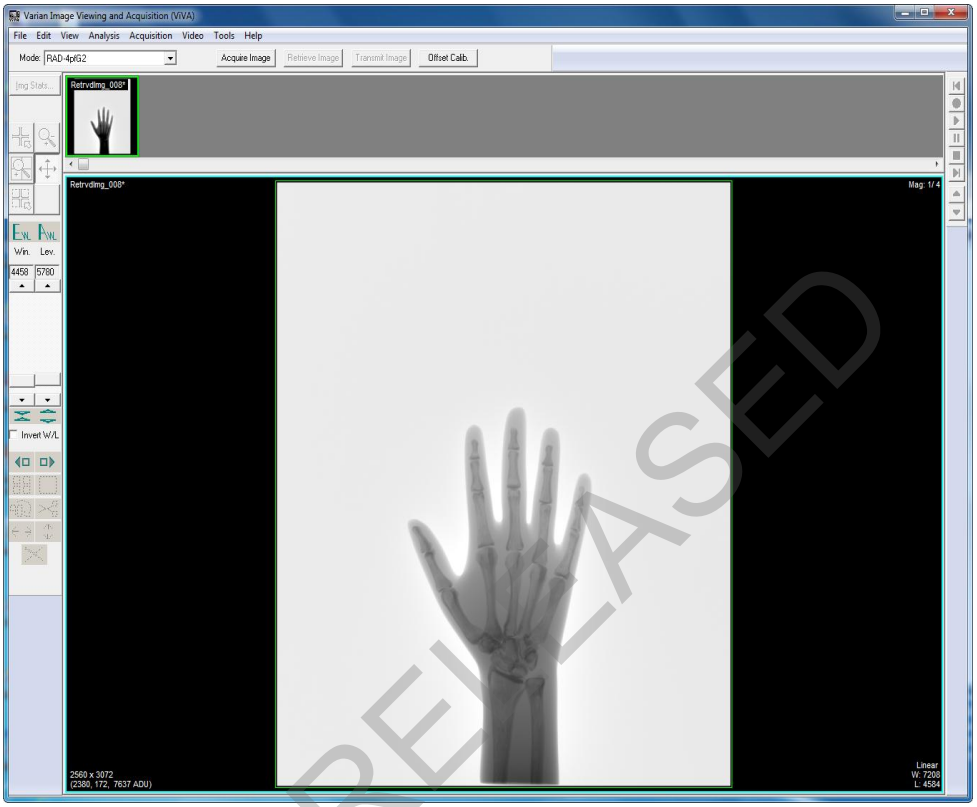


4. Depress *operator control* fully to "Expose" position to complete image capture and retrieval.



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 all circumstances; 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.

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) limit set by FCC/IC Canada (Less than 1.6W/kG) testing 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 1) positioning subject to be X-rayed away from the antennas (this also helps reduce image transfer time) and 2) removing the detector panel promptly when X-ray exposure is complete.

Electrical Protection

- External Power Supply Specification
  – type: XP Power model AHM85PS24 , ratings: Input Voltage 100 – 240V,
  Input Frequency 50/60Hz, Input Current 1.0 A, DC Output 24V
- 4336X model panel electrical rating if the power supply is not provided with the unit:
  – Continuous power rating is: 24 Watts
  – Input voltage is: 100 – 240V

Environment Limits

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

Temperature & Humidity

Category	Limits
Storage & Transport (ambient)	Receptor: -20º C to +70º C Battery: -20º C to +60º C
Storage & Transport 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)	30% to 75%

Altitude Limits

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

Lithium-Ion Rechargeable Battery

Please only use the lithium-ion rechargeable battery listed below that is supplied with the receptor.

Battery type: Lithium-ion
Battery model: Varian #30773 - Micro Power Electronics (OEM)
Rated voltage: 14.8V ⎓ 2.1Ah, 31.1 Wh

Caution: Risk of fire, explosion or burns. Do not short circuit, crush, heat above 100ºC, incinerate, or disassemble the battery. Charge only with the receptor or battery charger supplied. Please follow local governing ordinances and recycling plans regarding proper disposal or recycling of the lithium-ion rechargeable battery.

Note: Lithium-ion rechargeable battery is for use with the model Paxscan 4336W.

Regulatory

- The PaxScan® 4336W model family is a Type B component sub-system per Standard or Medical Electrical Equipment. The PaxScan® 4336W 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, IEC 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 Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance 1st ed., CAN/CSA-C22.2 NO. 601.1-M90, 2005 Medial Electrical Equipment Part 1: General Requirements for Safety, and CSA-C22.2 No 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance 2nd ed; and is RF compliant in accordance with FCC Part 15 Subpart B Class A, Part 15 Subpart C and Part 15 Subpart E.
- Class I, 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, and R&TTE Directive 99/5/EC
- A Declaration of Conformity has been filed for this product and available upon request by contacting Varian Medical Systems - X-Ray Products.

Radio Frequency (RF) Compliance Information

FCC/IC Compliance

This device complies with Part 15 of the FCC Rules and RSS-Gen (RSS-210, etc.) of IC Rules. Operation is subject to the following two conditions:

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

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 and Canadian ICES-003. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

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:

- 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.

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.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

In the 5150 to 5250 MHz frequency range this transmitter is restricted to indoor use only.

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 specifées 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.

European Community – CE Notice CE !

The CE! mark indicates compliance with the essential requirements of Directive 1999/5/EC. Such marking is indicative that this equipment meets or exceeds the following technical standards:

- EN 300 328
- EN 301 893
- EN 301 489-17
- EN 60950

Marking by the symbol: **!** indicates that usage restrictions apply in countries listed on this product's packaging.

Europe - Declaration of Conformity in Languages of the European Community.

cs Česky [Czech]	*Varian Medical Systems, Inc.* tímto prohlašuje, že tento Radiolan je ve shodě se základními požadavky a dalšími příslušnými ustanoveními směrnice 1999/5/ES.
da Dansk [Danish]	Undertegnede *Varian Medical Systems, Inc.* erklærer herved, at følgende udstyr Radiolan overholder de væsentlige krav og øvrige relevante krav i direktiv 1999/5/EF.
de Deutsch [German]	Hiermit erklärt *Varian Medical Systems, Inc.*, dass sich das Gerät Radiolan in Übereinstimmung mit den grundlegenden Anforderungen und den übrigen einschlägigen Bestimmungen der Richtlinie 1999/5/EG befindet.
et Eesti [Estonian]	Käesolevaga kinnitab *Varian Medical Systems, Inc.* seadme Radiolan vastavust direktiivi 1999/5/EÜ põhinõuetele ja nimetatud direktiivist tulenevatele teistele asjakohastele sätetele.
en English	Hereby, *Varian Medical Systems, Inc.*, declares that this Radiolan is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.
es Español [Spanish]	Por medio de la presente *Varian Medical Systems, Inc.* declara que el Radiolan cumple con los requisitos esenciales y cualesquiera otras disposiciones aplicables o exigibles de la Directiva 1999/5/CE.
el Ελληνική [Greek]	ΜΕ ΤΗΝ ΠΑΡΟΥΣΑ *Varian Medical Systems, Inc.* ΔΗΛΩΝΕΙ ΟΤΙ Radiolan ΣΥΜΜΟΡΦΩΝΕΤΑΙ ΠΡΟΣ ΤΙΣ ΟΥΣΙΩΔΕΙΣ ΑΠΑΙΤΗΣΕΙΣ ΚΑΙ ΤΙΣ ΛΟΙΠΕΣ ΣΧΕΤΙΚΕΣ ΔΙΑΤΑΞΕΙΣ ΤΗΣ ΟΔΗΓΙΑΣ 1999/5/ΕΚ.
fr Français [French]	Par la présente *Varian Medical Systems, Inc.* déclare que l'appareil Radiolan est conforme aux exigences essentielles et aux autres dispositions pertinentes de la directive 1999/5/CE.
it Italiano [Italian]	Con la presente *Varian Medical Systems, Inc.* dichiara che questo Radiolan è conforme ai requisiti essenziali ed alle altre disposizioni pertinenti stabilite dalla direttiva 1999/5/CE.
Latviski [Latvian]	Ar šo *Varian Medical Systems, Inc.* deklarē, ka Radiolan atbilst Direktīvas 1999/5/EK būtiskajām prasībām un citiem ar to saistītajiem noteikumiem.

Lietuvių [Lithuanian]	Šiuo *Varian Medical Systems, Inc.* deklaruoja, kad šis Radiolan atitinka esminius reikalavimus ir kitas 1999/5/EB Direktyvos nuostatas.
nl Nederlands [Dutch]	Hierbij verklaart *Varian Medical Systems, Inc.* dat het toestel Radiolan in overeenstemming is met de essentiële eisen en de andere relevante bepalingen van richtlijn 1999/5/EG.
mt Malti [Maltese]	Hawnhekk, *Varian Medical Systems, Inc.*, jiddikjara li dan Radiolan jikkonforma mal-ħtiġijiet essenzjali u ma provvedimenti oħrajn relevanti li hemm fid-Dirrettiva 1999/5/EC.
hu Magyar [Hungarian]	Alulírott, *Varian Medical Systems, Inc.* nyilatkozom, hogy a Radiolan megfelel a vonatkozó alapvetõ követelményeknek és az 1999/5/EC irányelv egyéb elõírásainak.
pl Polski [Polish]	Niniejszym *Varian Medical Systems, Inc*. oświadcza, że Radiolan jest zgodny z zasadniczymi wymogami oraz pozostałymi stosownymi postanowieniami Dyrektywy 1999/5/EC.
pt Português [Portuguese]	*Varian Medical Systems, Inc.* declara que este Radiolan está conforme com os requisitos essenciais e outras disposições da Directiva 1999/5/CE.
sl Slovensko [Slovenian]	*Varian Medical Systems, Inc*. izjavlja, da je ta Radiolan v skladu z bistvenimi zahtevami in ostalimi relevantnimi določili direktive 1999/5/ES.
Slovensky [Slovak]	*Varian Medical Systems, Inc.* týmto vyhlasuje, že Radiolan spĺňa základné požiadavky a všetky príslušné ustanovenia Smernice 1999/5/ES.
fi Suomi [Finnish]	*Varian Medical Systems, Inc.* vakuuttaa täten että Radiolan tyyppinen laite on direktiivin 1999/5/EY oleellisten vaatimusten ja sitä koskevien direktiivin muiden ehtojen mukainen.
sv Svenska [Swedish]	Härmed intygar *Varian Medical Systems, Inc.* att denna Radiolan står I överensstämmelse med de väsentliga egenskapskrav och övriga relevanta bestämmelser som framgår av direktiv 1999/5/EG.

Europe - Restrictions for Use of 2.4GHZ Frequencies in European Community.

België/ Belgique:	For private usage outside buildings across public grounds over less than 300m no special registration with IBPT/BIPT is required. Registration to IBPT/BIPT is required for private usage outside buildings across public grounds over more than 300m. For registration and license please contact IBPT/BIPT.
	Voor privé-gebruik buiten gebouw over publieke groud over afstand kleiner dan 300m geen registratie bij BIPT/IBPT nodig; voor gebruik over afstand groter dan 300m is wel registratie bij BIPT/IBPT nodig. Voor registratie of licentie kunt u contact opnemen met BIPT.
	Dans le cas d'une utilisation privée, à l'extérieur d'un bâtiment, au-dessus d'un espace public, aucun enregistrement n'est nécessaire pour une distance de moins de 300m. Pour une distance supérieure à 300m un enregistrement auprès de l'IBPT est requise. Pour les enregistrements et licences, veuillez contacter l'IBPT.
Deutschland:	License required for outdoor installations. Check with reseller for procedure to follow
	Anmeldung im Outdoor-Bereich notwendig, aber nicht genehmigungspflichtig.Bitte mit Händler die Vorgehensweise abstimmen.
France:	Restricted frequency band: only channels 1 to 7 (2400 MHz and 2454 MHz respectively) may be used outdoors in France.
	Bande de fréquence restreinte : seuls les canaux 1- 7 (2400 et 2454 MHz respectivement) doivent être utilisés endroits extérieur en France. Vous pouvez contacter l'Autorité de Régulation des Télécommuniations (http://www.art-telecom.fr) pour la procédure à suivre.
Italia:	License required for indoor use. Use with outdoor installations not allowed.
	E'necessaria la concessione ministeriale anche per l'uso interno. Verificare con i rivenditori la procedura da seguire.
Nederland	License required for outdoor installations. Check with reseller for procedure to follow.
	Licentie verplicht voor gebruik met buitenantennes. Neem contact op met verkoper voor juiste procedure.
All EU member states and EFTA countries	This device may only be used indoors in the frequency bands 5150 – 5250 MHz and 5250 – 5350 MHz.

To remain in conformance with European spectrum usage laws for Wireless LAN operation, the above 2.4GHz channel limitations apply for outdoor usage. The user should use the wireless LAN utility to check the current channel of operation. If operation is occurring outside of the allowable frequencies for outdoor use, as listed above, the user must contact the applicable national spectrum regulator to request a license for outdoor operation.

Japan Telecom Certification – JATE

本装置は、第二種情報装置（住宅地域またはその隣接した地域において使用されるべき情報装置）で住宅地域での電波障害防止を目的とした情報処理装置等電波障害自主規制協議会（ＶＣＣＩ）基準に適合しております。
しかし、本装置をラジオ、テレビジョン受信機に、近接してご使用になると、受信障害の原因となることがあります。本書の説明にしたがって正しい取り扱いをしてください。

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 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.

Cleaning and disinfecting of the battery/battery compartment should also be performed as needed using the same practices described above. Care should be taken when cleaning the battery contacts, use a non-abrasive cleaner that will not damage the copper contact material.

Repairs

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

The least replaceable units (LRU) are:

- Receptor Assembly
- I/O Box
- External Power Supply
- Tether Cable
- Battery
- Battery Charger (if applicable)

Proper Disposal

The 4336W/X 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

Do not dispose of the lithium-ion rechargeable battery in the garbage. Please consult local governing ordinances and recycling plans regarding proper disposal.

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 wireless connection or cable connections.
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 4336W/X Problem Report. 2. Email the error log file generated to: paxscan.service@varian.com. This log file is normally found at C:\Documents and Settings\All Users\Documents\DrWatson\ drwtsn32.log
I/O Box no power	1. Check the external power supply module. 2. Check the internal fuse (F1) Littlefuse PN: 0229004.HXP - Fuse 125V SLO-BLO 2AG 4A CART

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. If you prefer E-mailing the information to us, a .pdf version of this form is included on the CD you received with your system. You may also fax the completed form.

To speak with our technical support personnel:

- Call (800) 432-4422 or (801) 972-5000.
- E-mail the report to paxscan.service@varian.com, or
- Fax a copy of the Problem Report to (801) 972-5023

PaxScan 4336W/X 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):		

Fax to: (801) 972-5050 or E-mail: paxscan.service@varian.com

Appendix A

Interfacing Information

All the interfacing connections for the Paxscan 4336W/X are at the panel itself and the I/O box. 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 I/O box is supplied by a medical-grade "laptop" style supply whose dc supply cable can be up to 3 meters in length. The "laptop" style power supply is optional equipment.

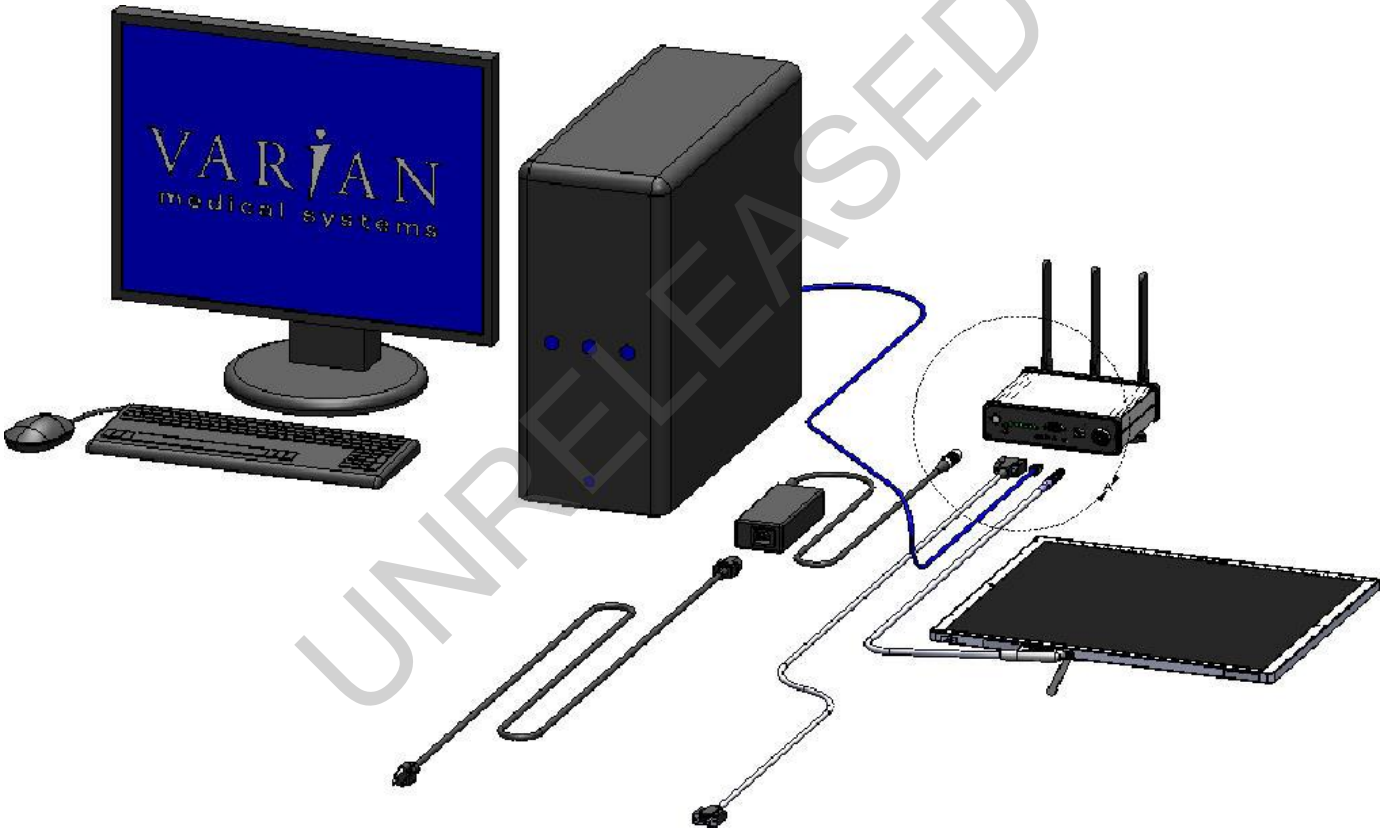


Figure A.1 Diagram of the 4336W/X Imager System

The synchronization interface to the panel consists of two inputs and one output, all isolated 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 4336W/X 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 on the next page.

NOTE: The maximum input voltage on the opto-couplers used in the 4336W/X is 5V. Refer to the TSM0505S datasheet for additional information.

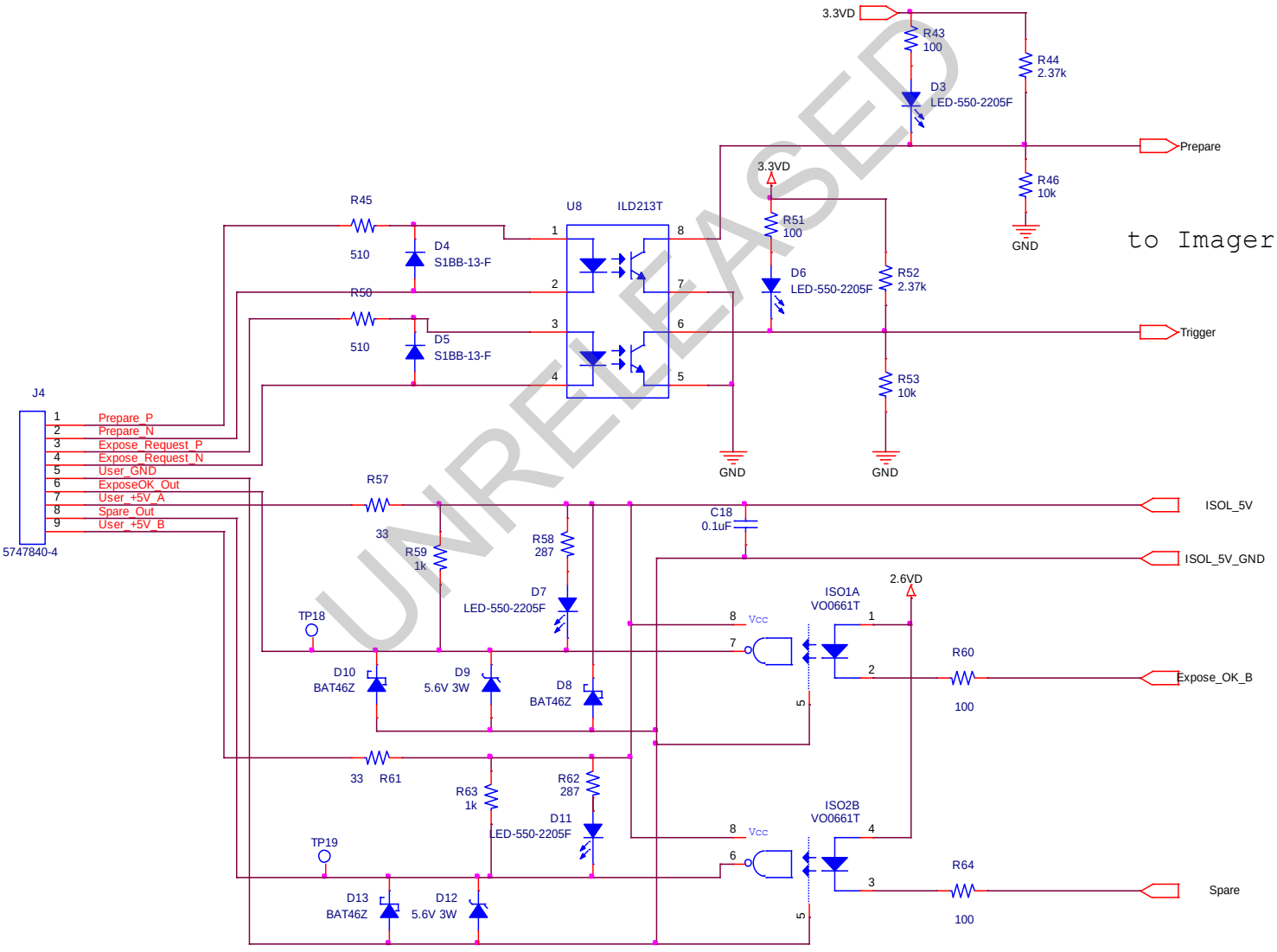


Figure A.2 Schematic for "Expose Ok" and "Expose Request" Signal

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.

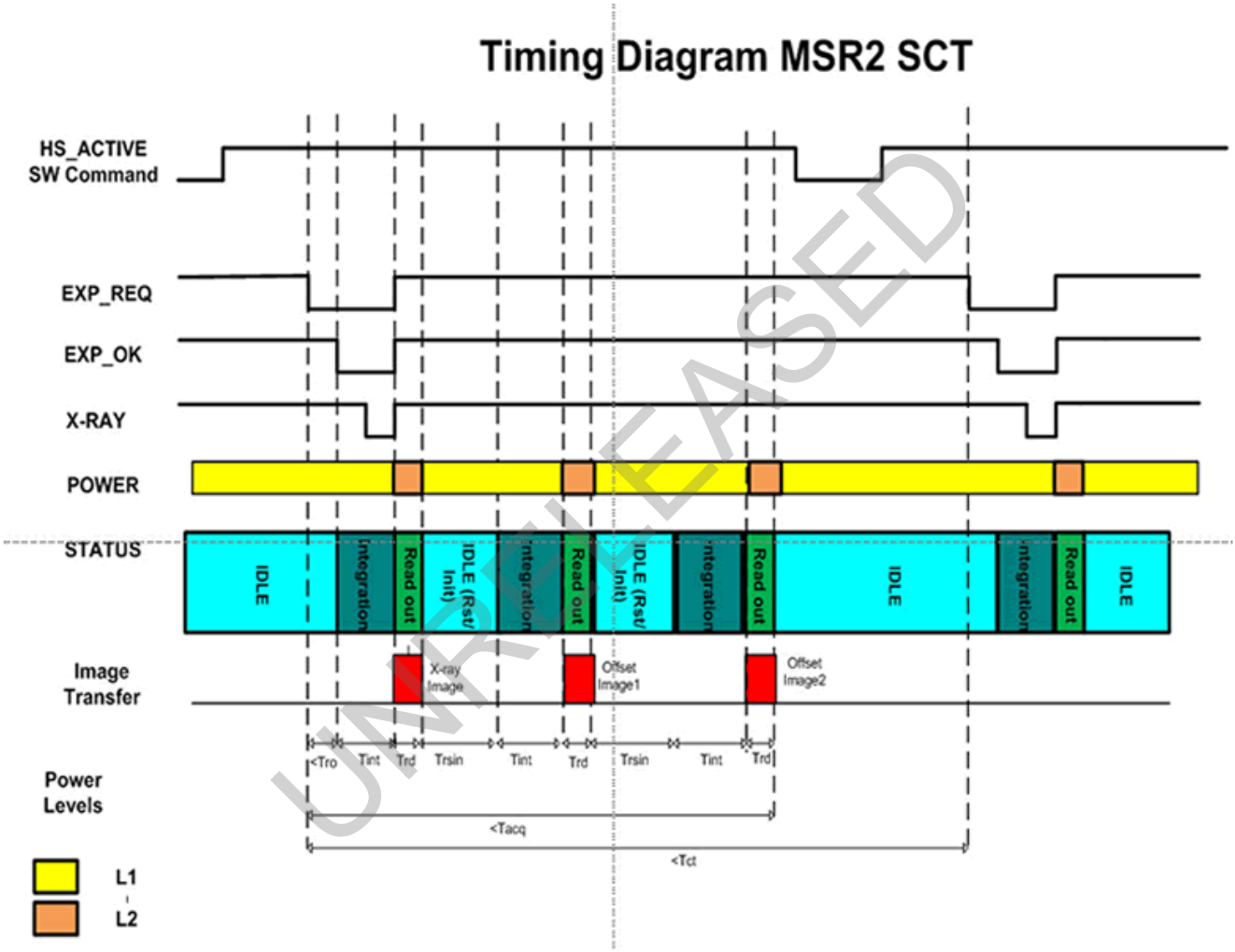


Figure A.3 4436X Timing

Timing Diagram MSR2 SCT

Time Description for the Charge Well Pixel

Name	Description	Time	Unit
Tro	Time between "Exp_Req" to "Exp_Ok"	0.35	s
Tint	Integration Time	0.5 to 2	s
Trd	Redaout Time/Transmission Time	0.5	s
Trsin	Time for Idle	1.32	s
Tacq	Acquisition time	>5.32	s
Tct	Cycle time	TBD	s

Power Description (Estimated)

L1	Stand by	14.25	W	0.95	A
L2	Acquisition	19.95	W	1.33	A

Figure A.4 4436X Timing

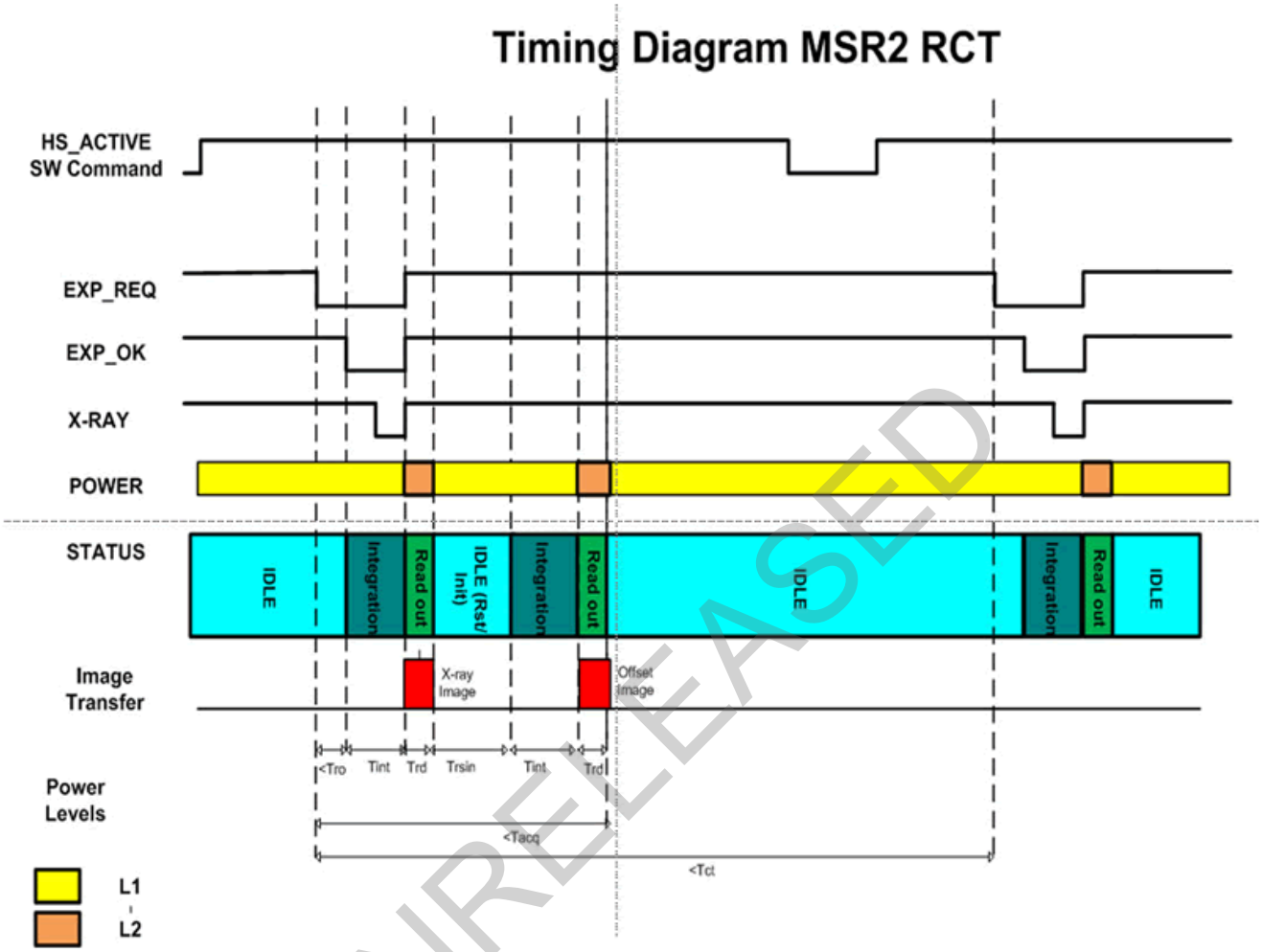


Figure A.5 4436X Timing

Timing Diagram MSR2 RCT

Time Description for the Charge Well Pixel

Name	Description	Time	Unit
Tro	Time between "Exp_Req" to "Exp_Ok"	0.35	s
Tint	Integration Time	0.5 to 2	s
Trd	Redaout Time/Transmission Time	0.5	s
Trsin	Time for Idle	1.32	s
Tacq	Acquisition time	<3	s
Tct	Cycle time	TBD	s

Power Description (Estimated)

L1	Stand by	14.25	W	0.95	A
L2	Acquisition	19.95	W	1.33	A

Figure A.6 4436X Timing

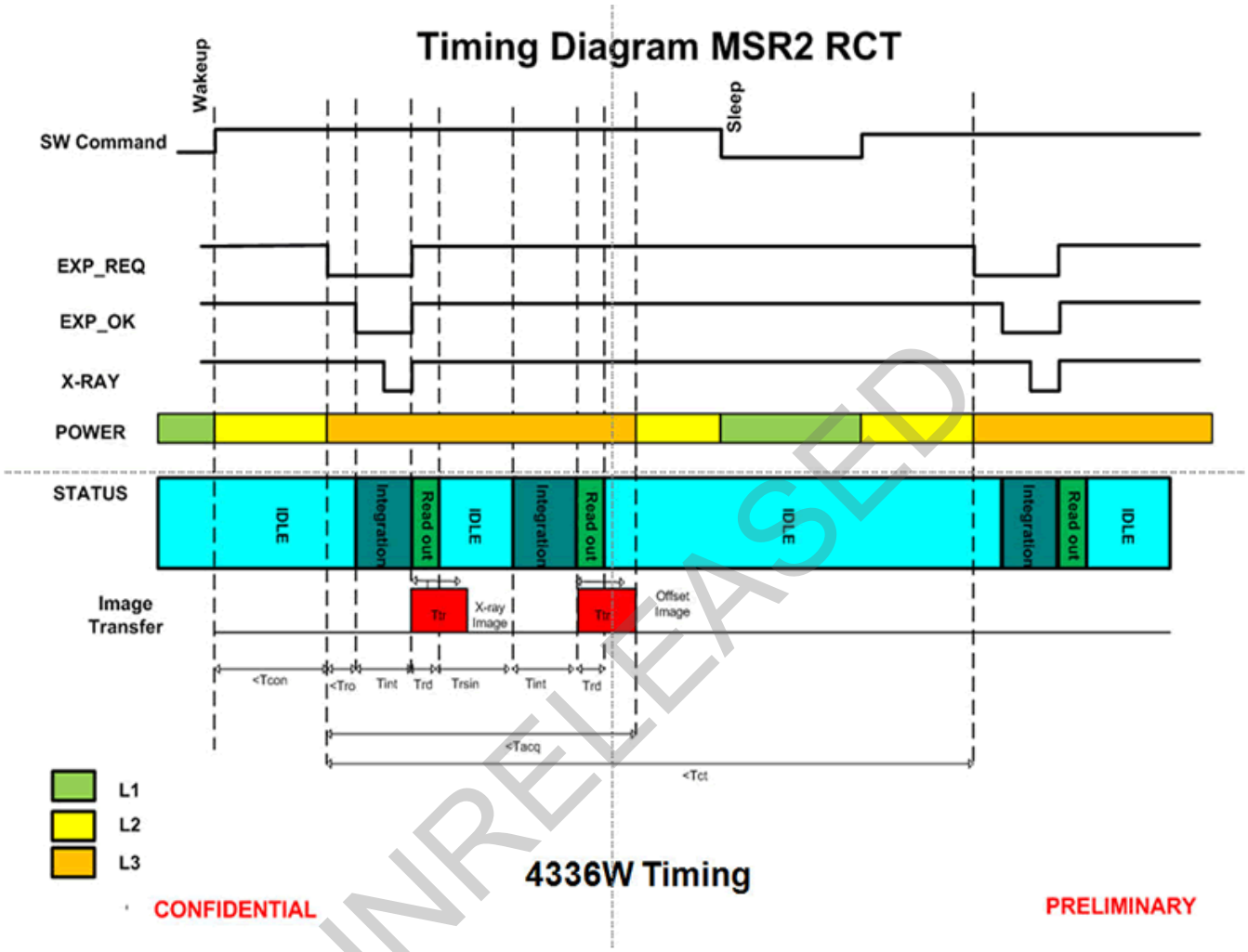


Figure A.7 4436W Timing

Timing Diagram MSR2 RCT

Time Description

Name	Description	Time	Unit
Tcon	Time to establish connection	6	s
Tro	Time between "Exp_Req" to "Exp_Ok"	0.35	s
Tint	Integration Time	0.5 to 2	s
Trd	Redaout Time	0.5	s
Ttr	Transmission Time	1.6	s
Trsin	Time for Idle	1.32	s
Tacq	Acquisition time	4.5	s
Tct	Cycle time	TBD	s

Power Description without Charging Battery

Name	Description	Power	Unit	Current	Unit
L1	Sleep	2.7	W	0.18	A
L2	Stand by	15.75	W	1.05	A
L3	Acquisition	21.6	W	1.44	A

Battery Voltage = 15V

Figure A.8 4436W Timing

Appendix B

Use Cases

The 4336W/X platform can be configured to meet several different use cases depending upon the desired application usage required by the end user. The following are potential application configurations:

Single Panel

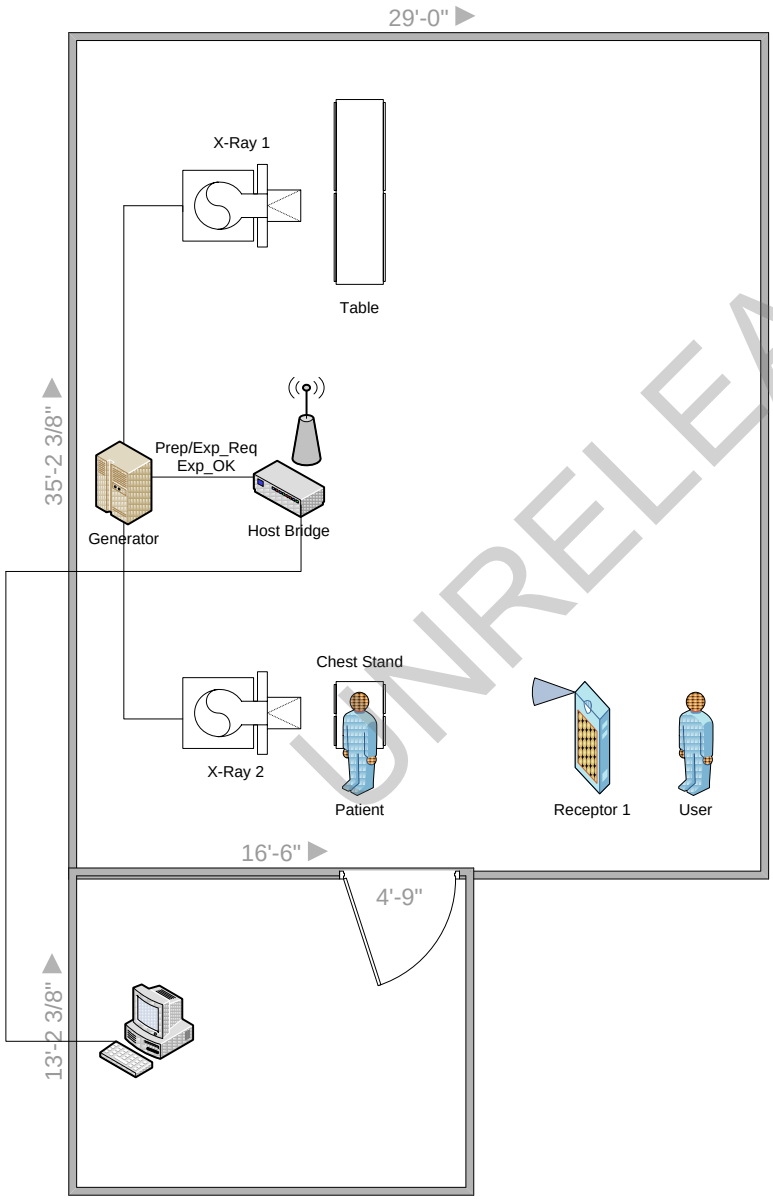


Figure B.1 Example of Single Panel Use

One Panel Per Room

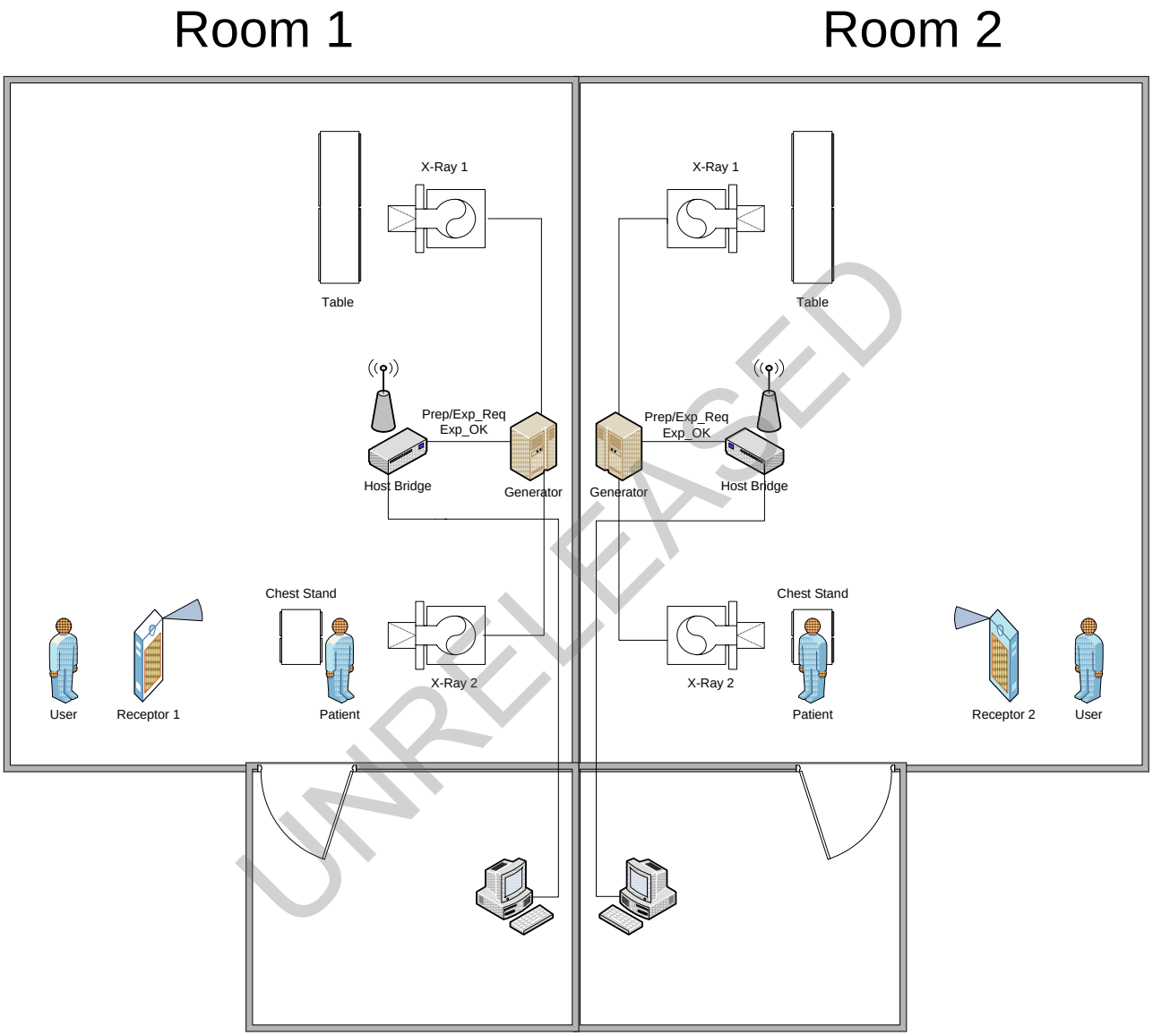


Figure B.2 Example of One Panel Per Room Use

Multiple Panel

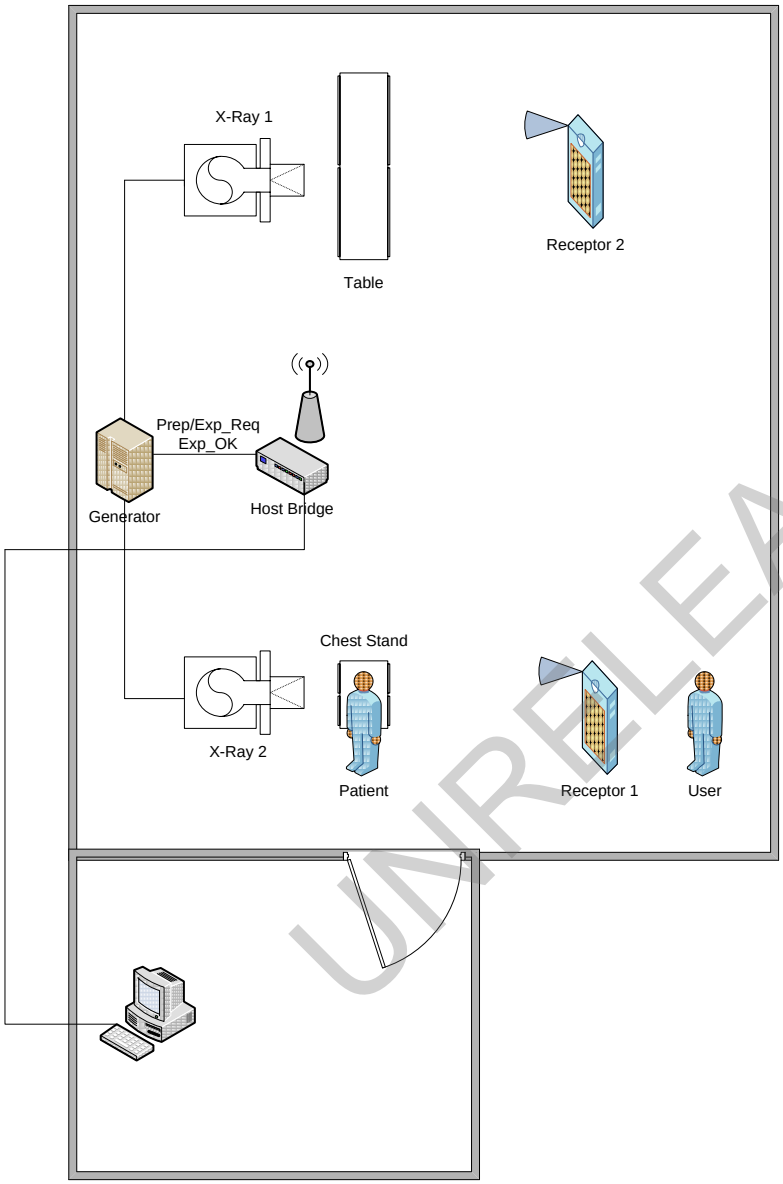


Figure B.3 Example of Multiple Panel Use

Appendix C

Panel Association

The 4336W receptor has three LEDs that indicate the present condition of the receptor:

Blue – Power On (lit when powered on)
Green – Wireless communitcation link (lit when connected)
Orange – Indicates when the receptor is ready for an exposure (lit when ready)

The 4336X receptor contains only the blue LED indicating the power status.

In addition, the sequence of interaction between the user, host computer, host bridge (I/O box), and receptor will follow certain sequences. A few of these panel associations are as follows:

Single Panel

This case occurs under normal ideal usage and the user steps are followed in a timely manner.

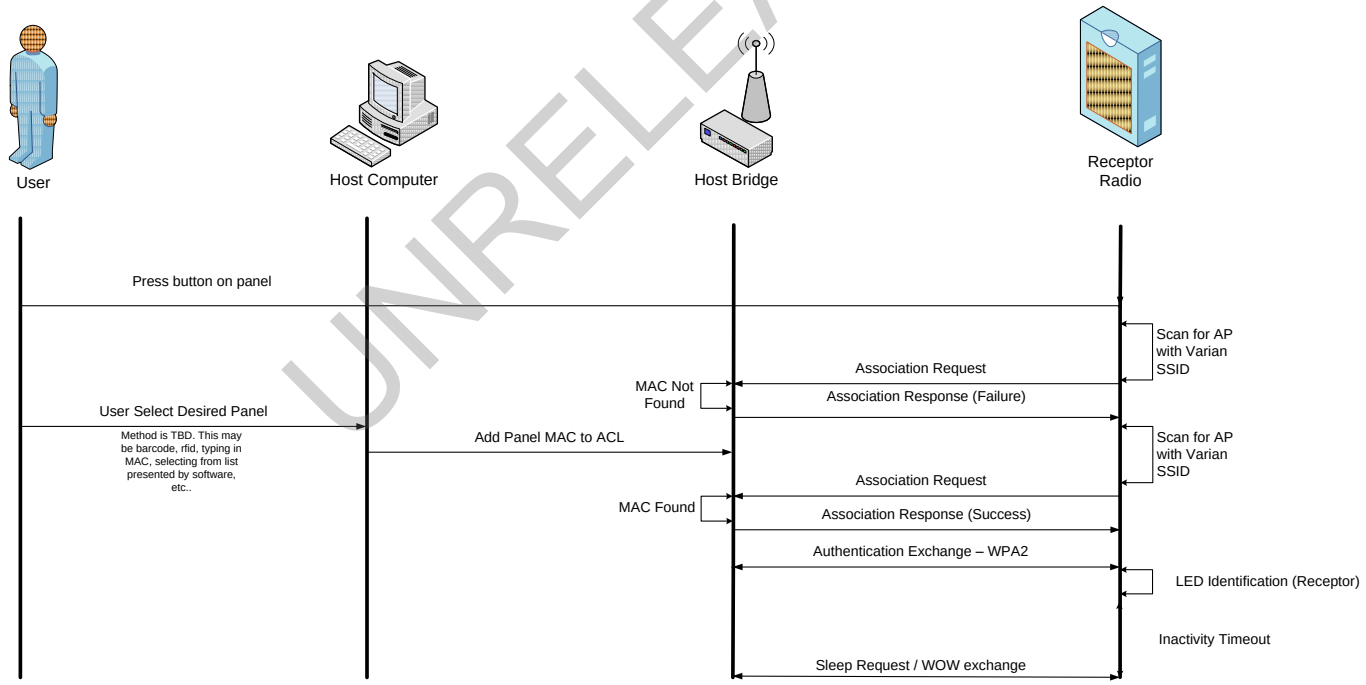


Figure C.1 Use case – Single Panel

Wrong Panel Selected

This sequence occurs when there is a mismatch between loaded MAC address information on the receptor and the host computer. This is state will also occur if there is no connection request on the host bridge triggered by the user on the host computer. The timeout will occur after one minute.

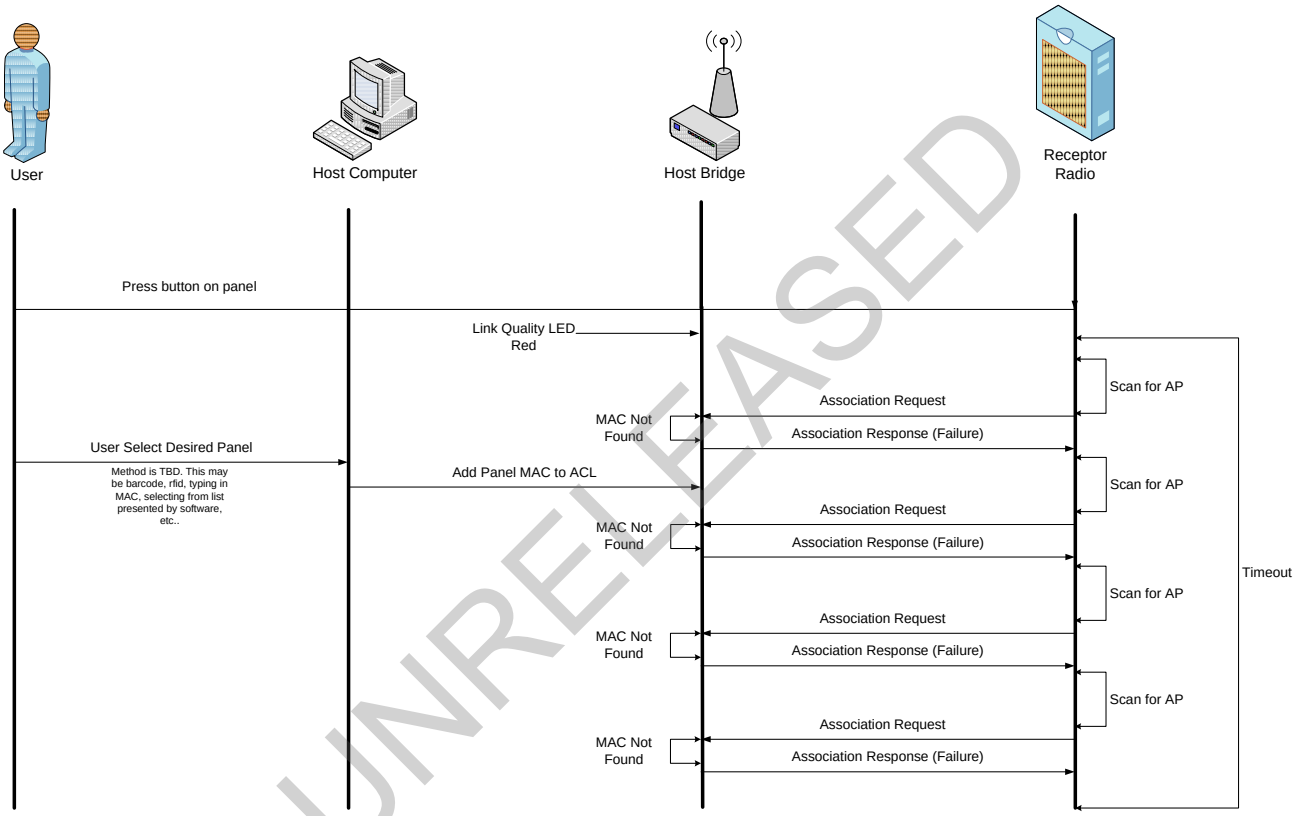


Figure C.2 Use case – Wrong panel selected

Changing Panel Battery

This case follows during a battery change on the receptor.

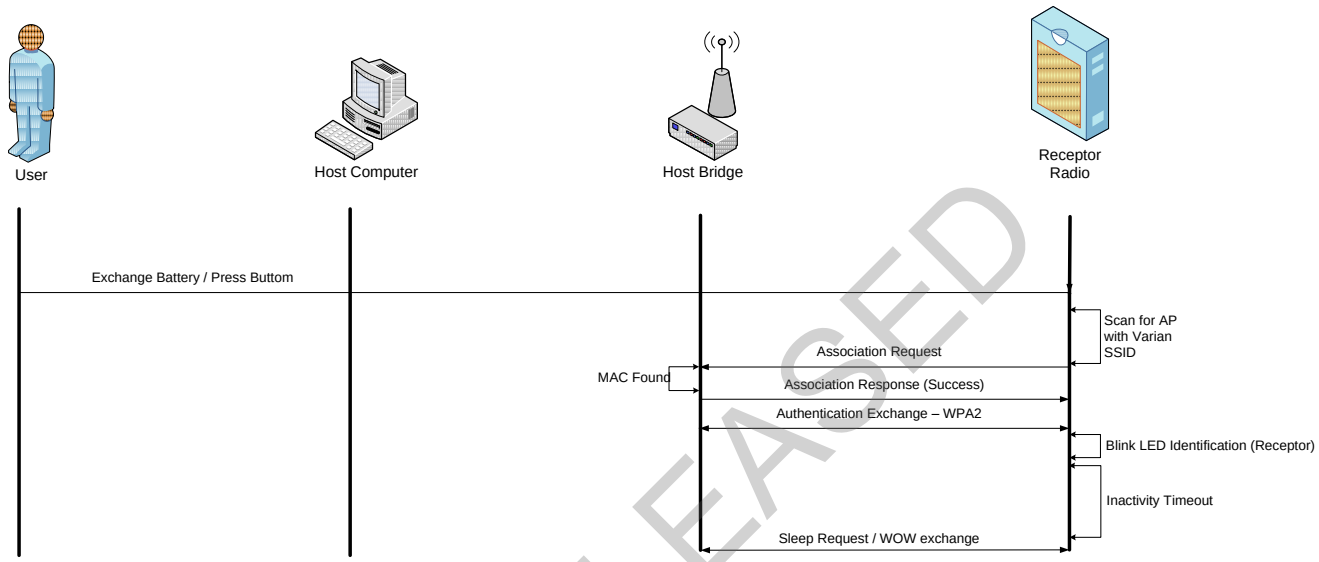


Figure C.3 Use case – Changing panel battery

Remove Panel

This case occurs when the user desires to remove the panel from the connection loop. This may occur for maintenance purposes, standard operation, or to switch to a second receptor utilizing the same host computer and host bridge.

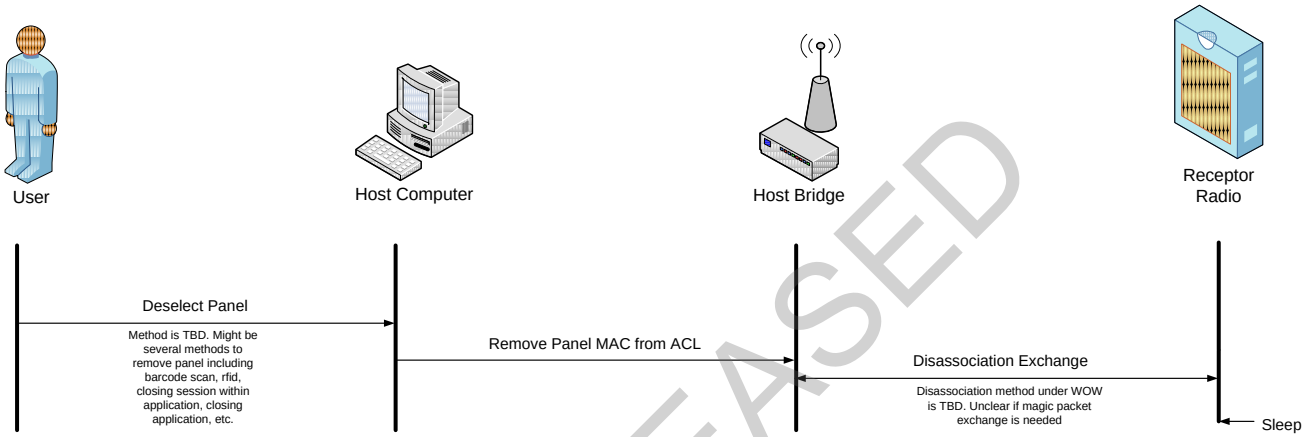


Figure C.4 Use case – Remove panel

Appendix D

Acquisition

The following details the sequence of events and signals during a standard acquisition cycle.

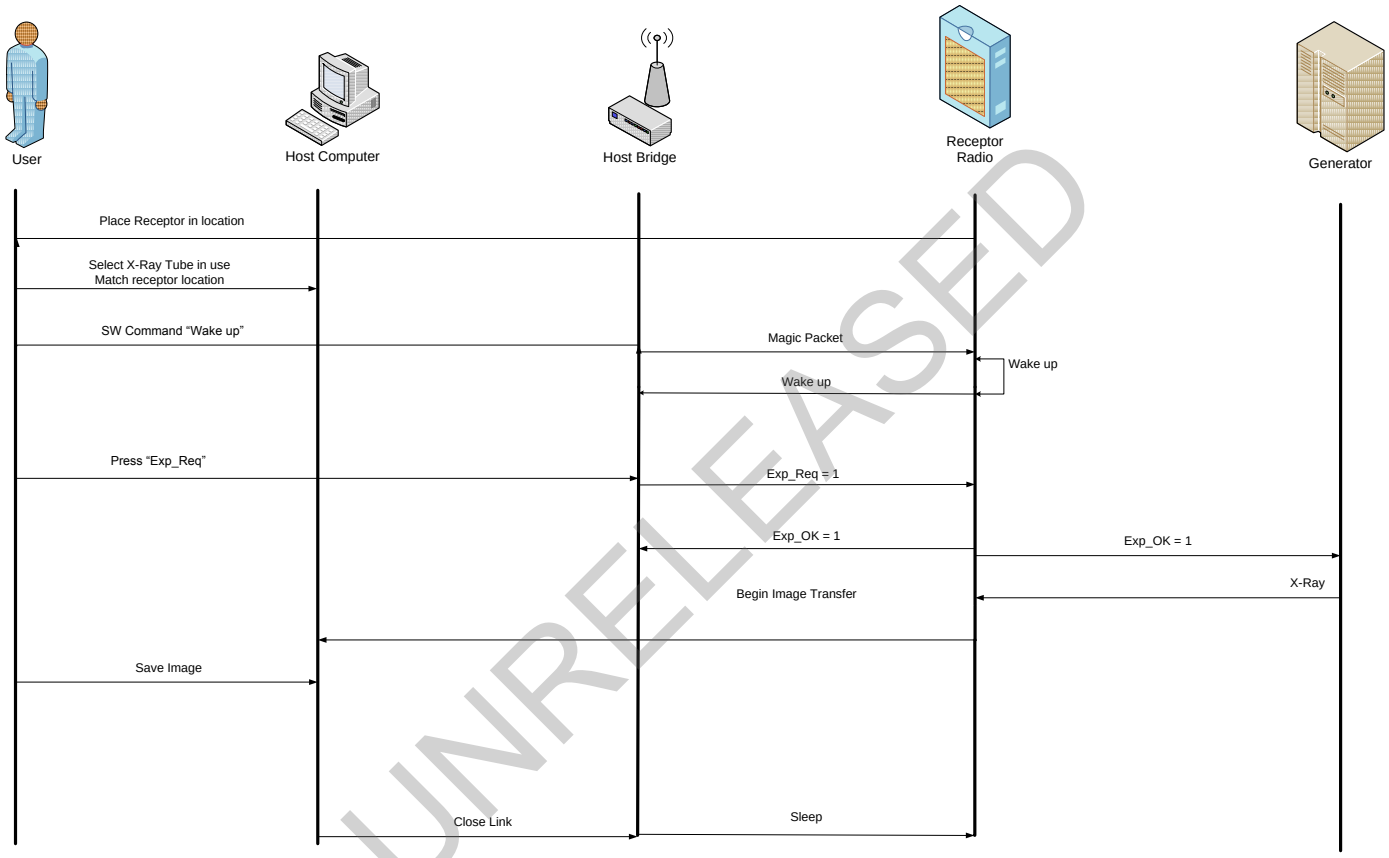


Figure D.1 Acquisition sequence

Appendix E

Power up Sequence for 4336W

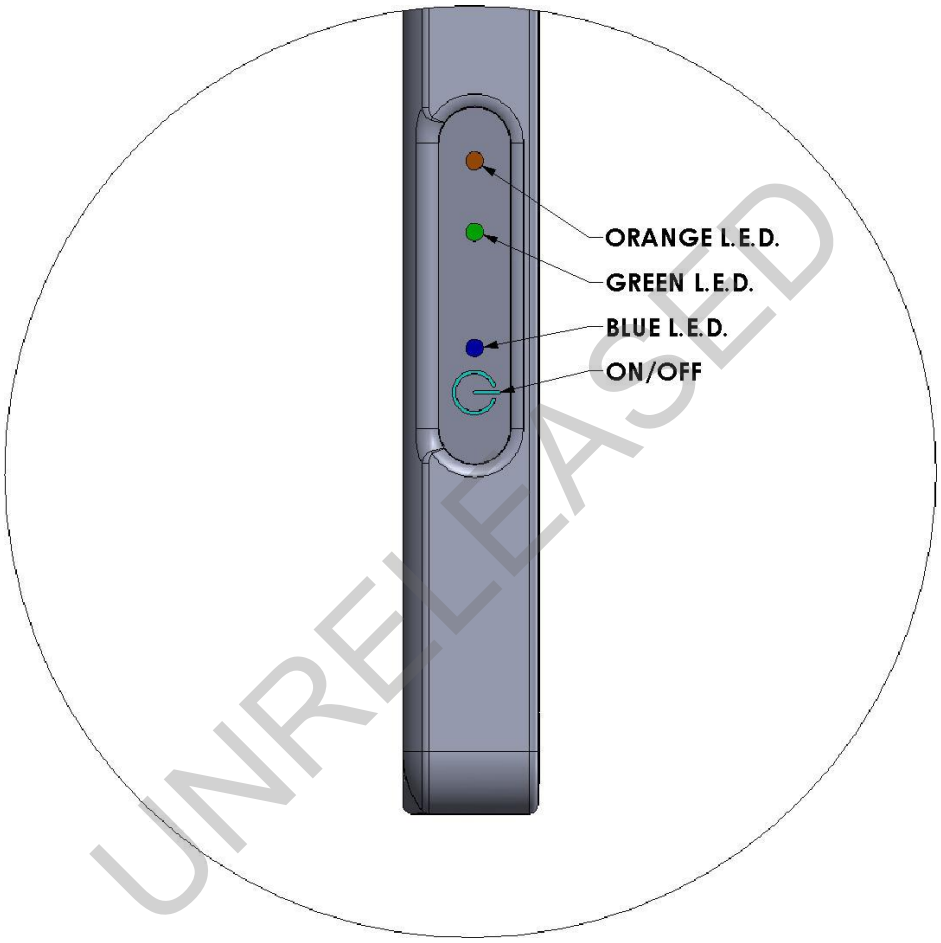


Figure E.1 4336W Power/LED panel detail

1. Press ON/OFF button for one second – blue LED will light
2. At the computer interface, initiate connection to the receptor
3. Once the connection has been established, the Green LED will light
   - Should the first two steps not be done within one minute of each other, the receptor will time out and the process will need to be repeated
4. The Orange LED, when lit, indicates a Ready-to-Expose state

Appendix F

Battery Installation/Removal for 4336W

When installing the battery for the 4336W:

First ensure that the receptor is powered off. Insert battery at a slight angle so that the side with contacts sits over the adjoining contacts in the battery compartment. Press down on the lifted side of battery snapping it into place in the battery compartment. Receptor is now ready for use.

When removing the battery for the 4336W:

First ensure that the receptor is powered off. Then press the battery latch button located near the tether cable connector, doing this will cause one side of the battery to lift out of the battery compartment. Grab the lifted side of the battery and finish removing.