ORTHOSCAN
IMAGING EXCELLENCE

SERVICE MANUAL

OrthoScan-HD Flat Detector

Mini C-arm Imaging System

Service Manual

ORTHOSCAN
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NOTES:

1 Introduction

Purpose

This service manual provides service information for every major component and sub-assembly of the OrthoScan-HD Flat Detector mini c-arm imaging system.

Scope

This document, diagrams, and schematics contained herein are written for technical personnel, such as biomedical engineers.

Precautions

Repair, maintenance, calibration or other types of service must always be carried out by suitably qualified personnel. OrthoScan can provide service directly, or can recommend trained service personnel in your area. Service by unauthorized service personnel will **VOID** any remaining warranty.

2 PRODUCT SPECIFICATIONS AND COMPONENTS

2.1 OrthoScan-HD Flat Detector Product Specifications

NOTE: Product design and specifications are subject to change without notice.

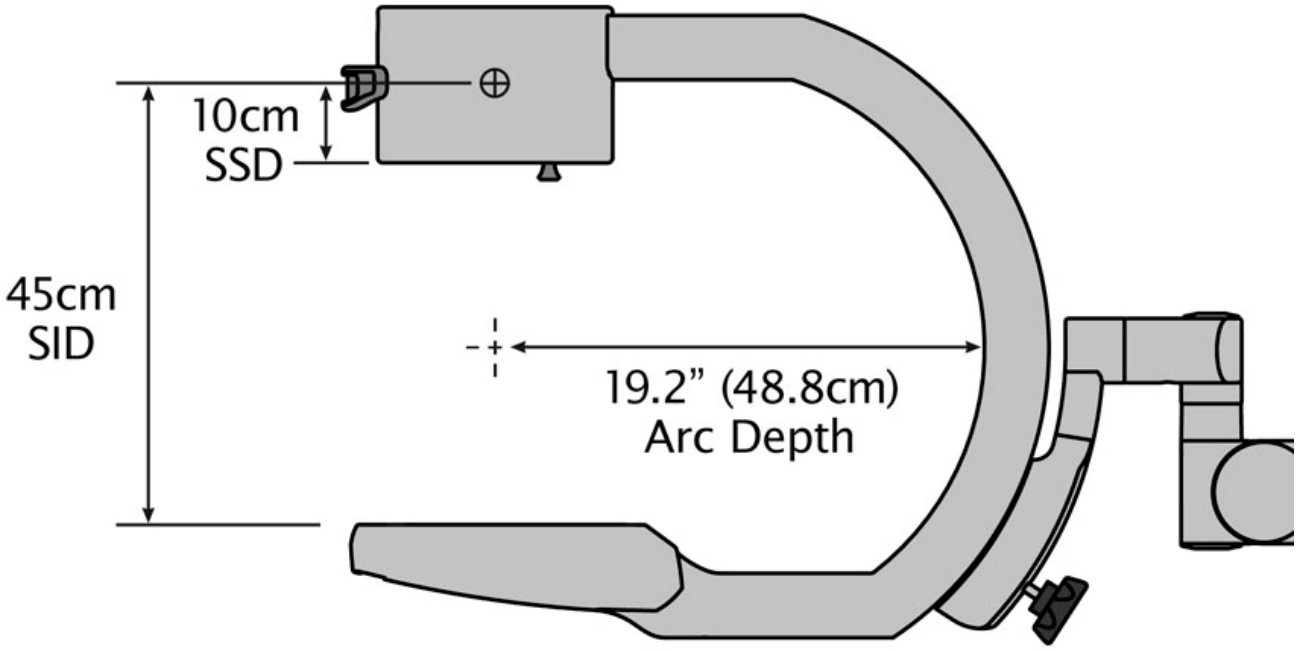
DEVICE CLASSIFICATIONS	
Equipment Classification (IEC 60601)	Class 1 Device
Water ingress protection classification	Ordinary Equipment
Mode of operation	Continuous Operation
Electric shock protection classification	Type B applied part
	Not suitable for use with flammable anesthetics
POWER REQUIREMENTS	
Nominal rated line voltage	100 / 120 / 230 V~ (factory preset)
Frequency	50 Hz or 60 Hz
Line voltage regulation	± 10% daily line reg.
Current	≤ 4A at 120 V~, ≤5A at 100 V~, ≤2A at 230 V~
Mains Fuses	100 V~: Bel Fuse 5ET 5 or Littelfuse 0213 0005(P) 120 V~: Bel Fuse 5ET 4 or Littlefuse 0213 0004(P) 230 V~: Bel Fuse 5ET 2 or Littlefuse 0213 0002(P)
LASER SPECIFICATION	
Max Power Output	4mWatts
Wavelength	635 nm
X-RAY SPECIFICATIONS	
Duty cycle at 75 kVp / 0.1mA	Continuous duty
X-ray source	Superior SXR-80
X-ray tube window	0.75 mm Beryllium
Beam filtration	2.5 mm Aluminum equivalent
Focal spot	50 microns
Field of view	Operator selectable 4"(11cm) x 3"(8cm) & 6"(15cm) x 5"(12cm)
Rated peak tube potential	80 kVp
Tube kVp range	40kVp to 75kVp (Boost Mode: 40kVp to 78kVp)
Tube current range	40 to 100 µA (Boost Mode: 40µA to 160µA)
Deviation from indicated values	kV ± 7%, µA ± 10%

ENVIRONMENTAL SPECIFICATIONS	
Storage Conditions	Temperature Range 32˚F (0˚C) to 131˚F (55˚C) Relative Humidity of >10% to < 100% (no condensation) Atmospheric Pressure of 500hPa to 1060hPa
Operating Temperature (Ambient)	15° to 32°C (59° to 90°F)
Operating Humidity (Ambient)	20% – 80% relative humidity, non-condensing
IMAGING SPECIFICATIONS	
Flat Detector	2k x 1.5k Resolution
Image processing	Digital
Monitor	Diagonal viewing size monochrome LCD
Nominal Width and Length	6" X 5"
Video Output Signal	VGA & DVI
WEIGHTS AND DIMENSIONS	
Source to Detector Distance (SID)	45 cm (17.72 in)
Source to Skin Distance (SSD)	10 cm (3.94 in)
C-arm Free Space	35 cm (14 in)
C-arm Depth of Arc	49 cm (19.2 in)
Height	147 cm (58 in)
Width	79 cm (31 in)
Weight	180 kg (400 lb)
Shipping Weight	194 kg (430 lb)
Ground Clearance	18 cm (7 in)
Power Cord Length	610 cm (20 ft)
Footprint	79 cm x 101 cm (40 in x 31 in)

ELECTROMAGNETIC COMPATIBILITY

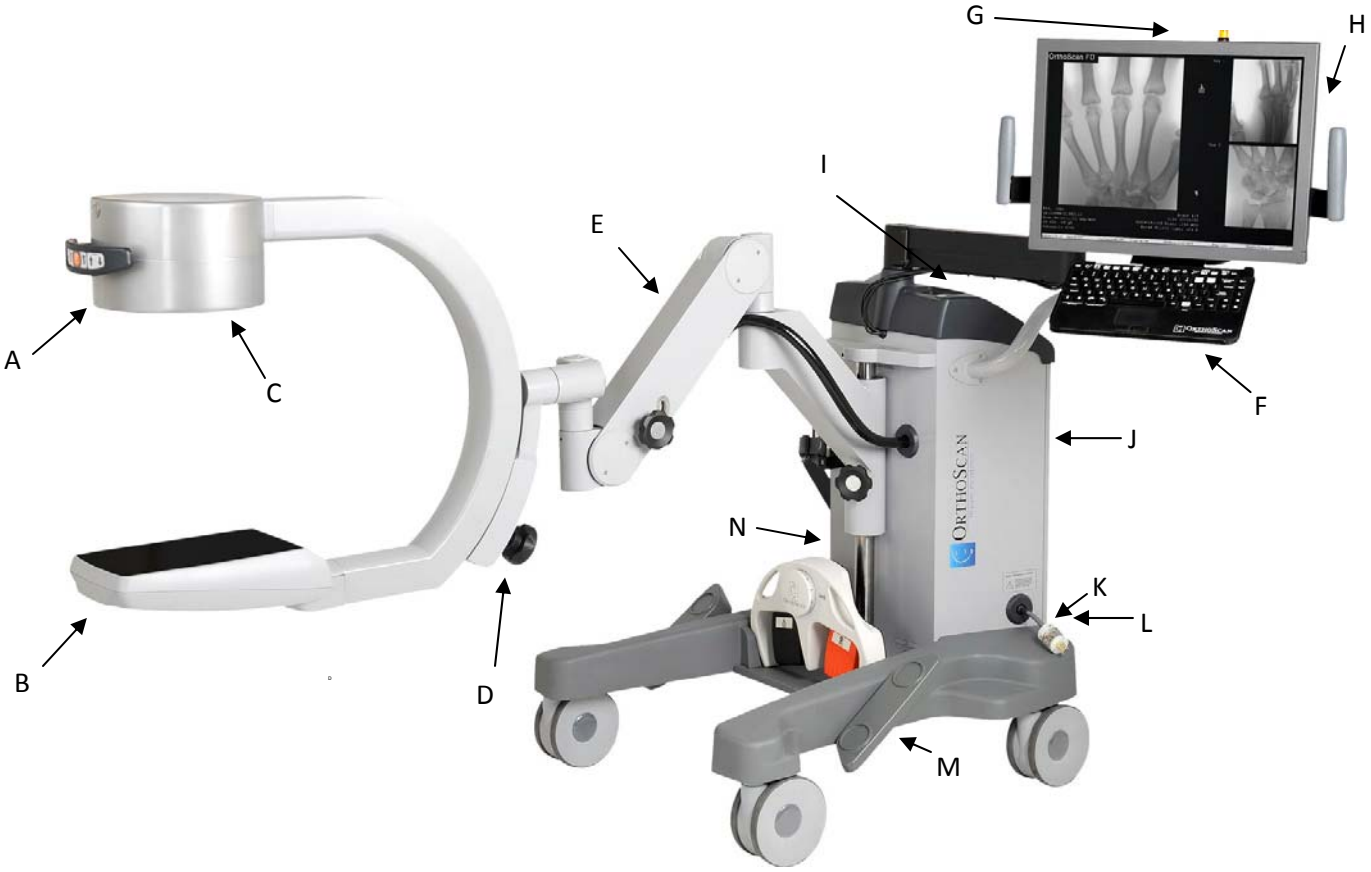
This equipment generates and uses radio frequency energy and, if not installed and used in strict accordance with the manufacturer's instructions, may cause or receive interference.
If this equipment seems to cause or receive interference when turned on (which may be determined by turning equipment off and on), try to correct the interference by one or more of the following steps: relocate the equipment with respect to other equipment in the room, or plug the system into a different outlet so that the circuit is not shared with the other equipment, or use other measures, as required. Call the phone number listed on the cover of this manual if you have questions concerning electrical power for the system.
Changes or modifications to this equipment not expressly approved by the agency responsible for compliance could void the authority of the owner/user to operate the equipment. If any modification is made, the owner/user is responsible for compliance of the equipment.

Focal Spot Location Diagram



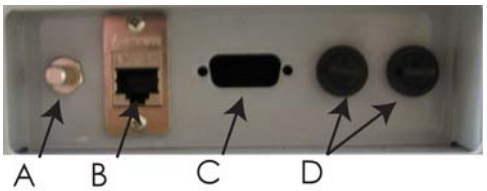
2.2 OrthoScan Major Components

The major components of the OrthoScan-HD Flat Detector mini c-arm imaging system are shown below:



A	X-Ray Source Assembly	H	Flat-Screen Monitor
B	Flat Detector	I	Power Switch
C	Collimator	J	Printer (Optional)
D	Orbital Lock	K	Retractable Power Cable
E	Flex Arm	L	Back Panel Connections
F	Keyboard	M	Brake
G	X-Ray On Light	N	Cabinet

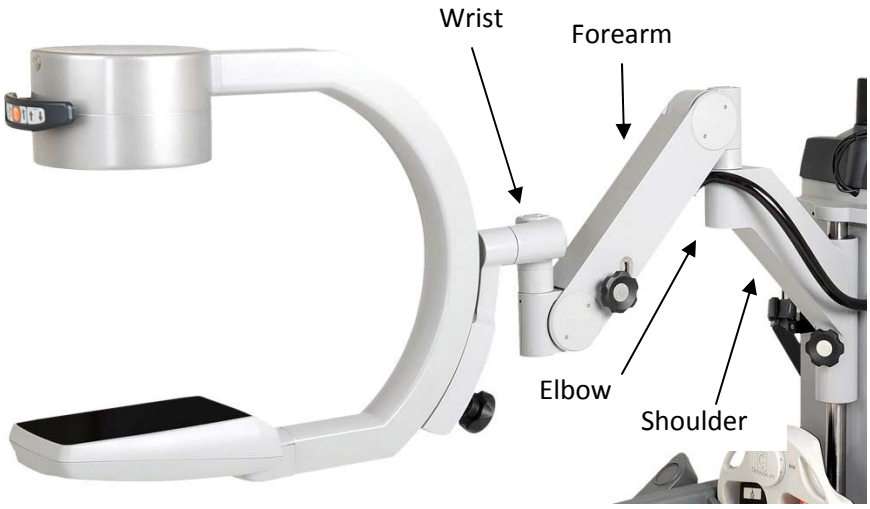
Back Panel Connections



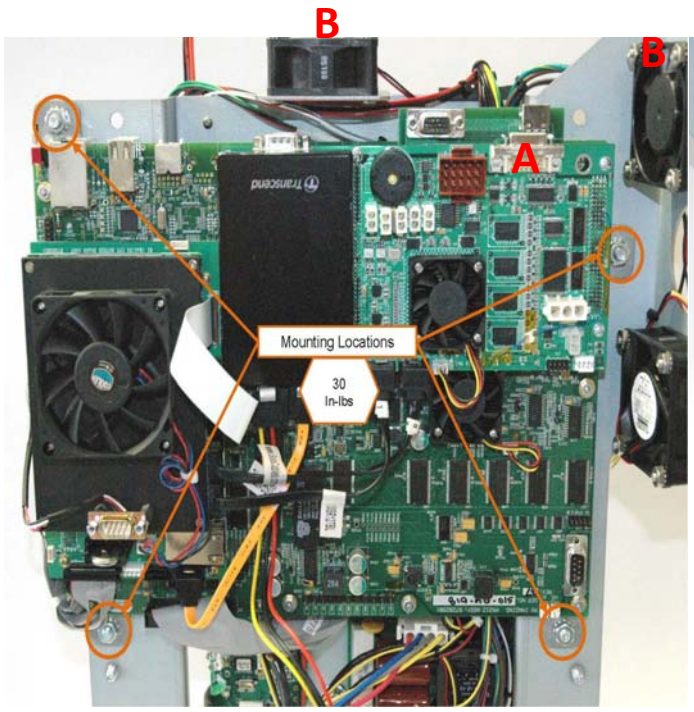
A	Ground Probe
B	Ethernet Port for PACS
C	VGA Output
D	Fuses

2.3 Flex Arm Components

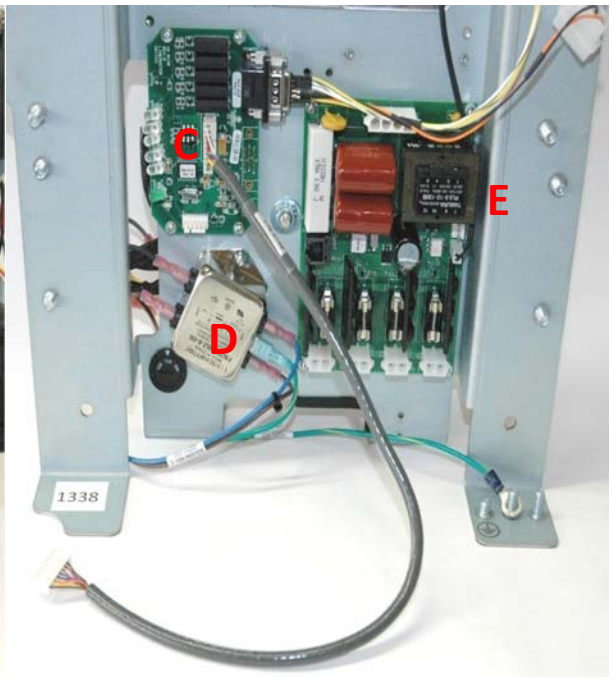
Flex arm is comprised of the wrist joint, forearm, elbow joint and shoulder as depicted below.



2.4 Electronic Chassis Components



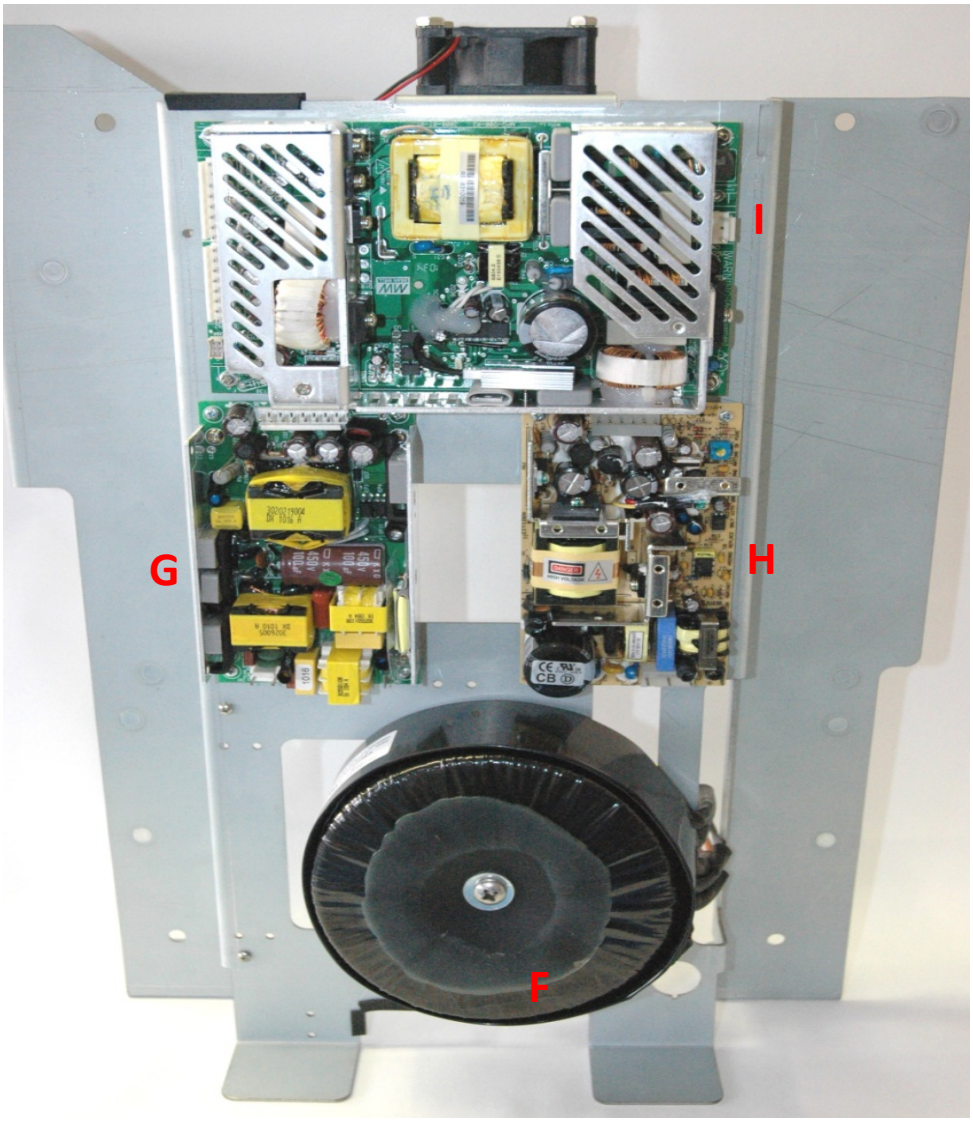
Front- with cord reel removed



Front- with Video CCA removed

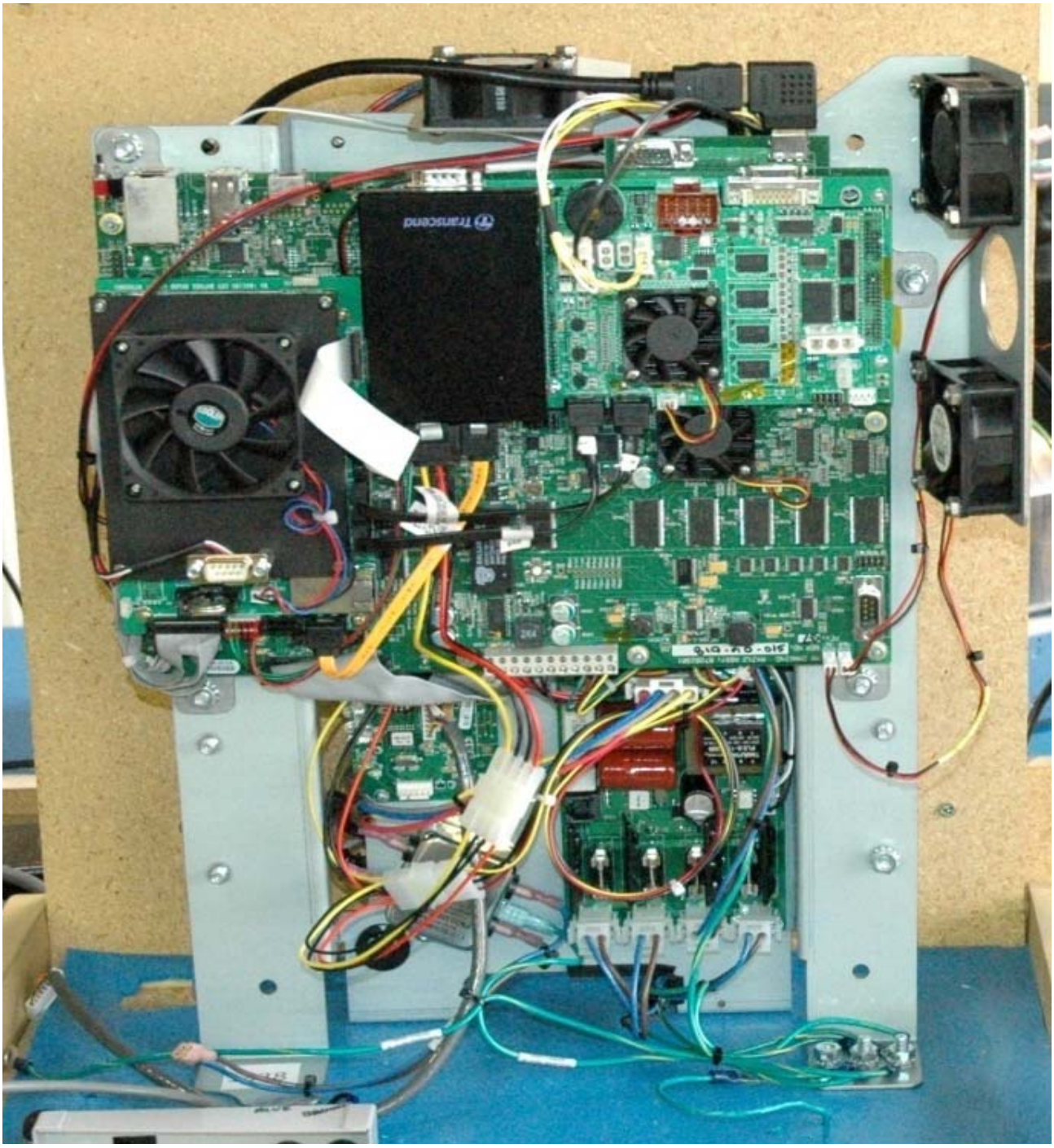
A- Video CCA (915-0013-01)
B- Cooling Fans (920-0078)
C- Wireless footswitch CCA (240-0054)- if equipped
D- EMI filter (230-0013)
E- Power control board (910-0009)

Chassis rear view



F- Torroid isolation transformer (230-0011)
G- 12v power supply (260-0035)
H- 6v power supply (260-0033)
I – 5v/24v power supply (260-0032)

Completed electrical chassis


Transcend

3 REMOVAL/REPLACEMENT INSTRUCTIONS

Caution! Ensure unit is unplugged prior to servicing!

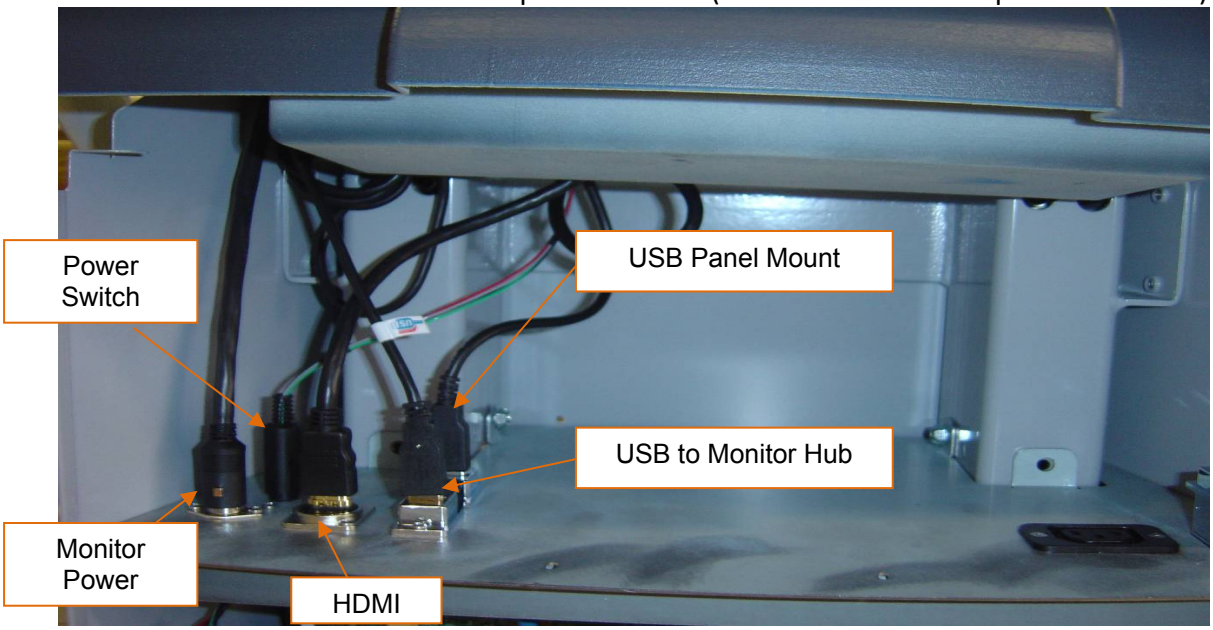
All service personnel must be properly grounded while working with and around sensitive electrical components.

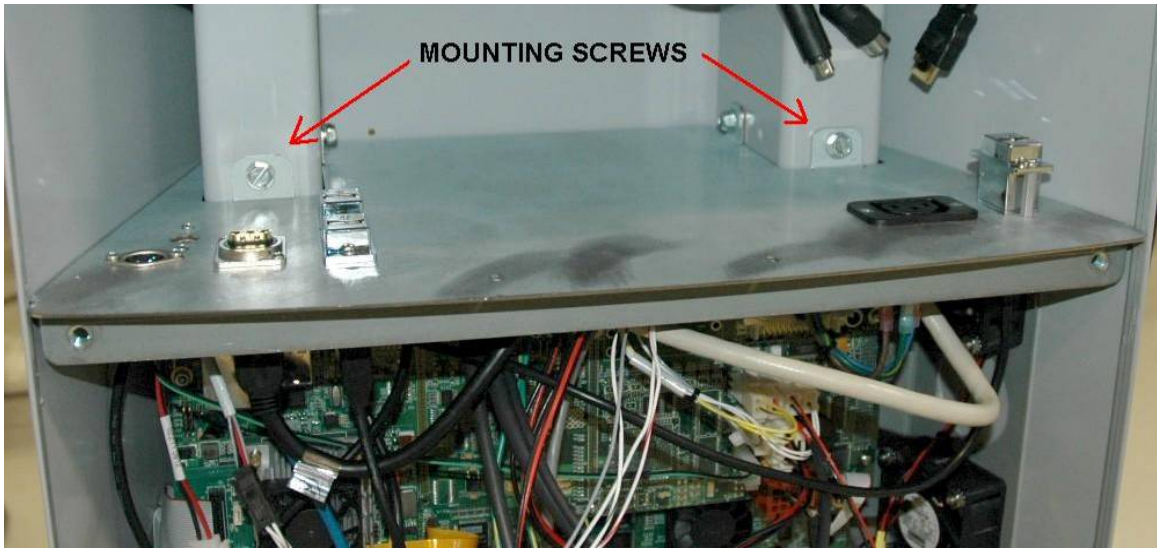
3.1.1 EMI Plate Removal

Tools needed:

(1) Ratchet
(2) 3/8" socket
(3) 1/4 " nut driver
(4) Small Phillips screwdriver
(5) Large Phillips screwdriver
(6) Nut Driver

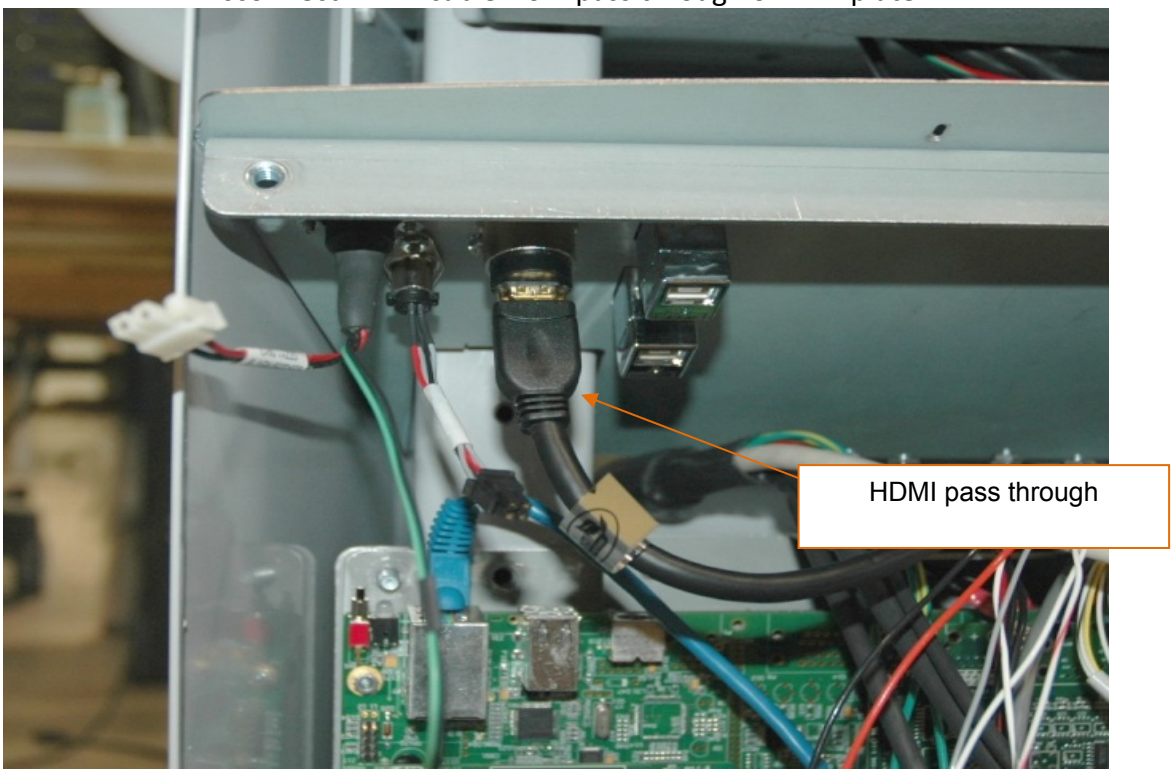
Remove back panel by loosening the 4 spring loaded screws
Remove Monitor connections as depicted below. (See Section **3.1.9** for printer removal)



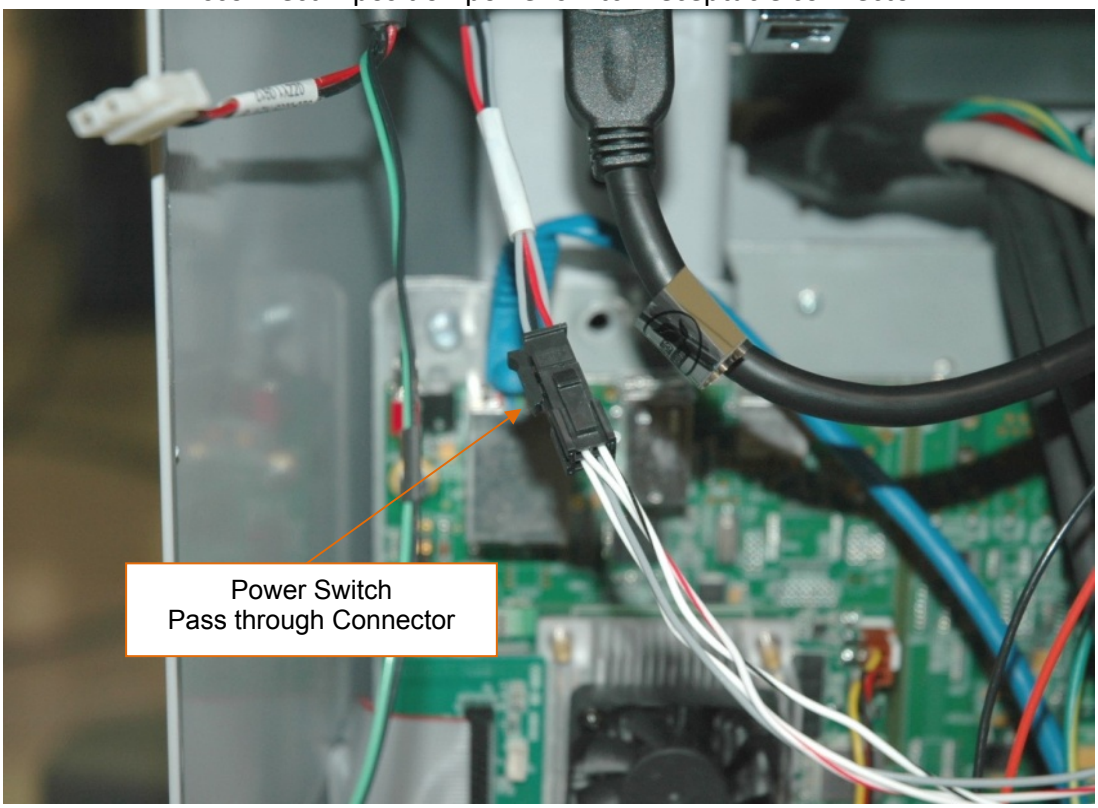


Remove EMI shield by loosening 2 self tapping screws (401-0940) using the 3/8” ratchet

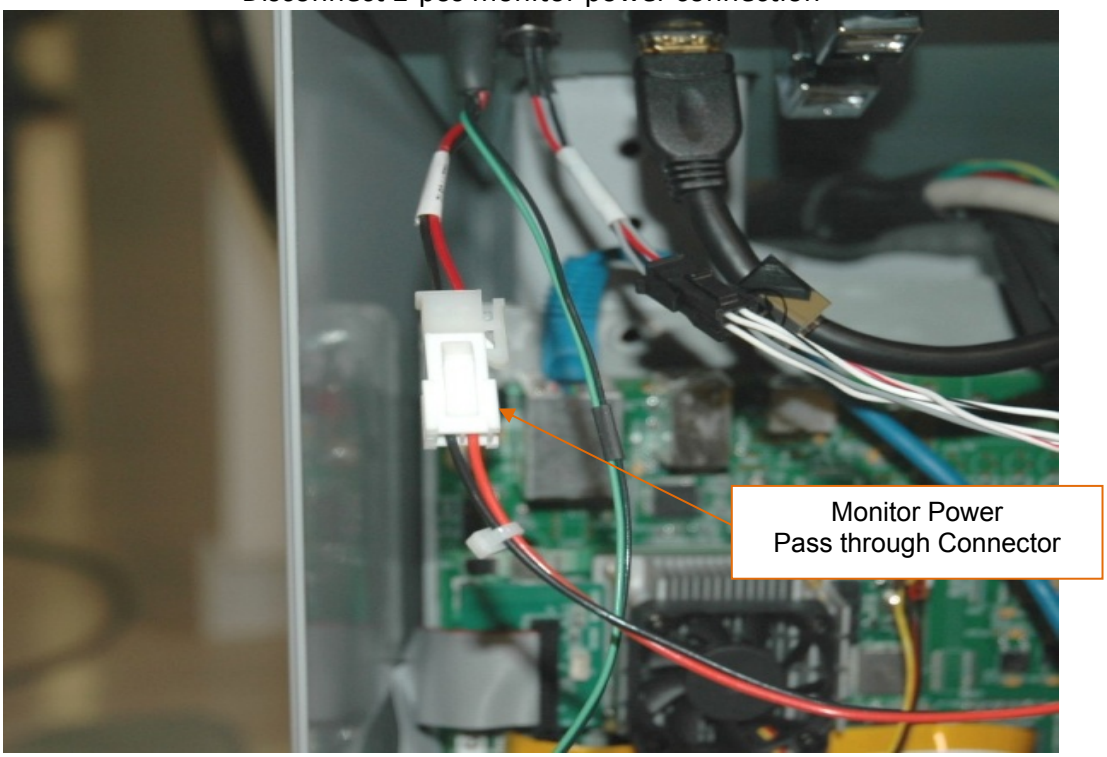
Disconnect HDMI cable from pass through on EMI plate



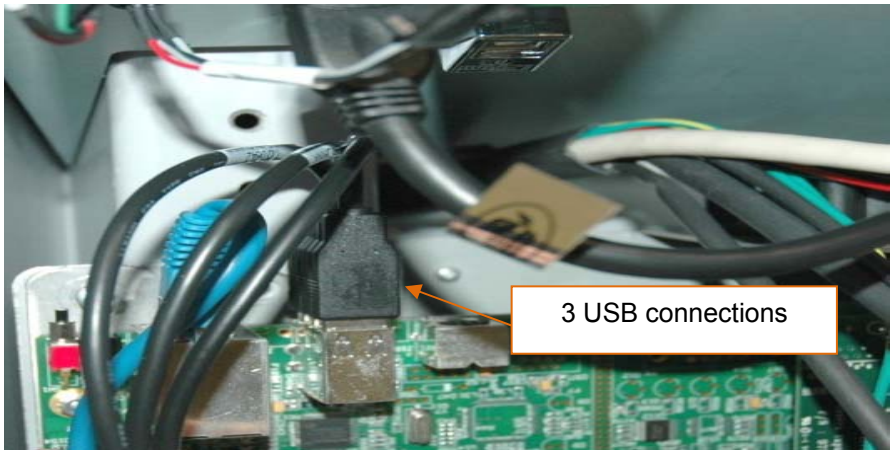
Disconnect 4-position power switch receptacle connector



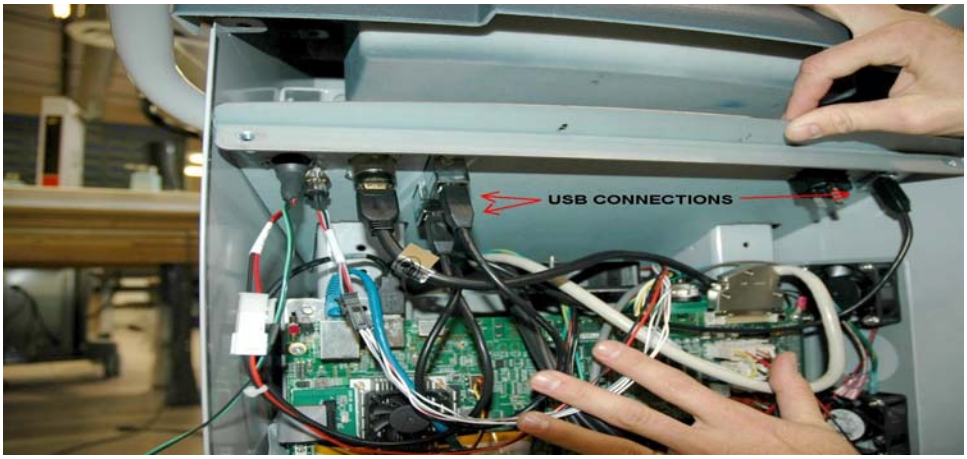
Disconnect 2-pos monitor power connection



Disconnect three USB cables from “J31” location on Video CCA to the three USB

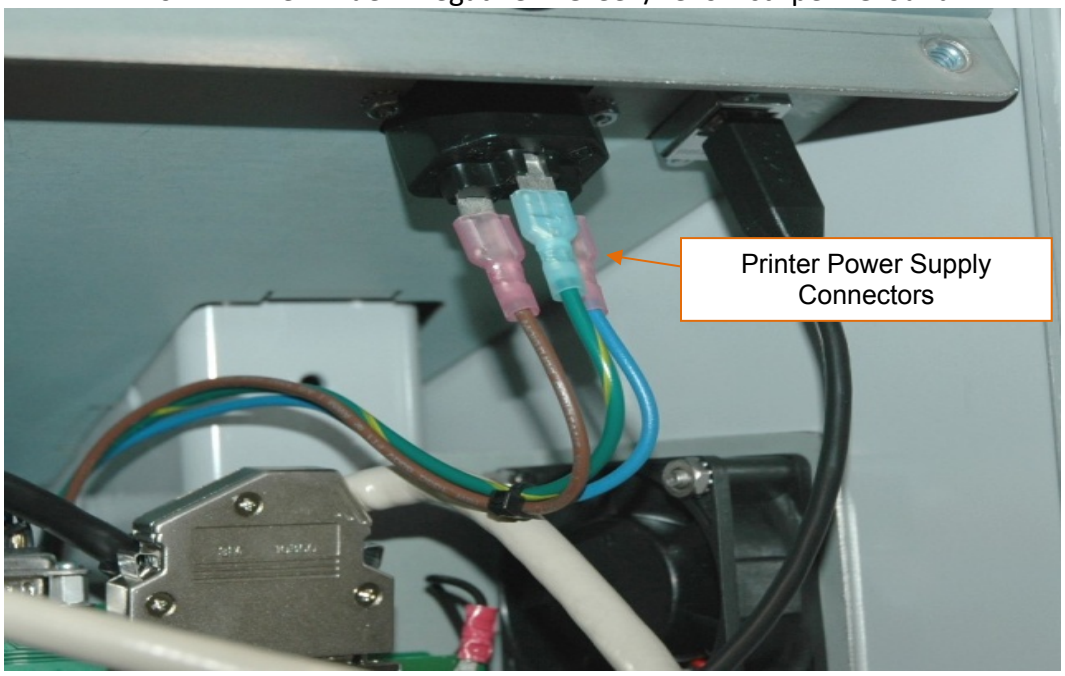


Feed thru Couplers on the bottom side of the EMI shield

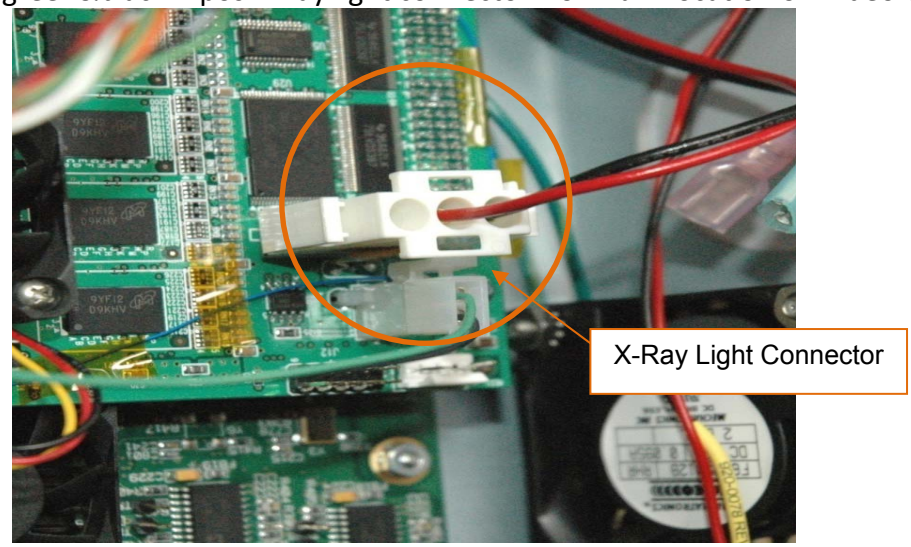


Disconnect the three printer power cables from the 920-0063 cable to the 250-0058 Black Outlet Connector.

*Brown = Live Blue = Negative Green/Yellow stripe = Ground



Disconnect green&black 2-pos X-Ray light connector from “J2” location on Video CCA



At this point the EMI plate can be completely removed and set aside.

3.1.2 Removing Electrical Chassis

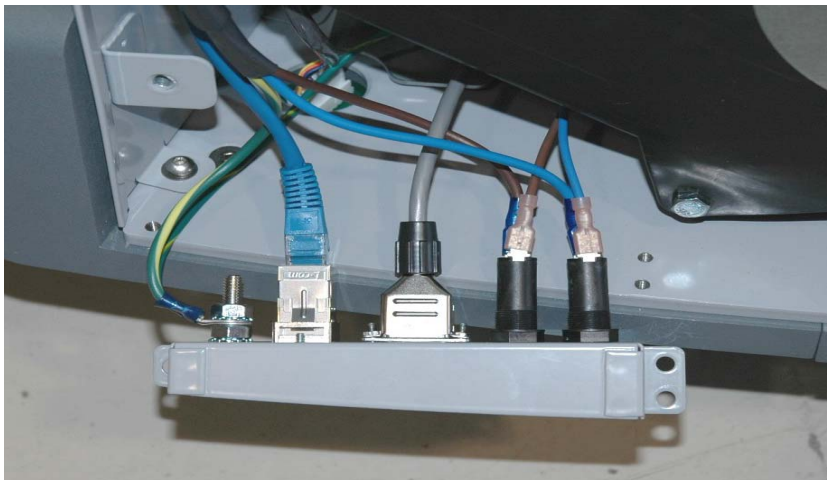
Caution! Ensure unit is unplugged prior to servicing!

All service personnel must be properly grounded while working with and around sensitive electrical components.

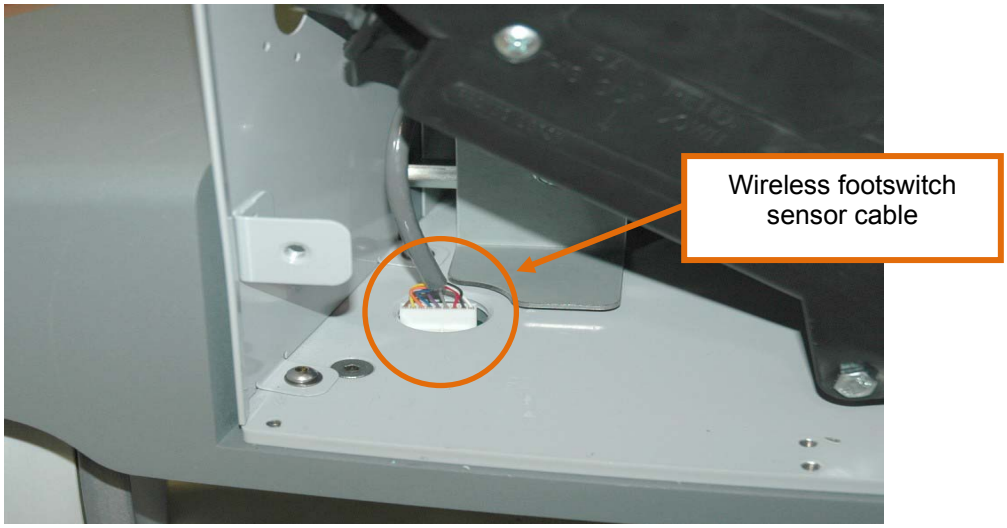
Tools:

(1) Ratchet
(2) 10mm socket
(3) 3/8” socket
(4) 1/4” nut driver
(5) Small Phillips screwdriver
(6) Large Phillips screwdriver
(7) 10mm Nut Driver
(8) 7/16” open end wrench

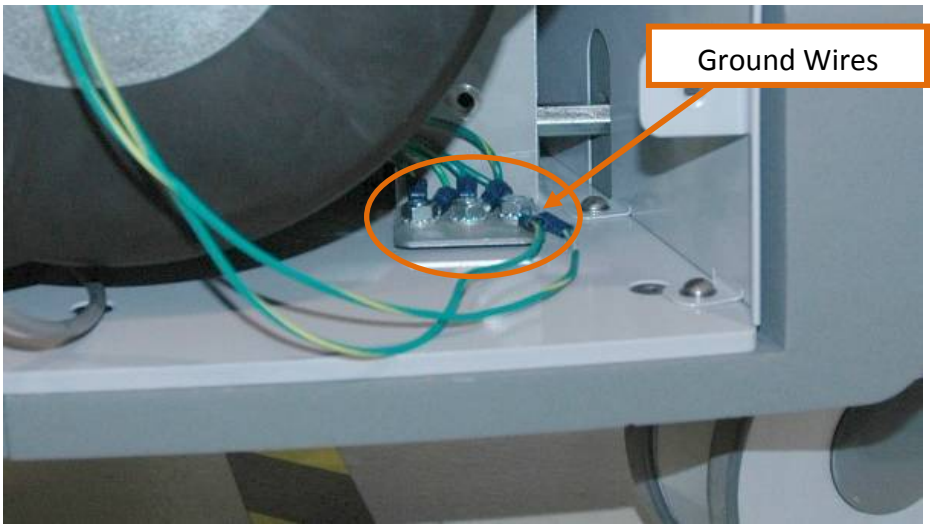
Before removing the electrical chassis first remove the EMI plate as described in section 3.1.1
Once EMI plate has been removed remove fuse box and disconnect all of the cables from the fuse box.

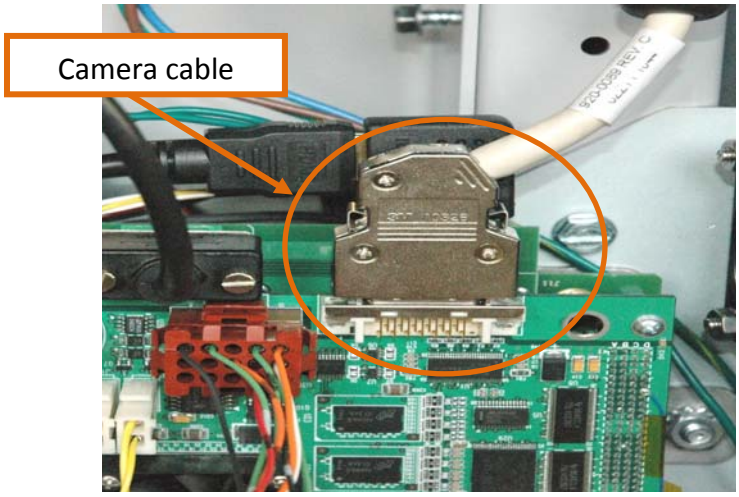


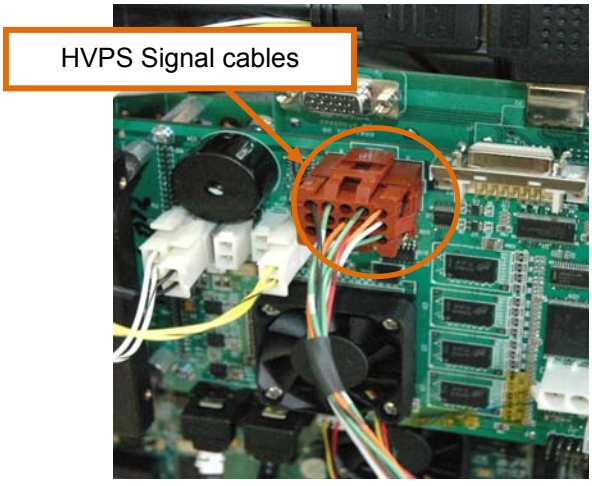
With fuse box removed check to see if unit is equipped with a wireless receiver. If present disconnect the wireless footswitch sensor cable.

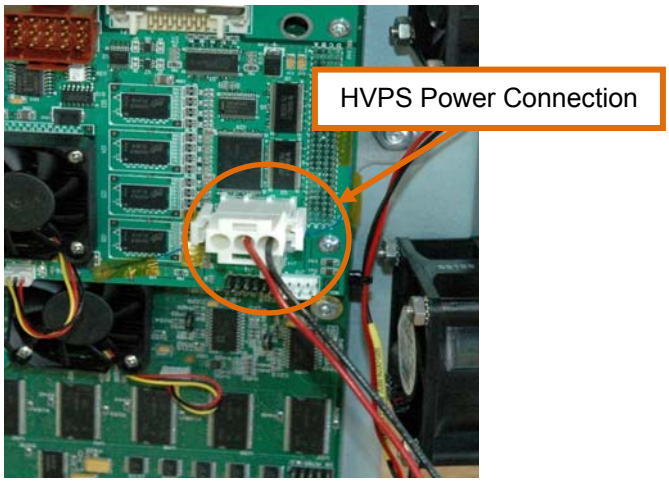


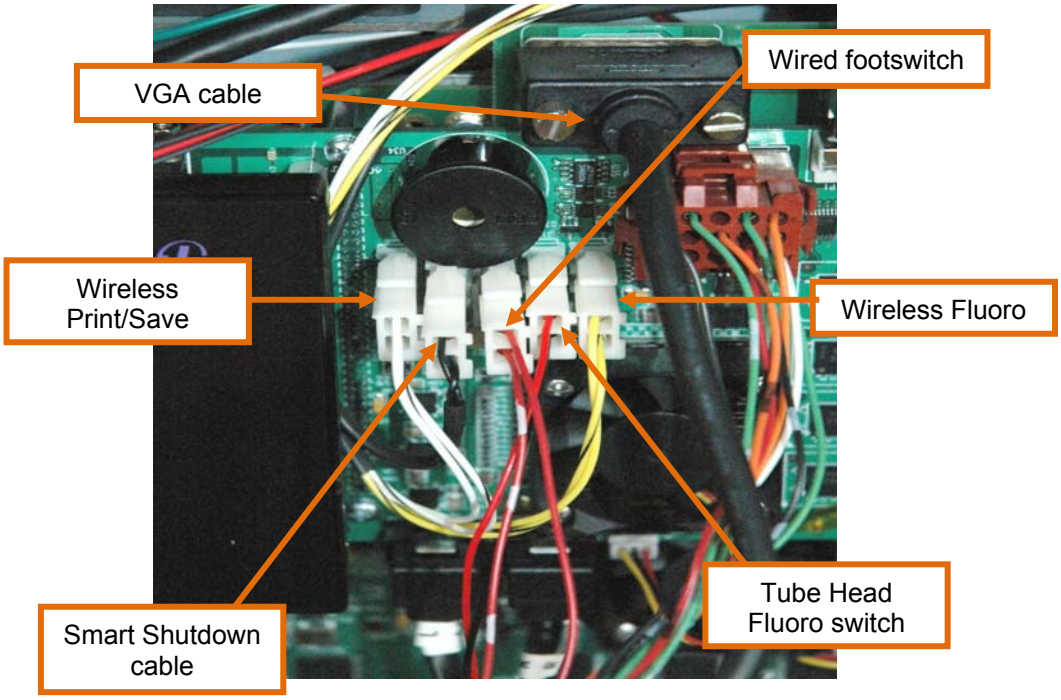
Next disconnect all cable connections indicated in the pictures below.

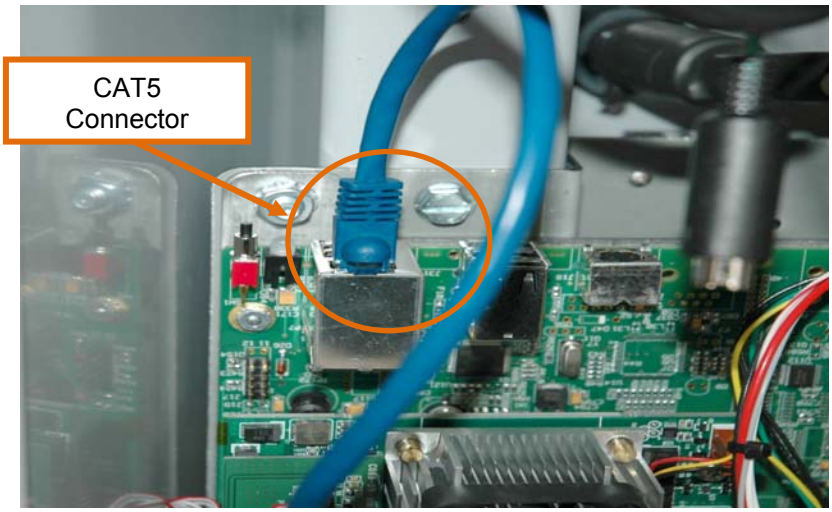


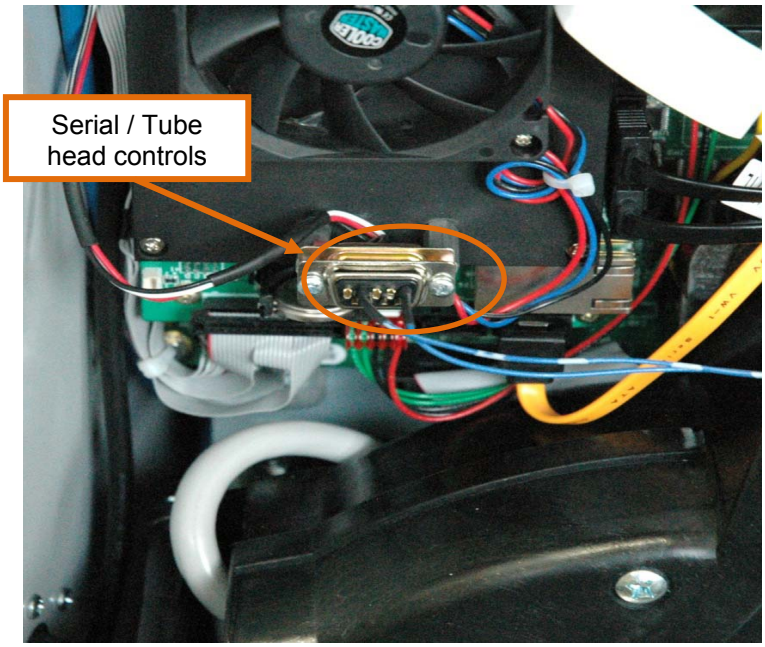







VGA cable
Wired footswitch
Wireless Print/Save
Wireless Fluoro
Tube Head Fluoro switch
Smart Shutdown cable

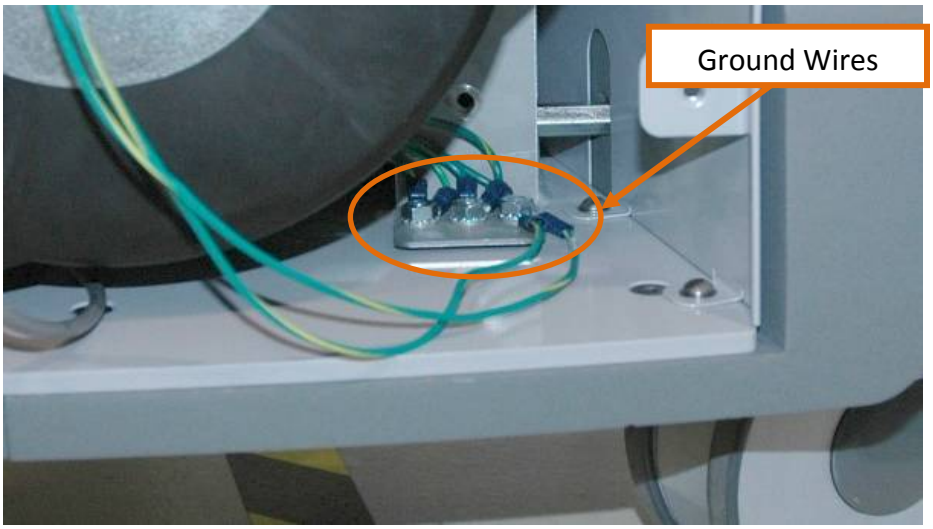

CAT5 Connector

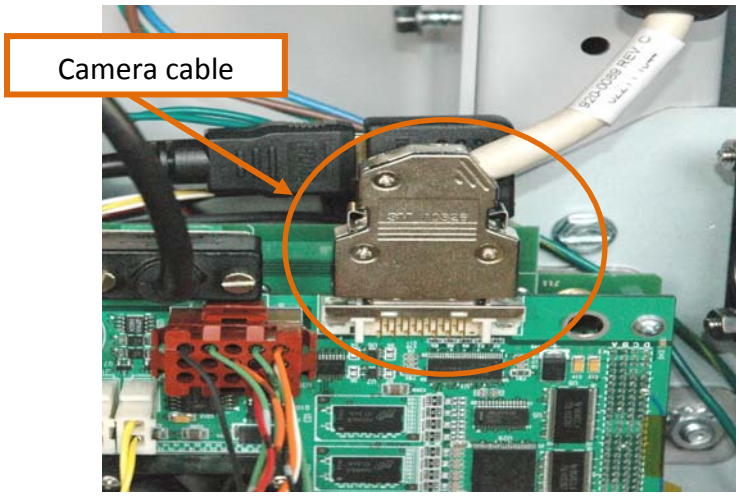

Serial / Tube head controls

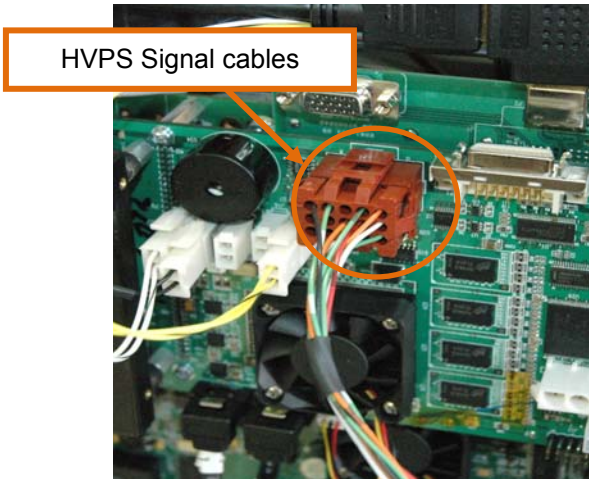
Remove cord reel with three bolts using a 10mm wrench (white arrows) and brown, blue and green (grnd) electrical connections, then swing cord reel out of the way. At this point user can loosen the four #14 x ¾" self tapping screws (red arrows) and remove electrical chassis.

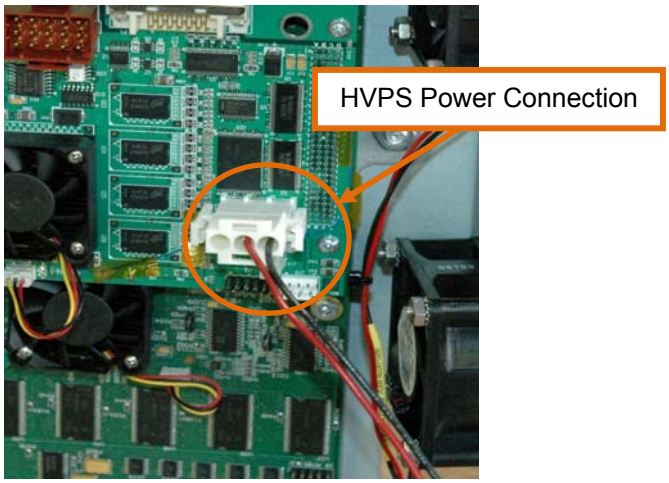
3.1.3 Video Processor CCA Removal

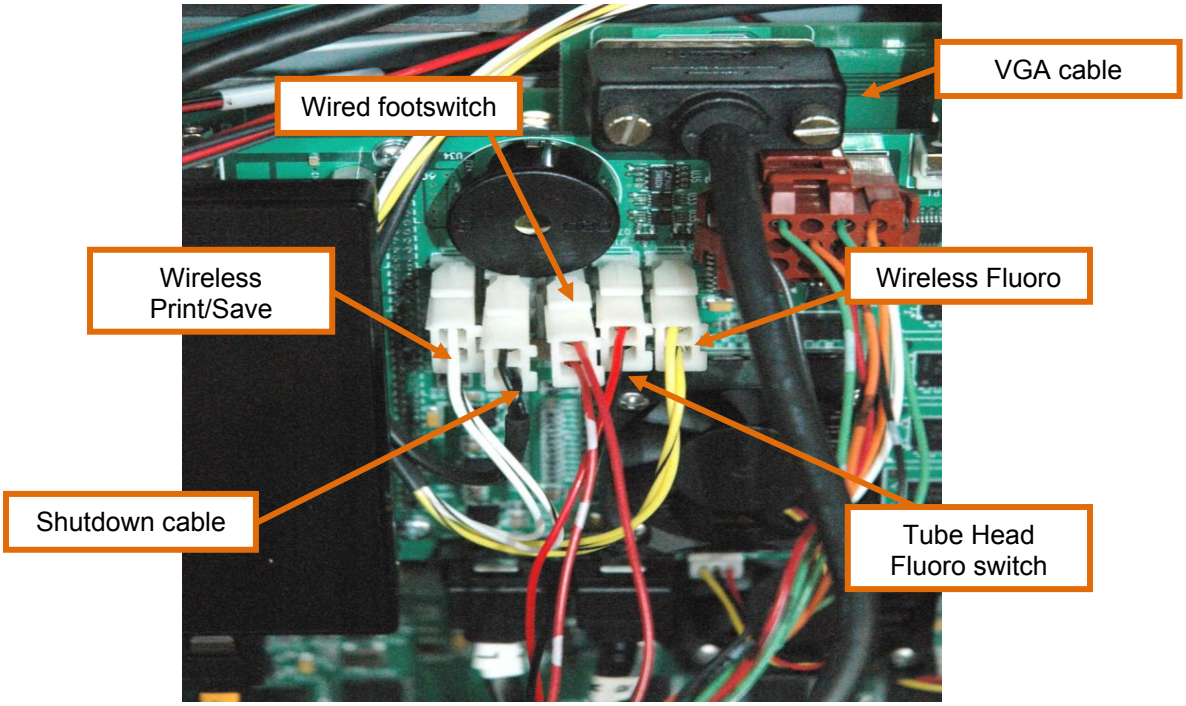
Disconnect all cable connections to the video processor board as indicated in the pictures down below.

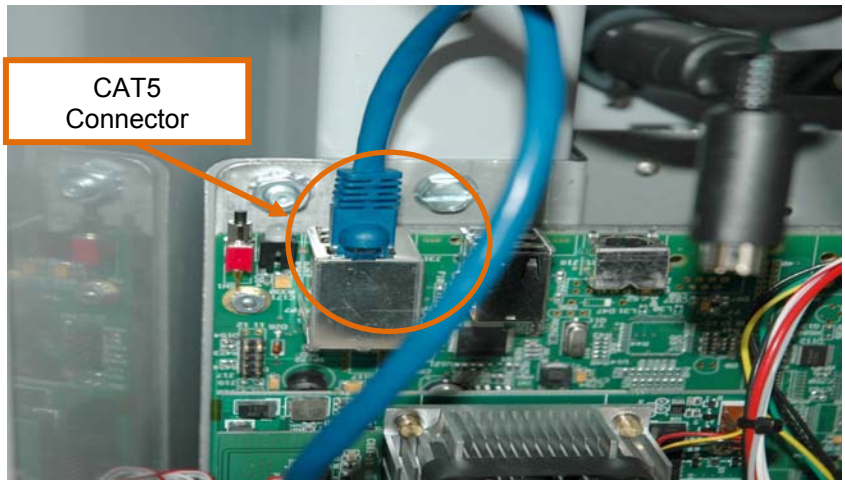


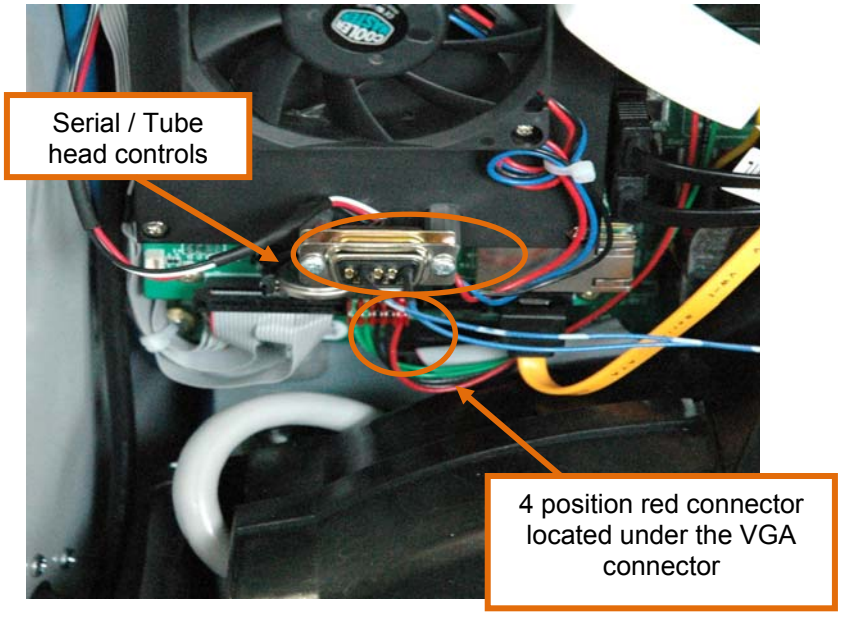


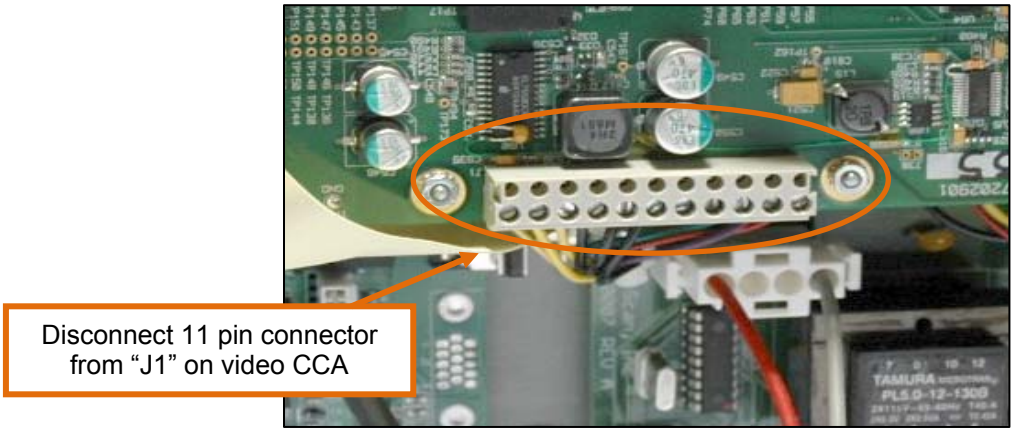




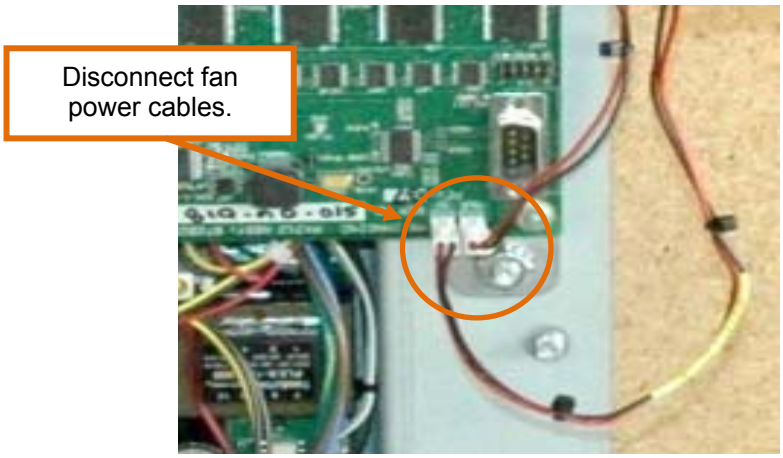

VGA cable
Wired footswitch
Wireless Print/Save
Wireless Fluoro
Shutdown cable
Tube Head Fluoro switch


CAT5 Connector

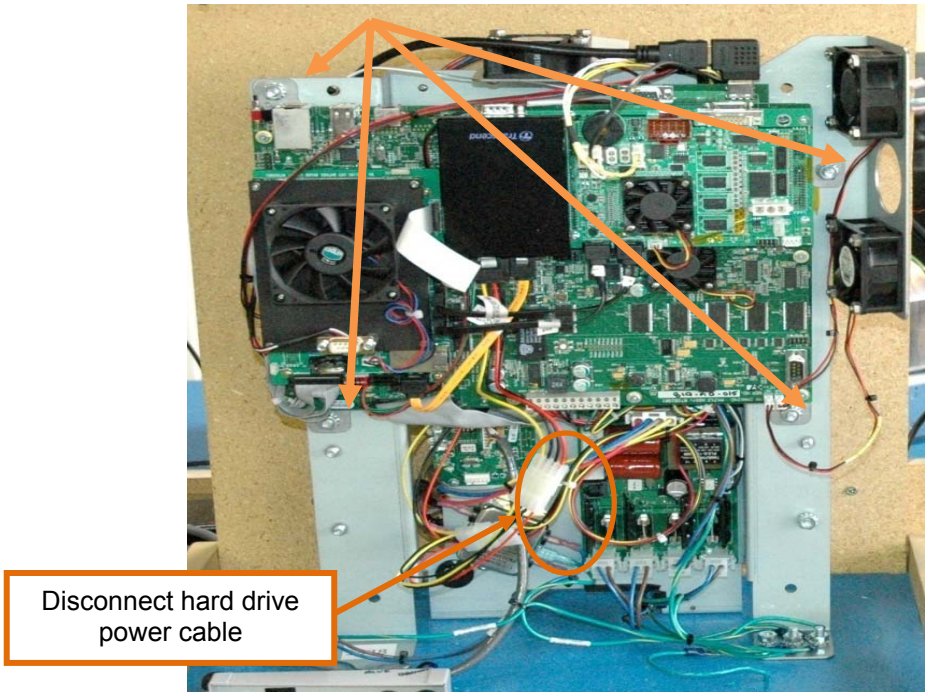

Serial / Tube head controls
4 position red connector located under the VGA connector



Disconnect 11 pin connector from “J1” on video CCA by pulling up on the entire connector. The individual wires do not need to be removed from the block connector itself.

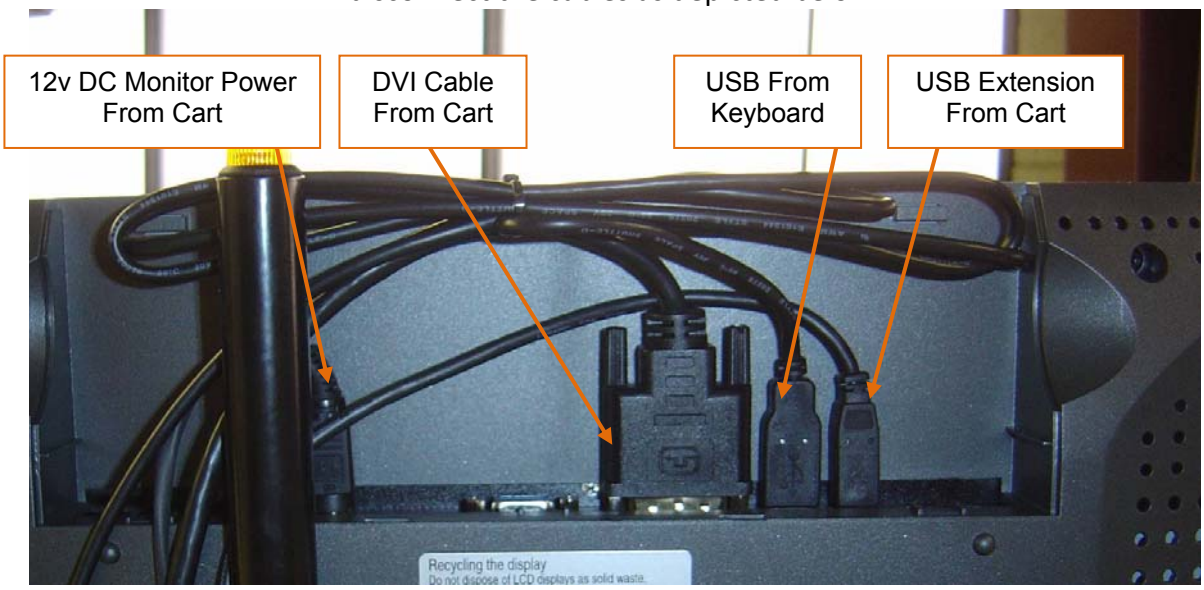


Remove (4) bolts with 7/16” socket on long extension from video processor board. Video CCA can now be removed from electrical chassis.

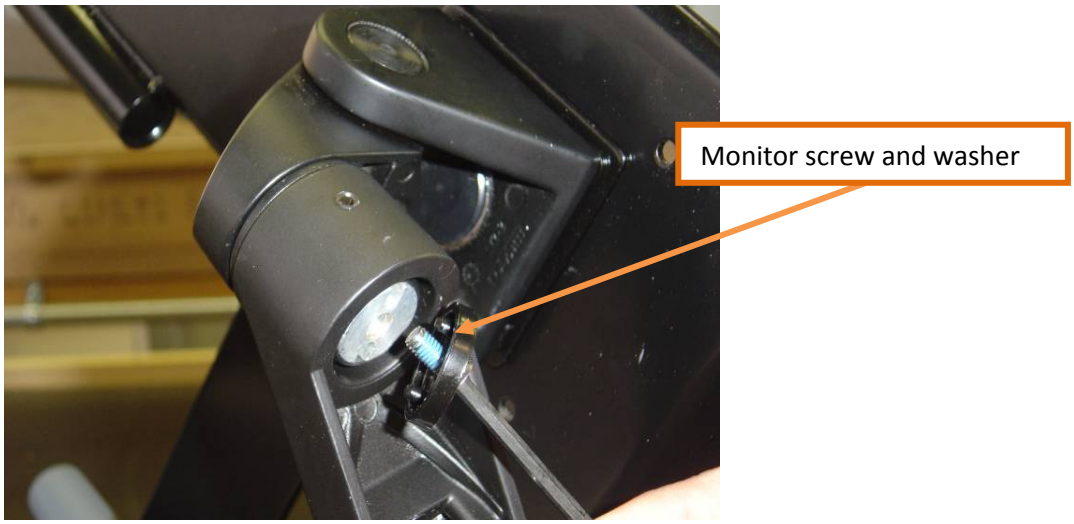


3.1.4 Monitor keyboard assembly Removal

To remove monitor keyboard assembly, first remove monitor cable cover and disconnect the cables as depicted below.

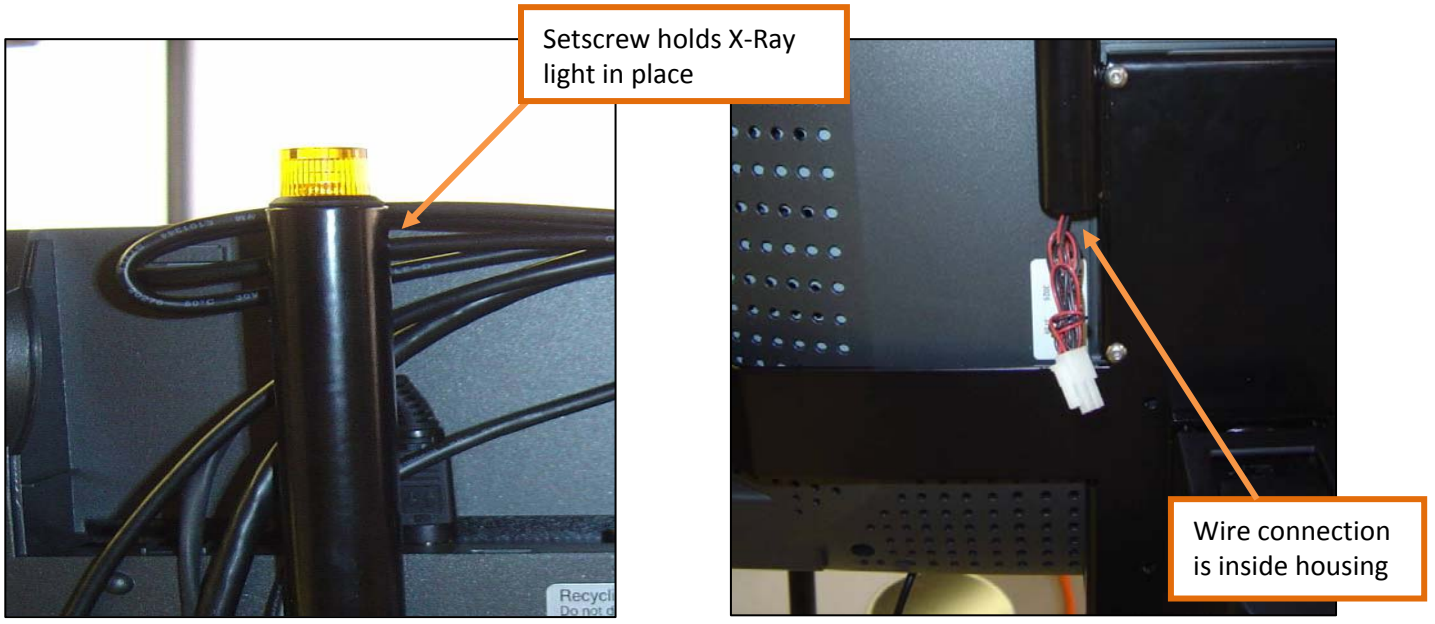


Once cables have been disconnected remove 10-32 x 1/2” screw (401-0462) and anti-rotate washer.



3.1.5 X-Ray light replacement

X-ray light is screwed into monitor arm support bracket. To replace, remove set screw, then simply disconnect light and unscrew light housing from bracket.



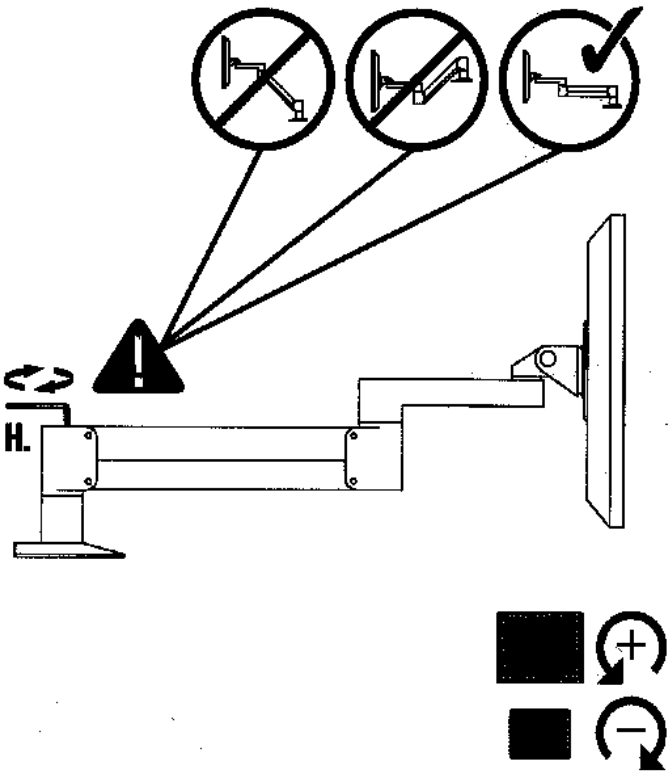
3.1.6 Monitor Arm Removal

Tools: Wire cutters
To remove monitor arm first remove zip ties securing cables to monitor arm to allow cables to hang freely.

Once the cables are free, the arm is just a press fit into the top of the chassis/tray (see circled area below)
Monitor arm can now be removed from cabinet by lifting up on the whole assembly.

3.1.7 Monitor Arm Tension Adjustment

If the monitor height does not stay in place, the tension can be adjusted with the screw located in the knuckle. As depicted below loosening the screw will strengthen the tension and tightening the screw will loosen the tension.



3.1.8 Monitor Removal

Tools:
Allen wrench set
Wire cutters
Zip ties

To remove monitor keyboard assembly, first remove monitor cable cover and disconnect the cables as depicted below.

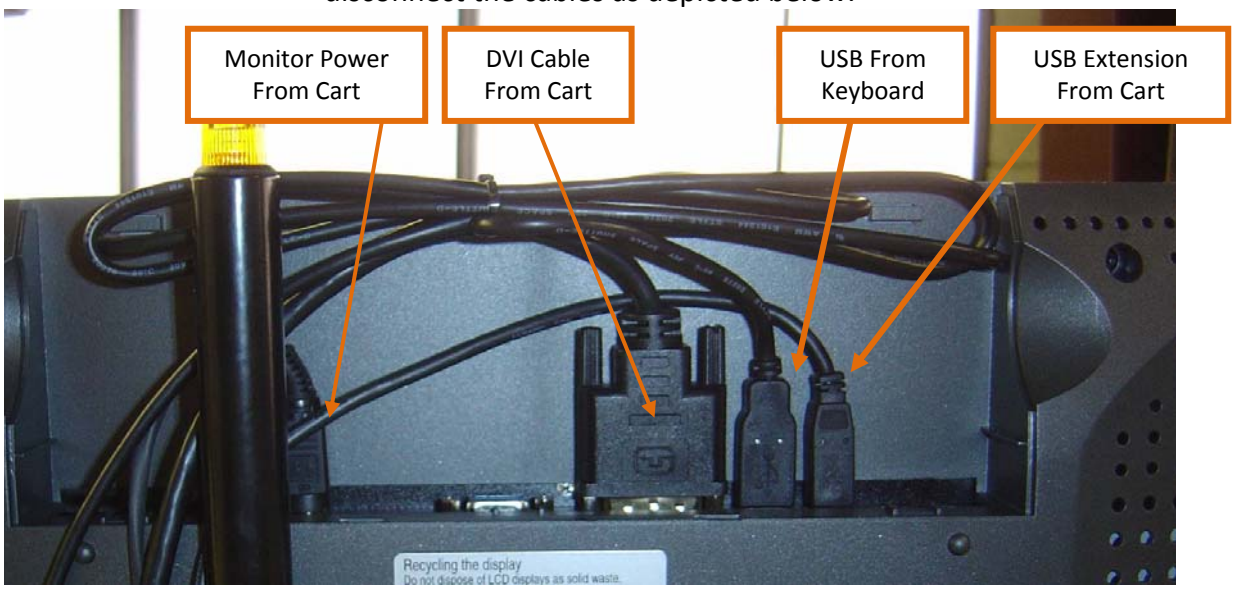


Figure 3-40

Once all of the cables are free, unscrew four M4.7x25 screws to remove monitor.

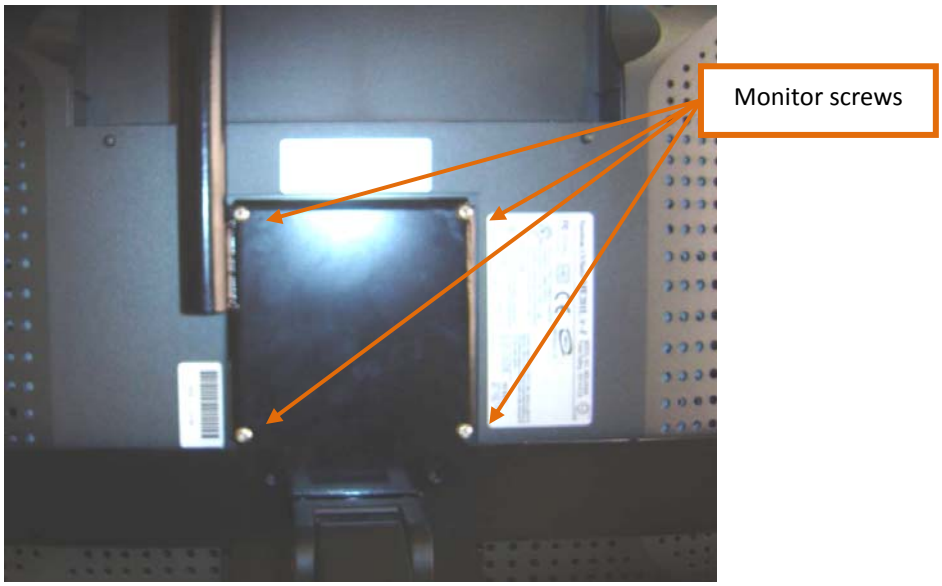


Figure 3-41

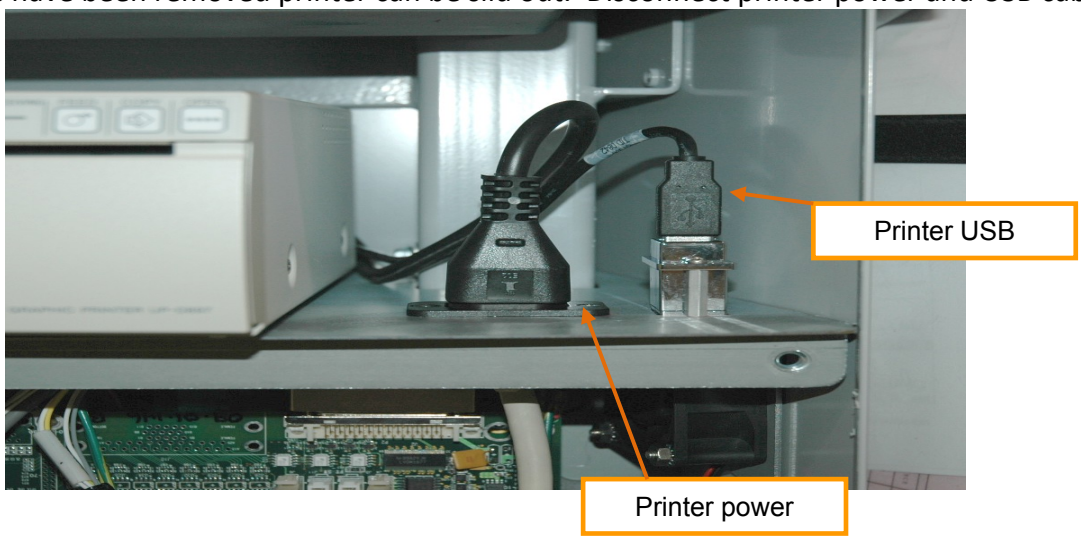
Installation is the reverse of removal.

3.1.9 Printer – installation, removal, replacement

Tools: Large and small Philips head screw driver

Remove back panel using large Philips head screw driver. Once back panel has been removed unscrew two Philips head screws that hold printer in place.

Once screws have been removed printer can be slid out. Disconnect printer power and USB cables.

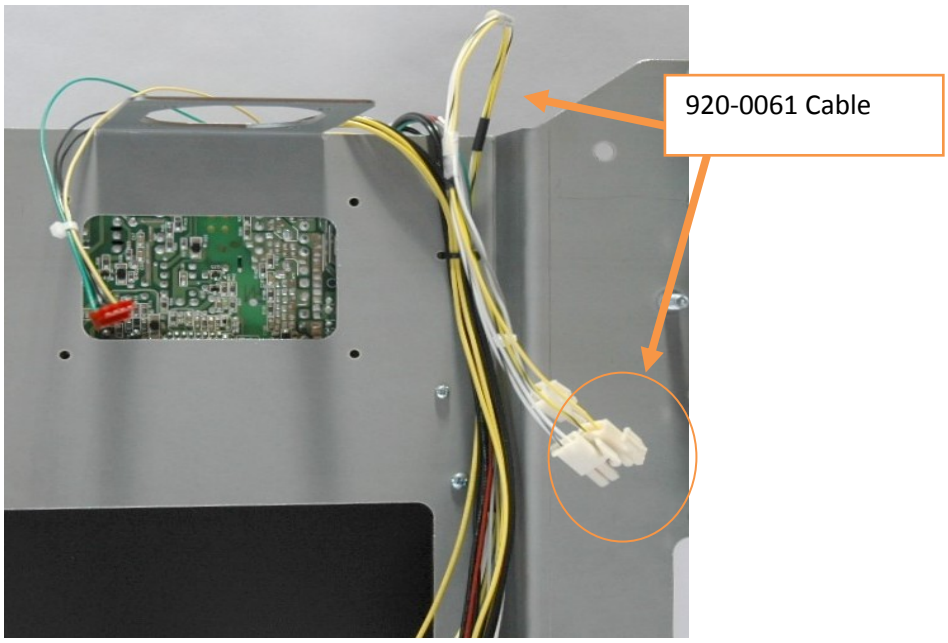


Installation is the reverse of removal.

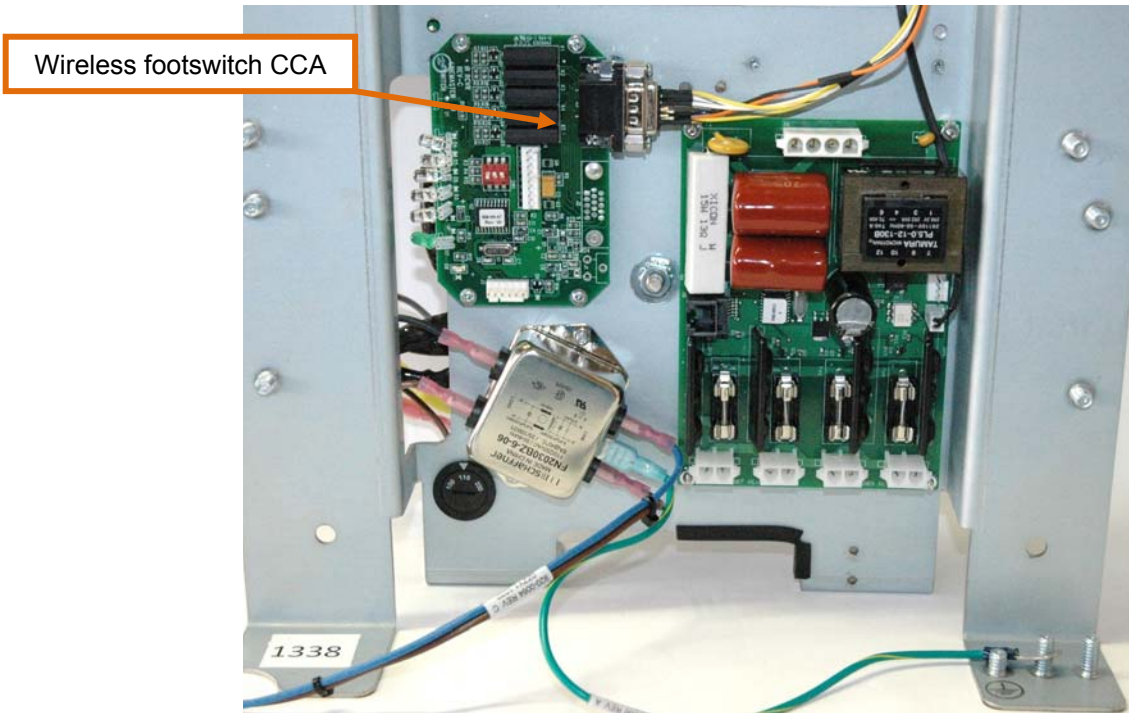
3.2.1 Foot Switch Control Removal

Tools: Phillips screwdriver

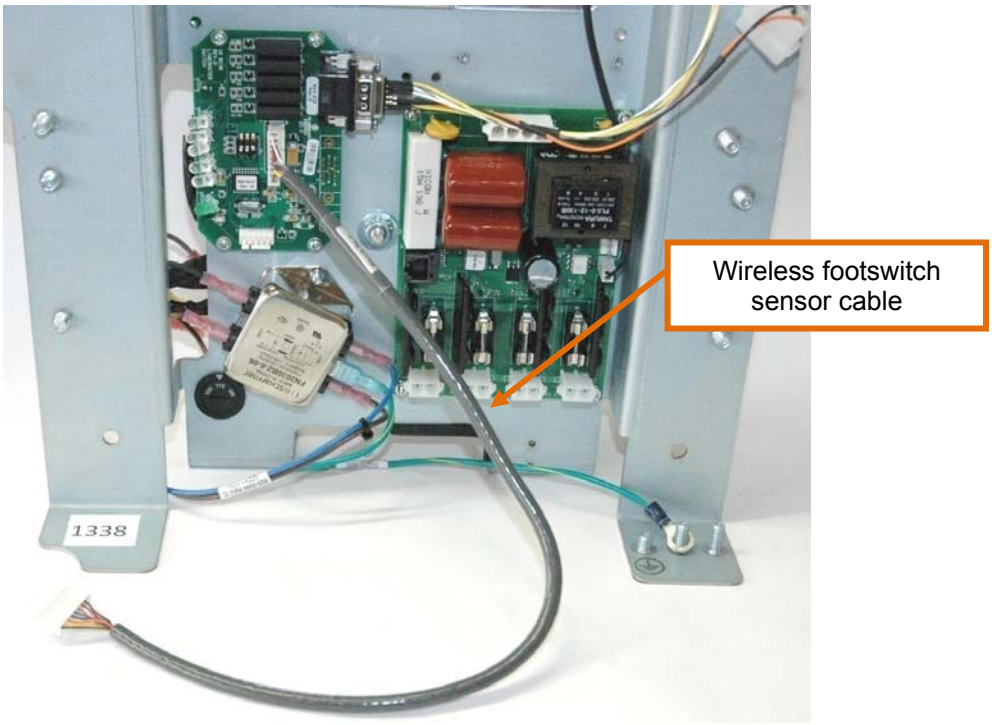
The 920-0061 footswitch interface cable (two 2-pos connectors) with the cable bundle runs along the front of the chassis.



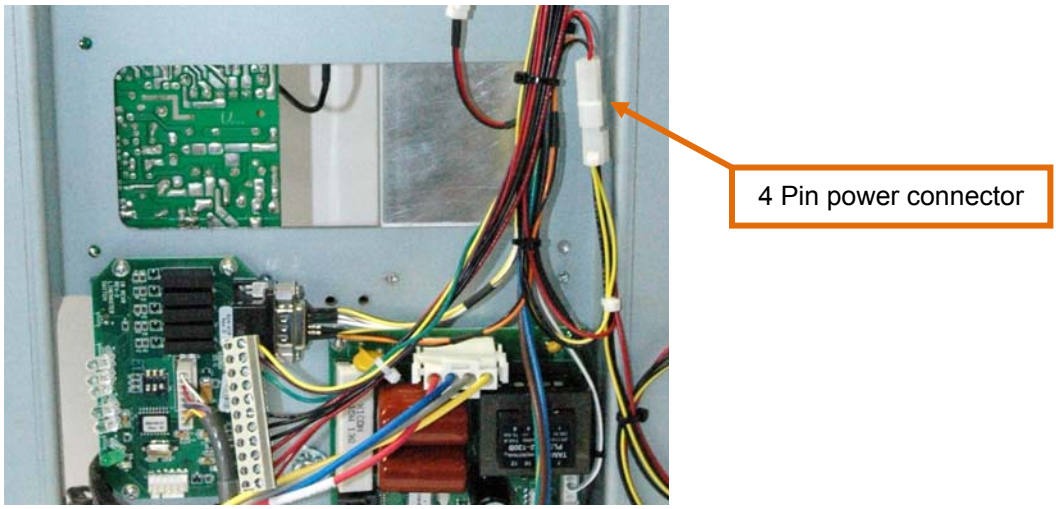
The wireless footswitch CCA is attached to the chassis by four screws. The 920-0061 cable is connected to the CCA by the D-sub connector.



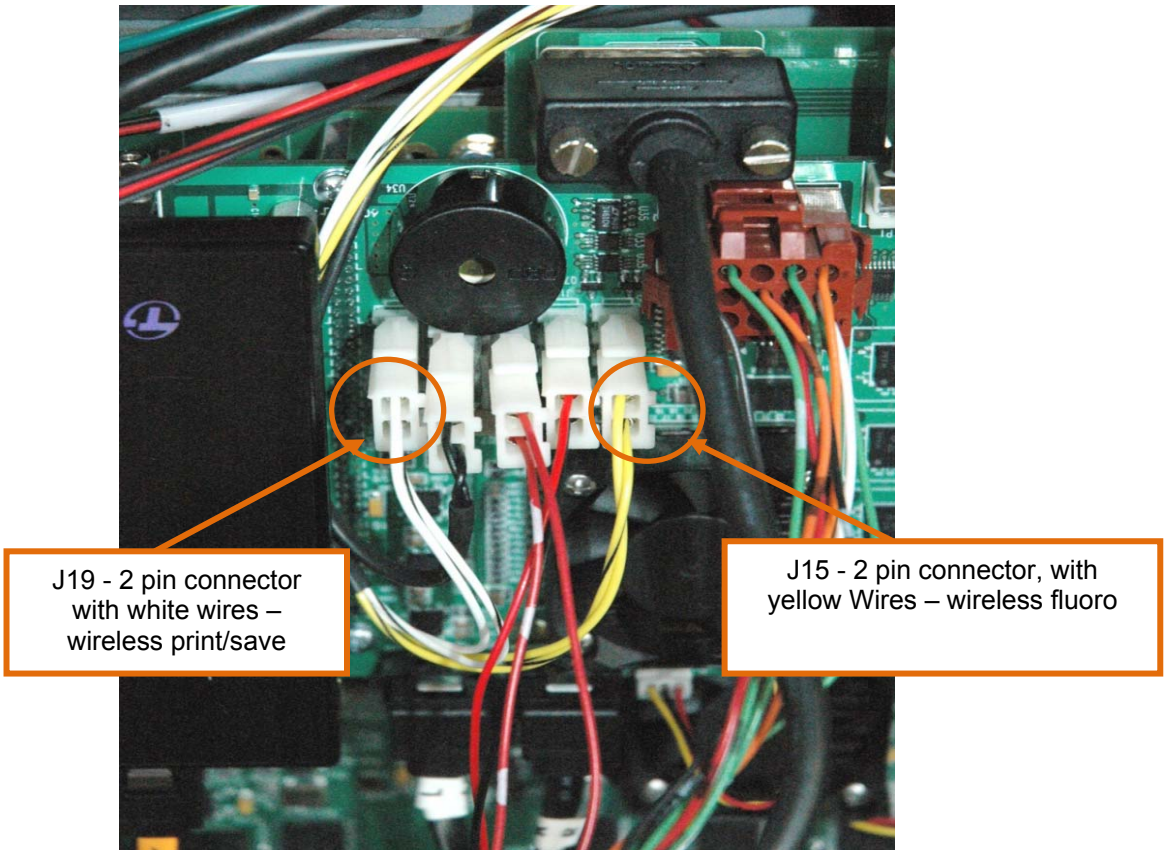
One end of the Wireless Footswitch sensor cable is connected to the CCA. The other end will be attached to the sensor and will be shown in a later step.



The four pin power connector from the wireless footswitch interface cable is connected to the available four pin power connector prior to the MX board installation.



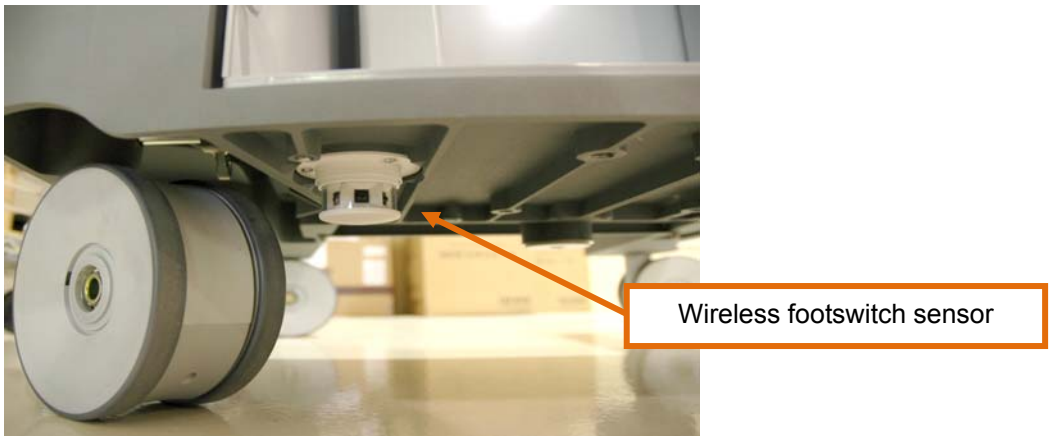
The 2-pin connector with the white wires (920-0061) is connected to “J19” on the Video CCA.
The 2-pin connector with the yellow wires (920-0061) is connected to “J15” on the Video CCA.



3.2.2 Infrared Sensor Removal

Sensor at underside of Cart:

The wireless footswitch sensor is mounted to the underside of the cart assembly using three 401-0015 screws.
The sensor cable from the CCA is connected to the wireless footswitch sensor, use caution that all pins are mated properly.



3.2.3 Wireless Footswitch

Three “AA” batteries are installed into the Wireless Footswitch. In the case of an inoperative wireless footswitch, first check that the batteries have not dislodged from their proper position, and/or change the batteries.

Footswitch infrared emitter operation can be verified using a cell phone camera pointed directly at the LED emitters, and pressing either button on the footswitch. The camera display will show the LED emitting a faint blinking bluish light. It is not necessary to actually “take” a picture.

Each footswitch utilizes a unique channel to operate with its respective Orthoscan unit. In the case of multiple Orthoscan units in one facility, always ensure that the proper footswitch is being used for each unit.

If a new footswitch is required, please note the channel number of your current footswitch when ordering. It is a 3 digit number sticker found on the top of the unit, or the last number of the serial number on the bottom of the footswitch. If for any reason it is necessary to change the channel of operation, please contact the Orthoscan Service Department for assistance. (1-866-996-0472)

3.2.4 X-Ray Tube (HVPS)

Tools:

(1) Latex Gloves
(1) Blue Masking Tape
(1) ¼" Nut Driver
(1) Allen Wrench Set
(1) #2 Phillips Screwdriver

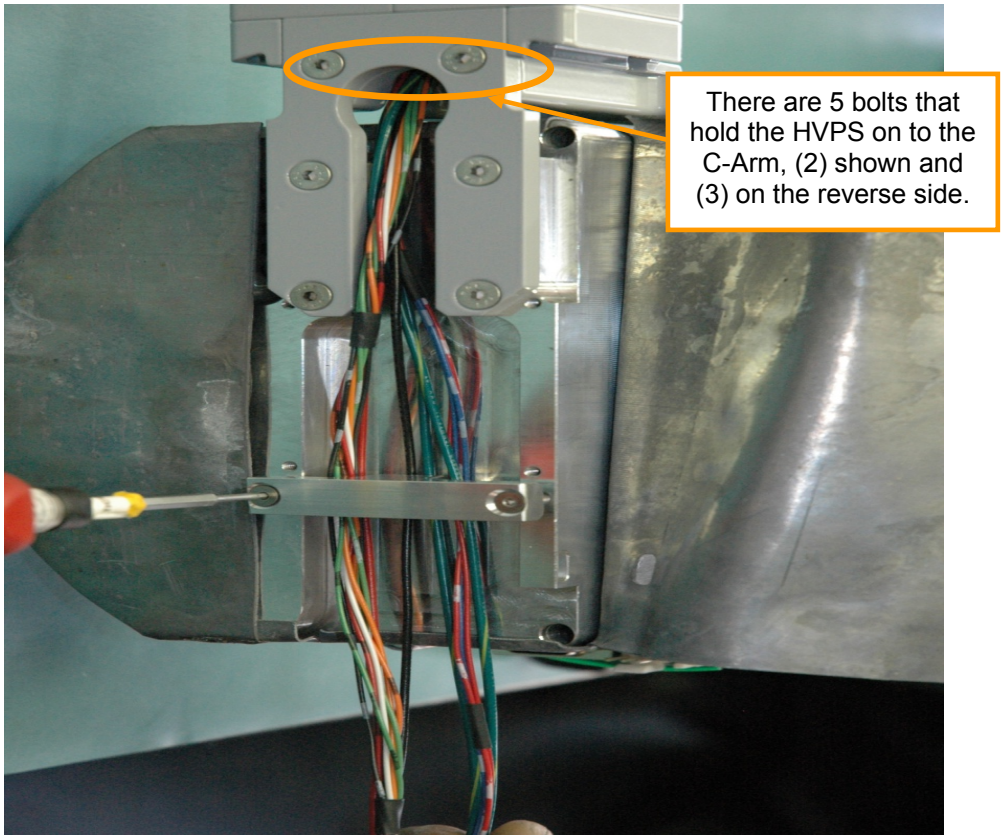
Secure all the cables up and out of the way by taping them to the top of the "C" rail.

NOTE: Wear Latex gloves when handling HVPS due to the lead shielding.

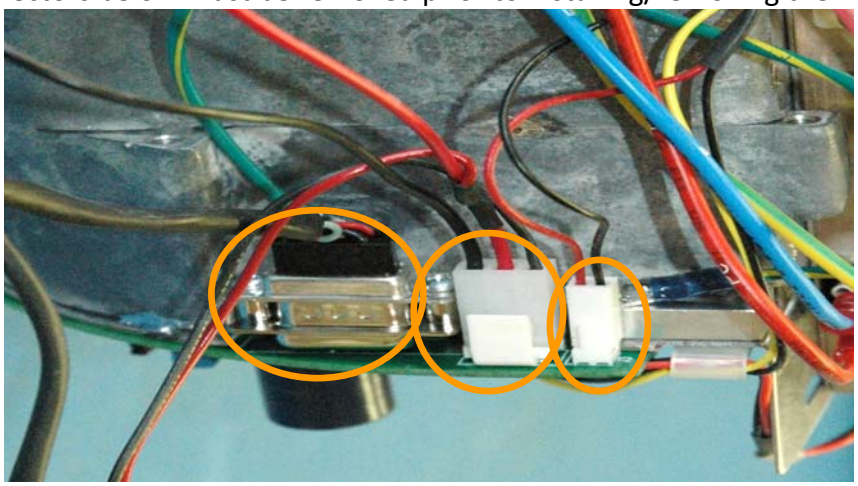
Fold back the HVPS lead shield over the mount points. Install the HVPS onto the C-rail using four screws from the bottom (401-0725) and four from the top (401-0462). When installing, gently guide the cables up and over the HVPS.

NOTE: Ensure the cables do not get pinched between the HVPS and the Bracket at the top or rear.

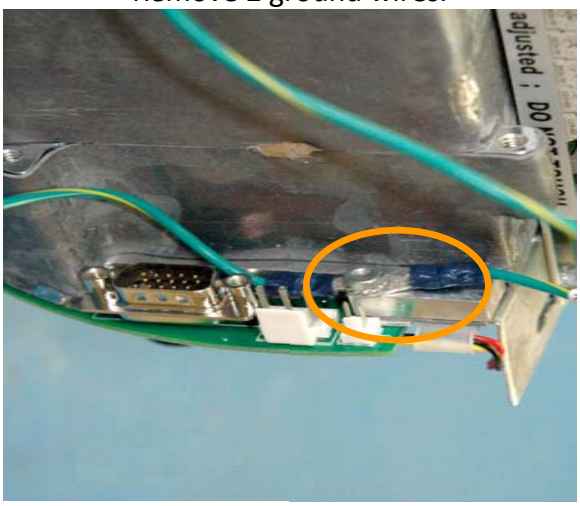
The cables over the top of the HVPS as shown are separated by a cable separator clamp (100-0401-01) and secured with two 6-32 x ½" screws (401-0425).



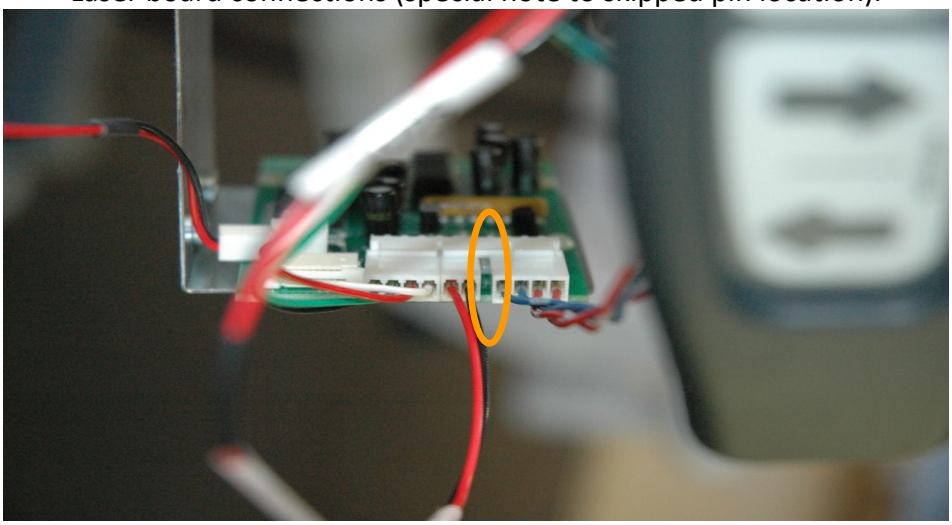
Connectors below must be removed prior to installing/removing the HVPS.



Remove 2 ground wires.

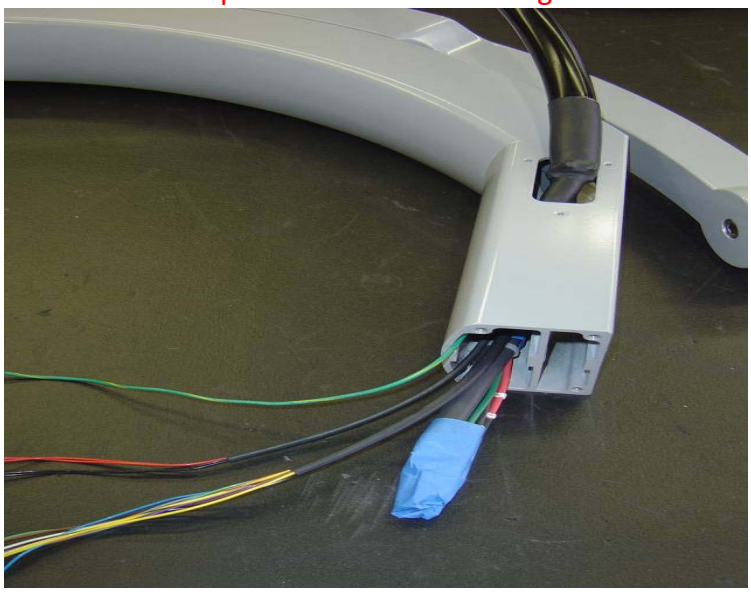


Laser board connections (special note to skipped pin location).



Below is a view of the HVPS side of the C-Arm with the HVPS removed.

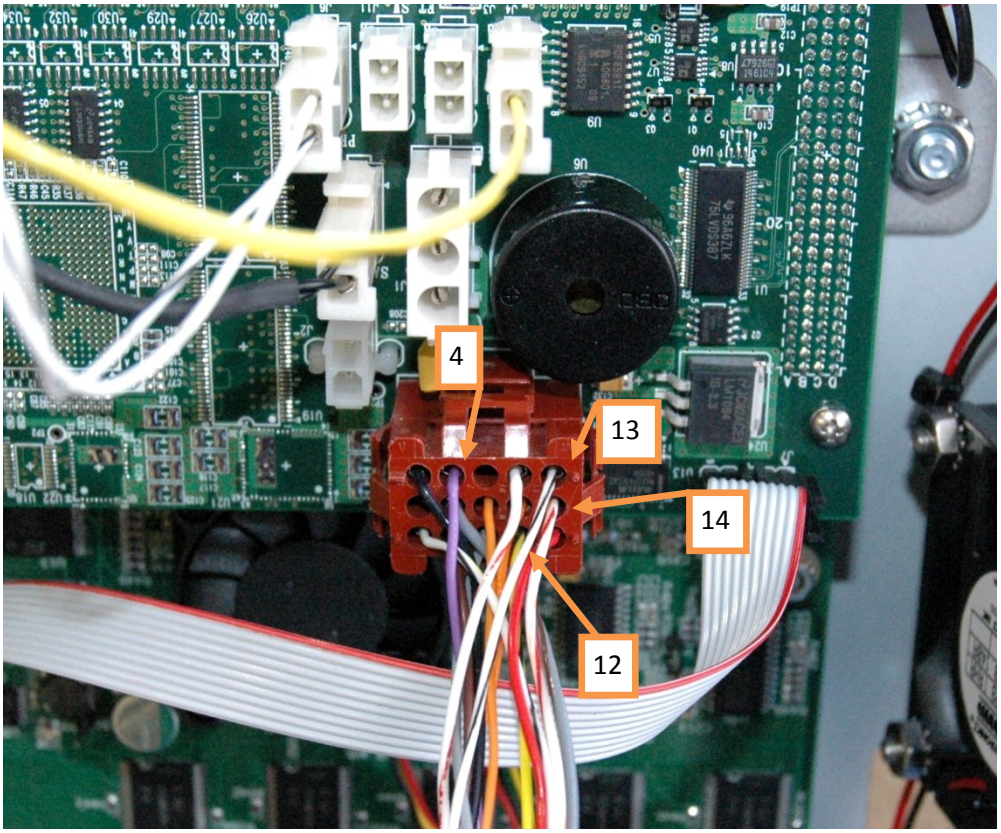
NOTE: A pull wire must be attached to the II cable prior to removal; this is used to pull the new cable through the C-Arm.



3.2.5 Generator Testing

This is a very useful procedure for testing whether or not the generator is functioning correctly, especially if you don't have access to an Unfors meter.

The indicated kV/uA value on the screen should match the control voltage measured at the appropriate control pin (see above), and this should match the feedback value +/-7% for kV, +/-10% for uA. To measure the control or feedback voltage, you simply set a multimeter to read d.c. volts and probe the appropriate pin number.



Pin assignment of generator I/O control connector (P7 on the FD):

4: uA Feedback
12: uA Program
13: kV Feedback
14: kV Control

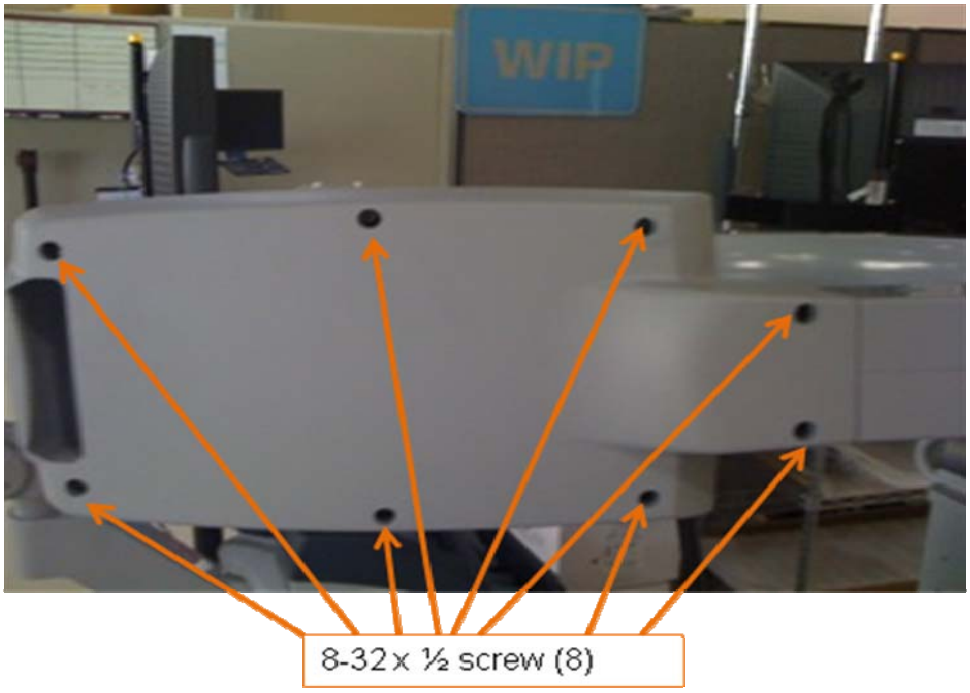
Control/Feedback voltages for all models:

INDICATED VALUES		NON-BOOST - TARGET		BOOST - TARGET	
kV	µA	kV control	µA control	kV control	µA control
40	40	2.15	1.6	2.05	1
41	41	2.2	1.65	2.1	1.03
42	43	2.25	1.7	2.16	1.08
43	45	2.3	1.8	2.21	1.13
44	46	2.35	1.85	2.26	1.15
45	48	2.4	1.9	2.31	1.2
46	50	2.45	2	2.36	1.25
47	52	2.5	2.05	2.41	1.3
48	53	2.55	2.1	2.46	1.33
49	55	2.65	2.2	2.51	1.38
50	57	2.7	2.25	2.57	1.43
51	58	2.75	2.3	2.62	1.45
52	60	2.8	2.4	2.67	1.5
53	62	2.85	2.5	2.72	1.55
54	64	2.9	2.55	2.77	1.6
55	65	2.95	2.6	2.82	1.63
56	67	3	2.7	2.87	1.68
57	69	3.05	2.75	2.92	1.73
58	70	3.1	2.8	2.98	1.75
59	72	3.15	2.9	3.03	1.8
60	74	3.2	2.95	3.08	1.85
61	76	3.25	3.05	3.13	1.9
62	77	3.3	3.1	3.18	1.93
63	79	3.4	3.15	3.23	1.98
64	81	3.45	3.25	3.28	2.03
65	82	3.5	3.3	3.34	2.05
66	84	3.55	3.35	3.39	2.1
67	86	3.6	3.45	3.44	2.15
68	88	3.65	3.5	3.49	2.2
69	89	3.7	3.55	3.54	2.23
70	91	3.75	3.65	3.59	2.28
71	93	3.8	3.7	3.64	2.33
72	94	3.85	3.75	3.69	2.35
73	96	3.9	3.85	3.75	2.4
74	98	3.95	3.95	3.8	2.45
75	100	4	4	3.85	2.5
76	120	N/A	N/A	3.9	3
77	140	N/A	N/A	3.95	3.5
78	160	N/A	N/A	4	4

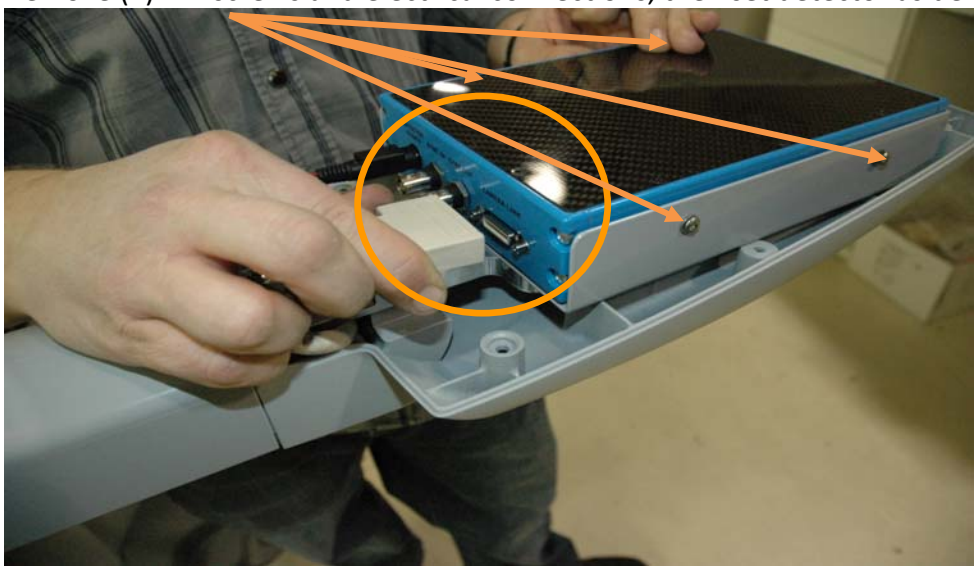
3.2.6 Flat Detector Replacement

Tools:
(1) Latex Gloves
(1) Blue Masking Tape
(1) 1/4” Nut Driver
(1) Allen Wrench Set
(1) #2 Phillips Screwdriver

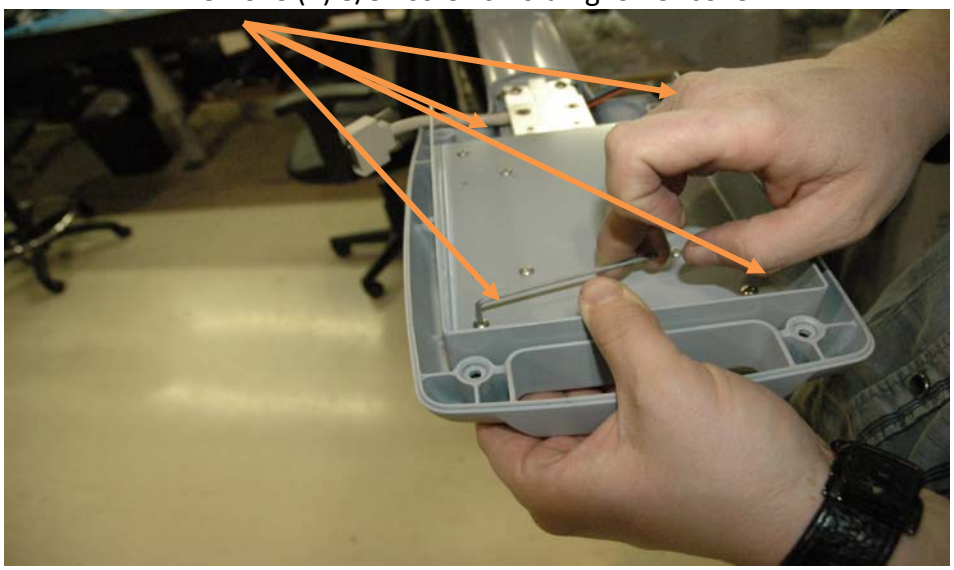
Remove (8) 6mm bolts from bottom of flat detector and remove top cover.



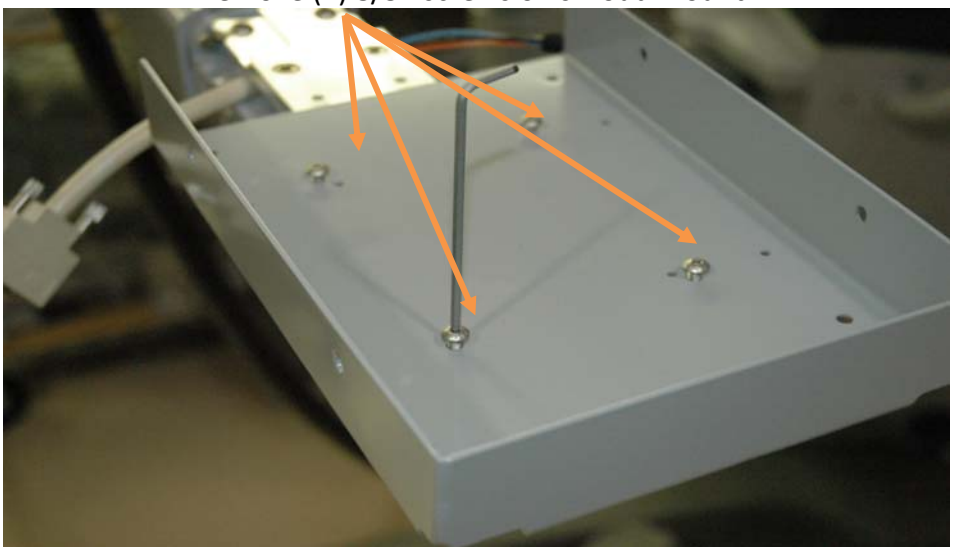
Remove (4) M4 screws and electrical connections, then set detector aside.



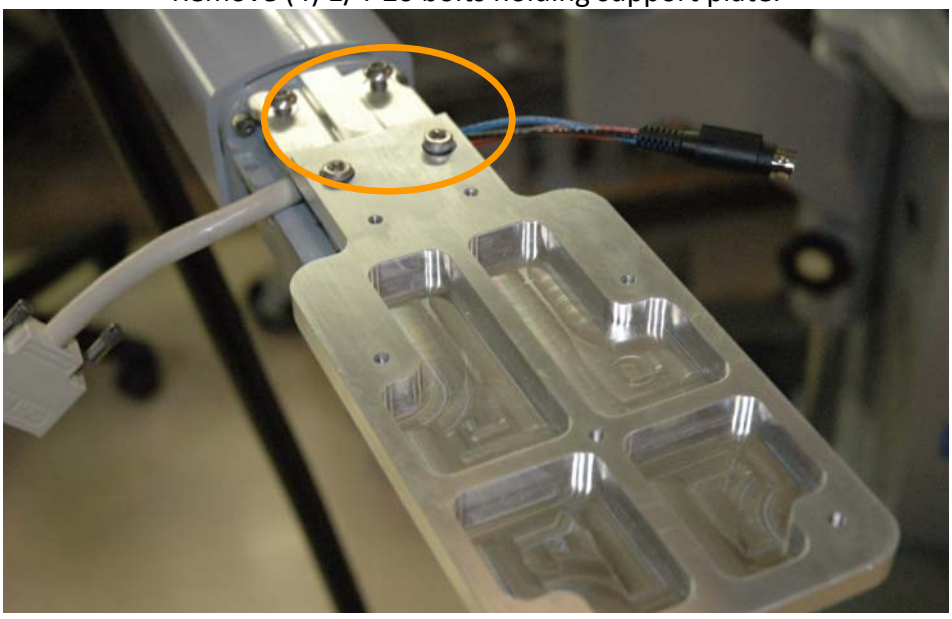
Remove (4) 8/32 screws holding lower cover.



Remove (4) 8/32 screws on shroud mount.



Remove (4) 1/4-20 bolts holding support plate.



Remove knuckle mount 10/32 screws (4)

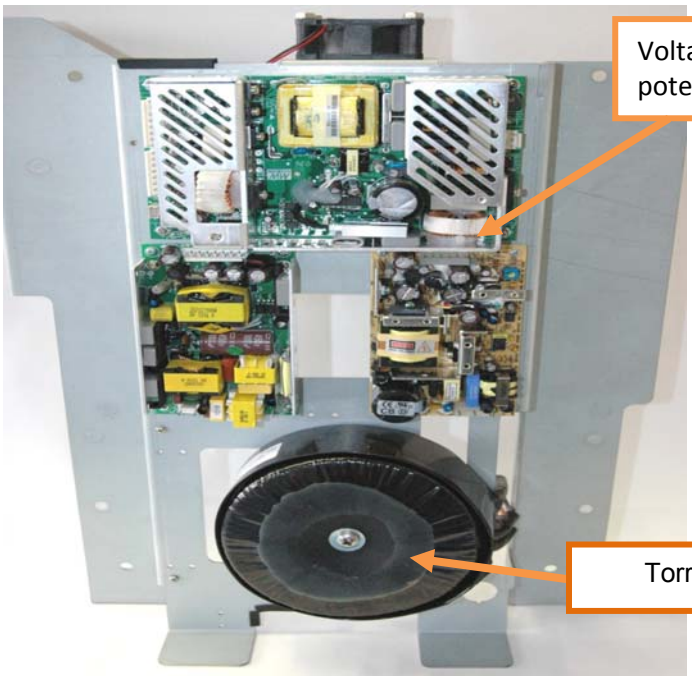
Installation is reverse of removal.

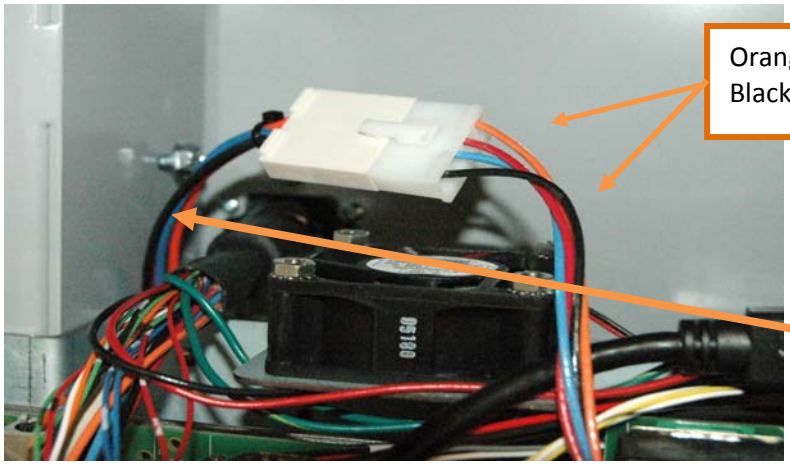
You will need to calibrate the new Flat Detector, see section 3.2.8

3.2.7 Flat Detector Power Supply

The Flat Detector power supply (260-0033) will need to be calibrated for use with the Flat Detector.

See Section 3.1.2 for chassis removal to gain access to the power supply.





Adjust Flat Detector power supply voltages

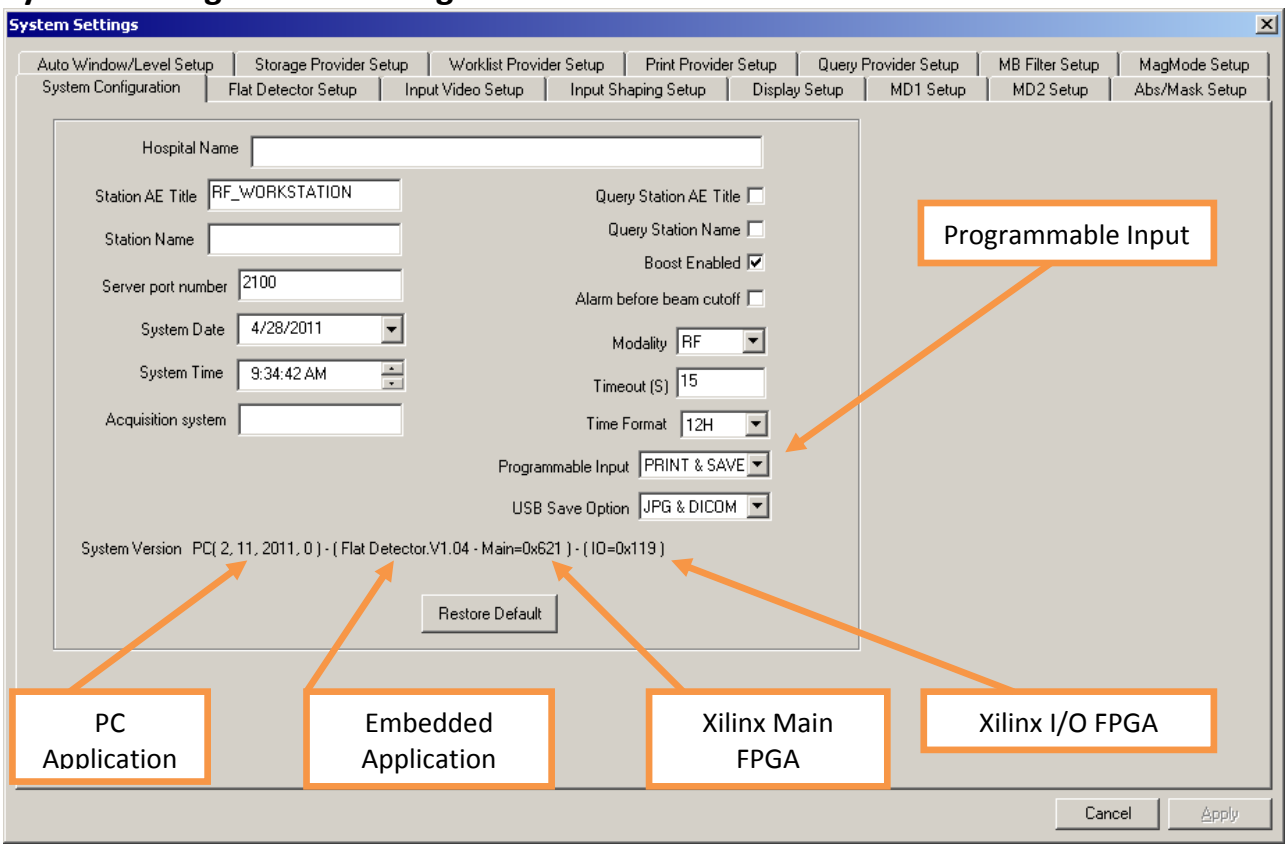
Operation Steps:

1. Set the multimeter to measure volts DC.
2. Measure the initial voltages at the Black (ground) and Orange (+7vDC) leads. A new power supply will be set at 6v from the factory. **(If possible a more accurate voltage measurement can be obtained from the leads at the flat detector itself)**
3. Locate the Blue potentiometer VR1 on the FD power supply. Using a small Philips screwdriver, adjust the potentiometer until the multimeter reads 7.0v (± 0.1v).
4. Apply 1 drop of blue loctite 242 to the potentiometer to prevent it from moving.

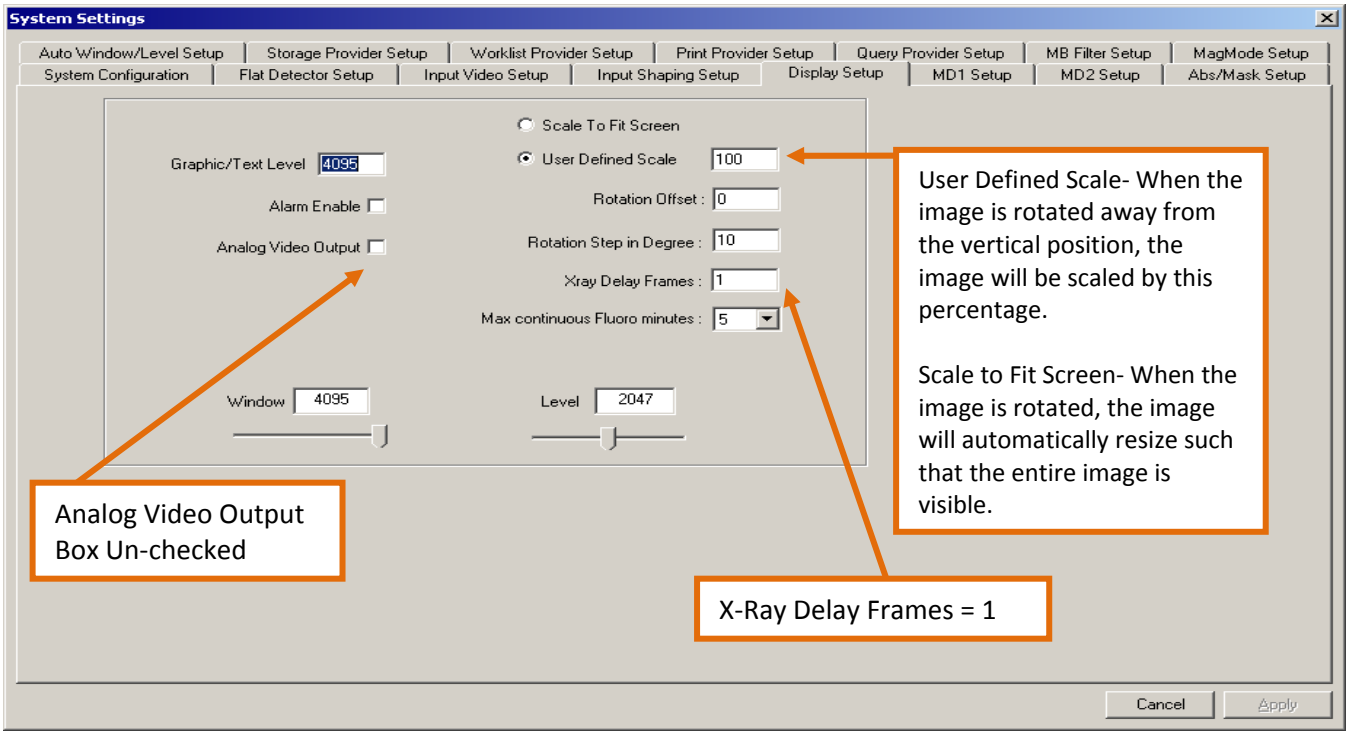
3.2.8 Flat Detector Calibration and Settings

To access System Configuration, right click anywhere on the screen, select System Configuration, and enter password: techuser

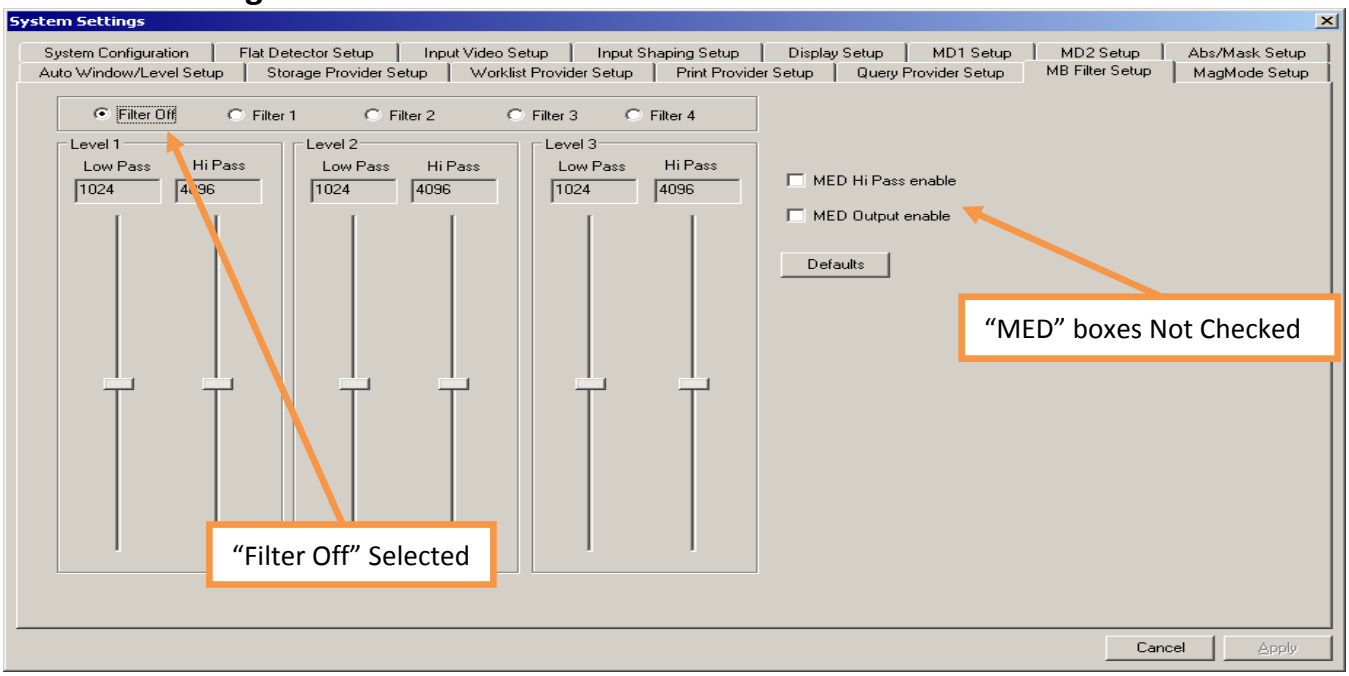
System Configuration Settings Tab



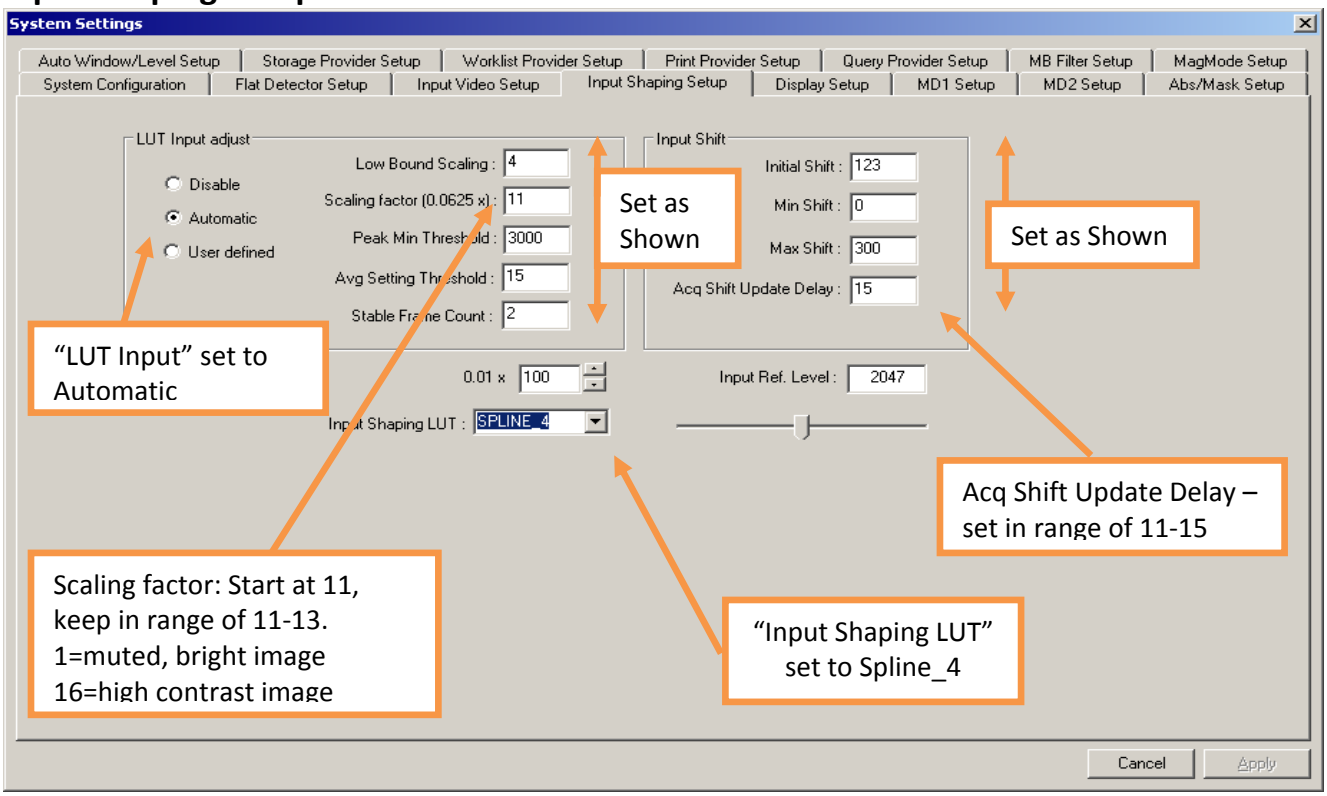
Display Setup Tab



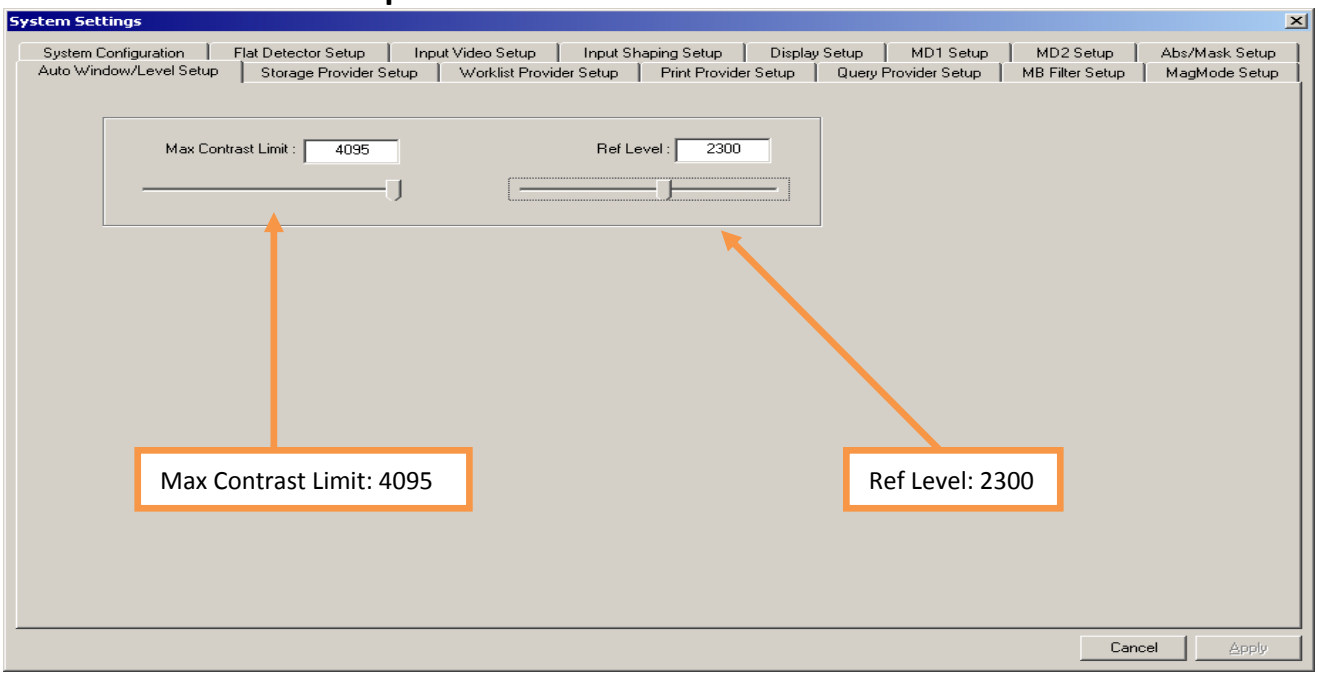
MB Filter Settings



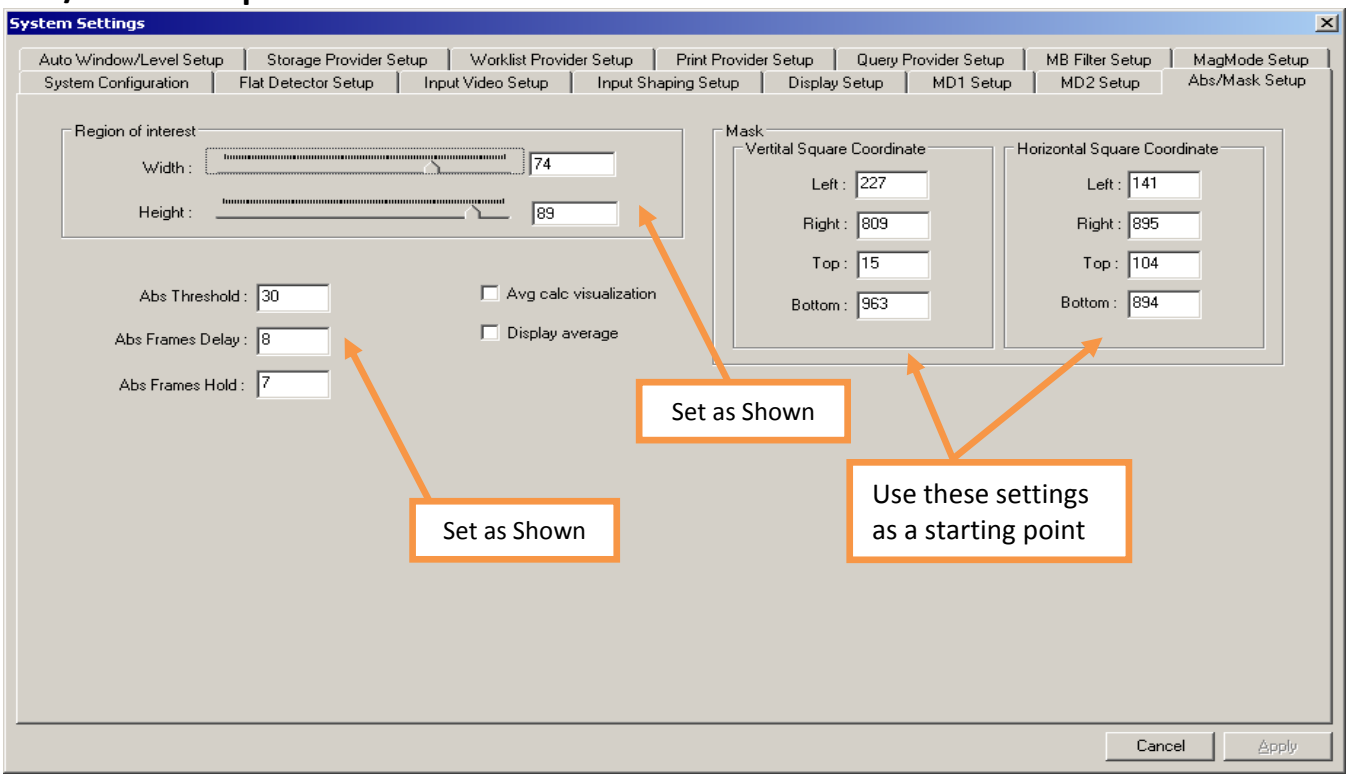
Input Shaping Setup Tab



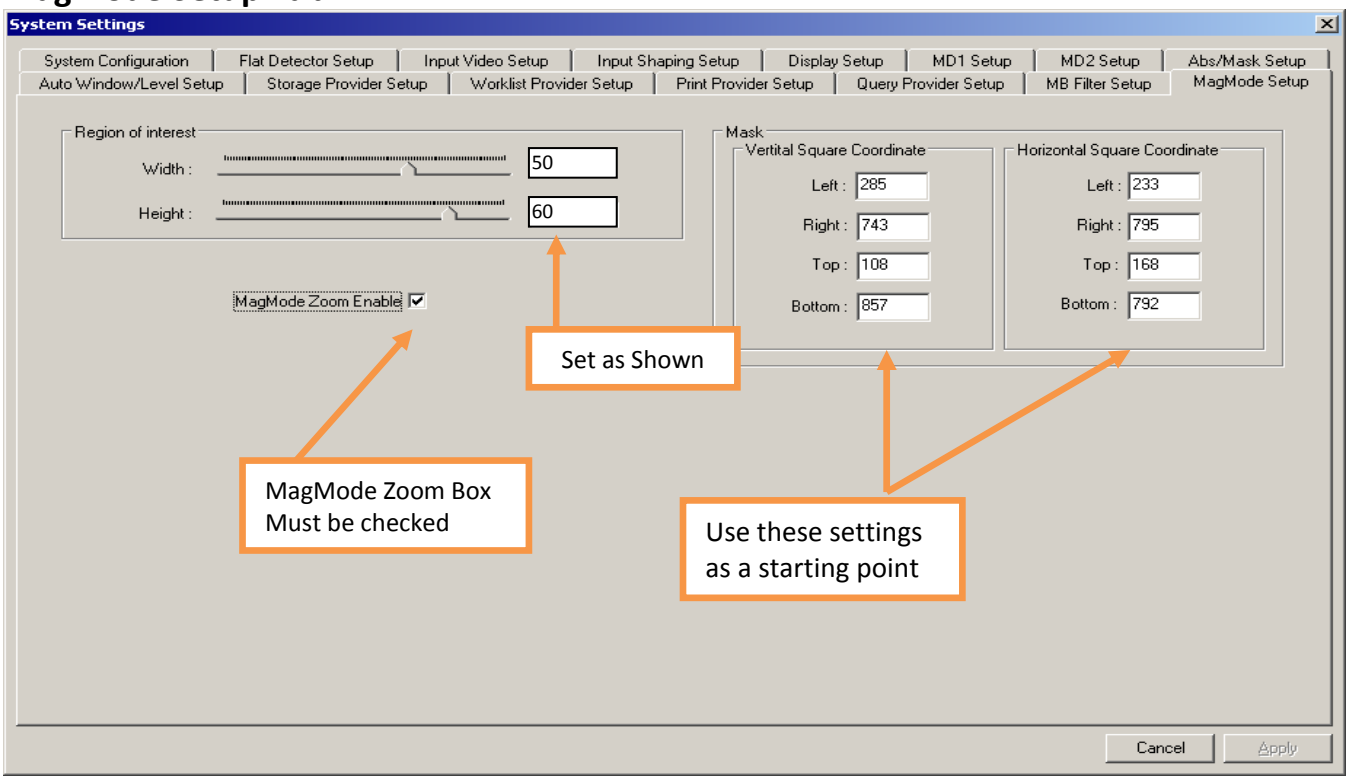
Auto Window Level Setup Tab



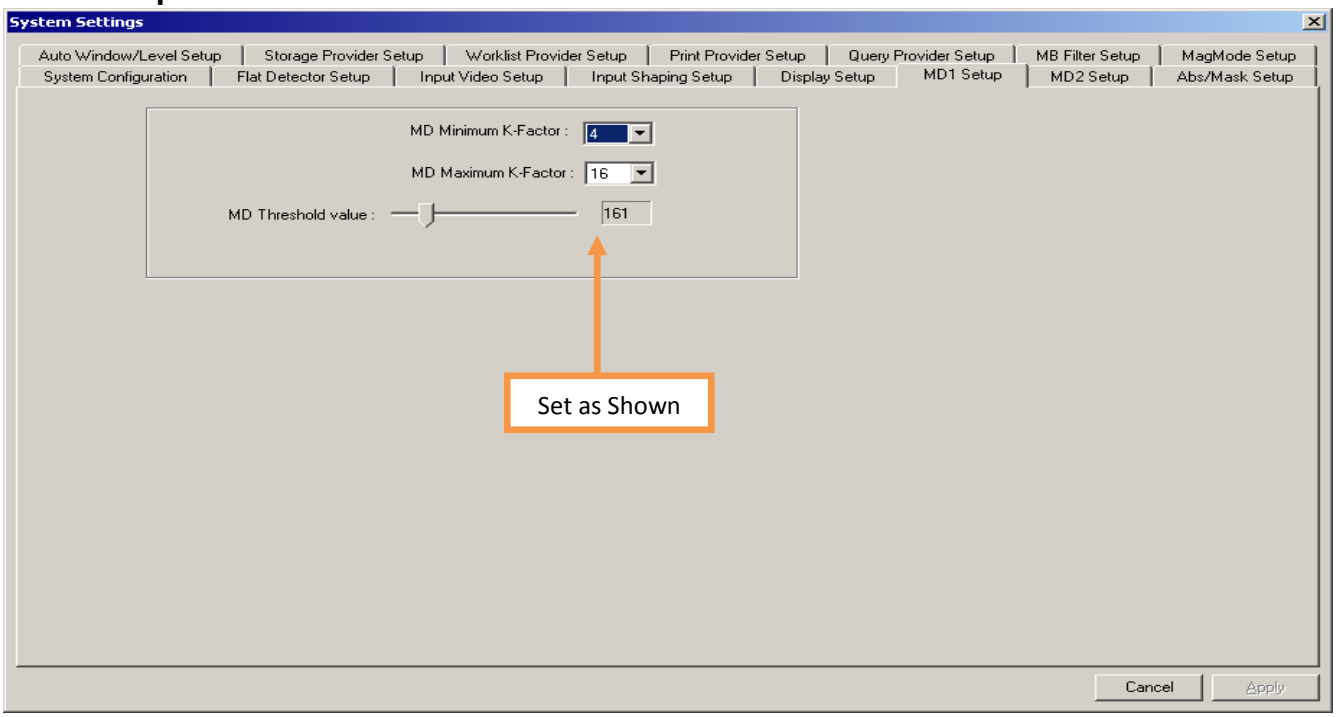
ABS/Mask Setup Tab



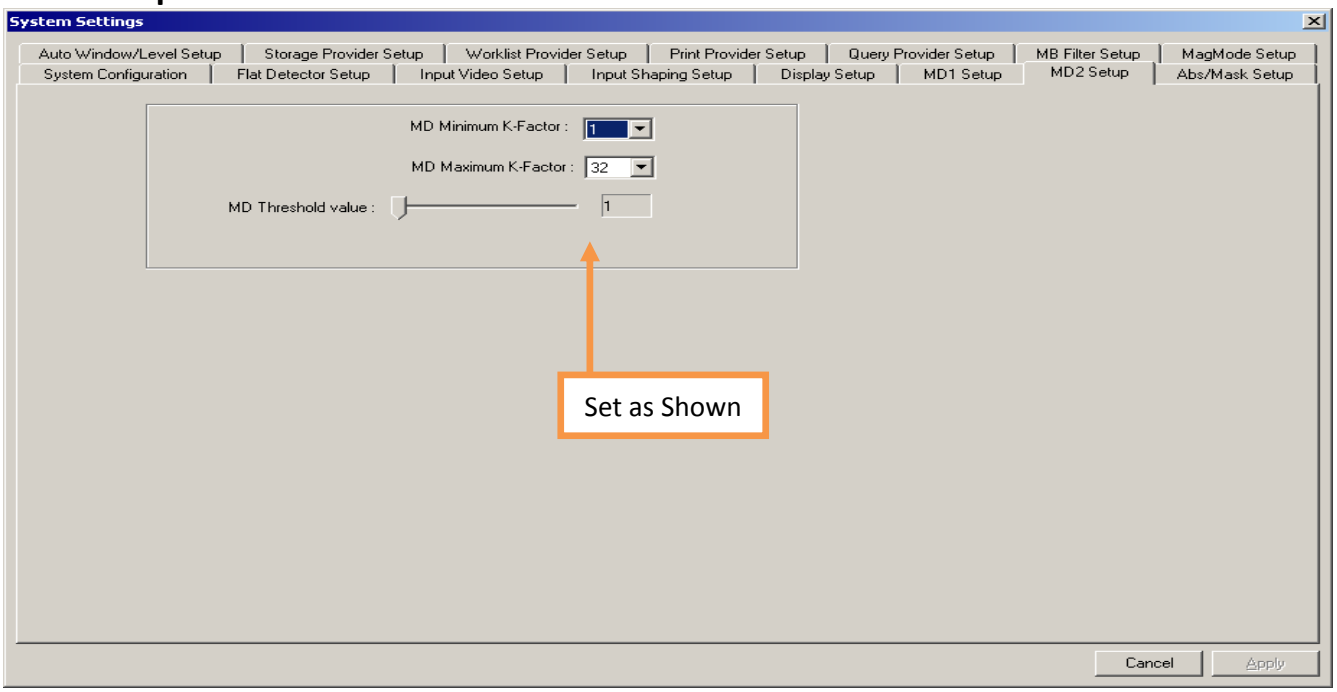
MagMode Setup Tab



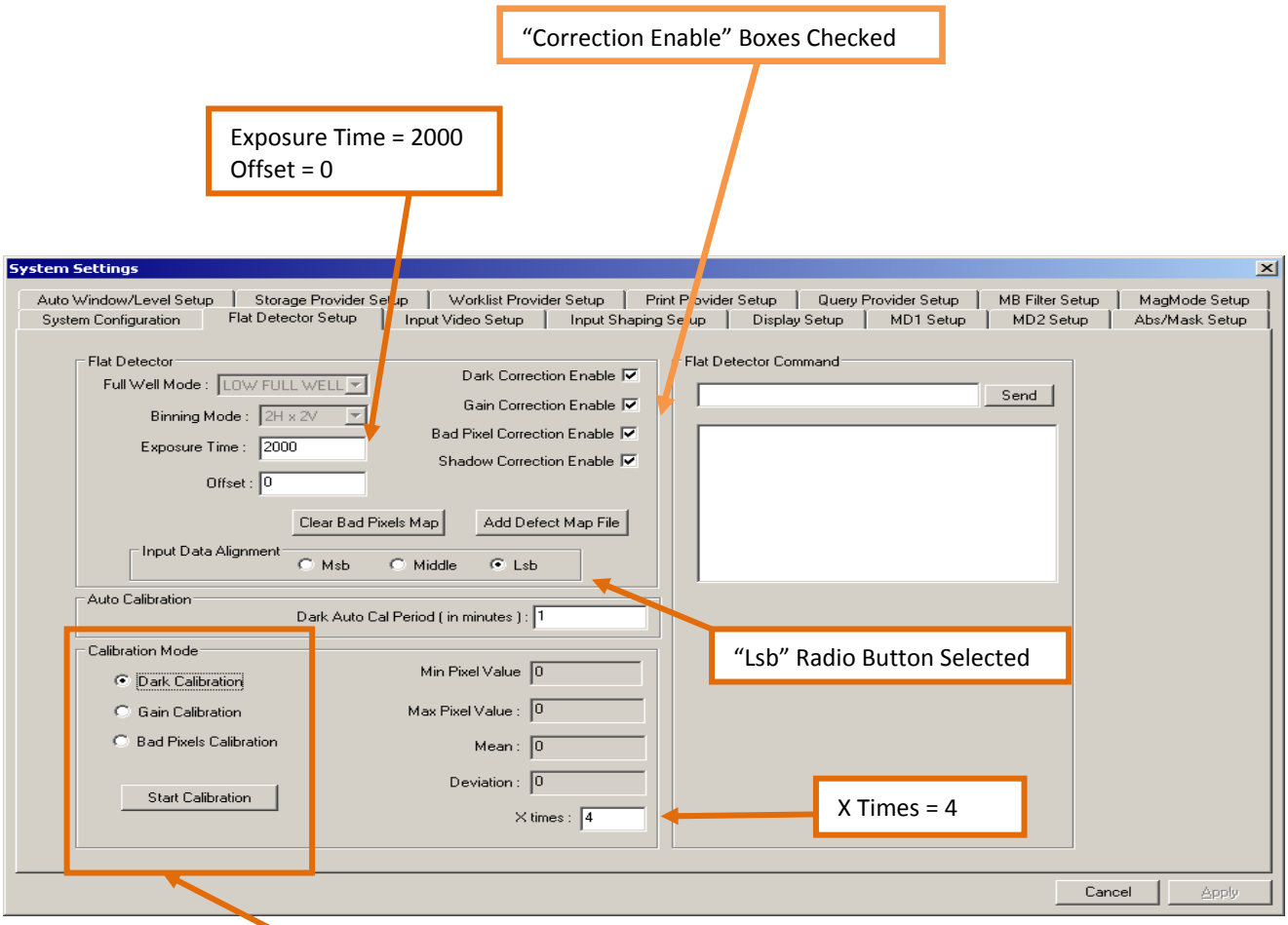
MD1 Setup Tab



MD2 Setup Tab



Flat Detector Setup Tab

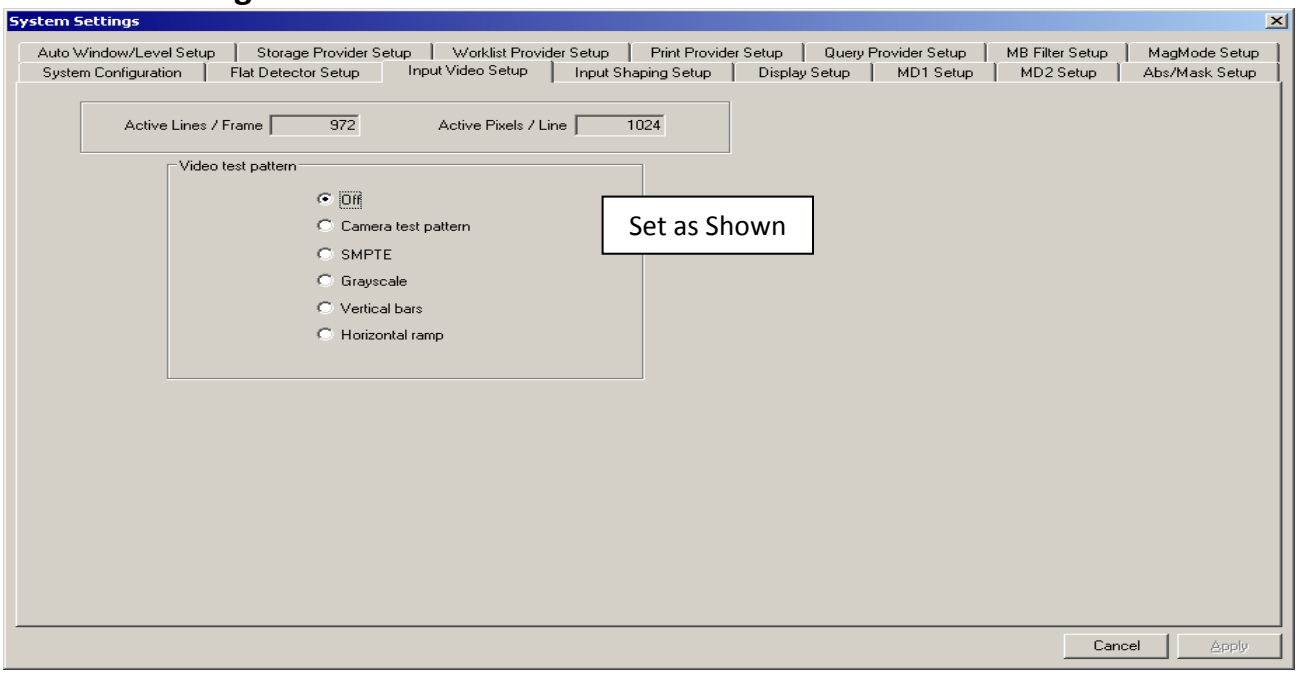


Calibrations:

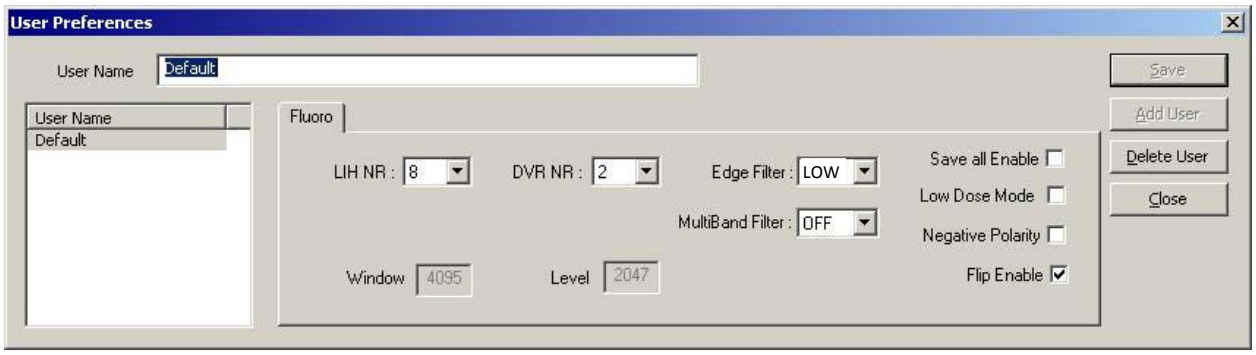
Ensure no objects are in the detector field of view!

1) Manually set the kV to 60 kV. (Manual mode)
2) Take a blank image.
3) Click "clear bad pixel map"
4) Click "add defect map"
5) Select "Dark Calibration" then click "Start Calibration". This happens quickly and will not appear to do anything.
6) Select "Gain Calibration". Click "Start Calibration" and hold down the fluoro switch until "Calibration Complete" appears.
7) Select "Bad Pixel Calibration". Click "Start Calibration" and hold down the fluoro switch until "Calibration Complete" appears.
8) Set the unit back to Automatic Mode (Esc)
9) You may repeat steps 5-7 until desired image quality is achieved.

Input Video Settings Tab



User Preferences



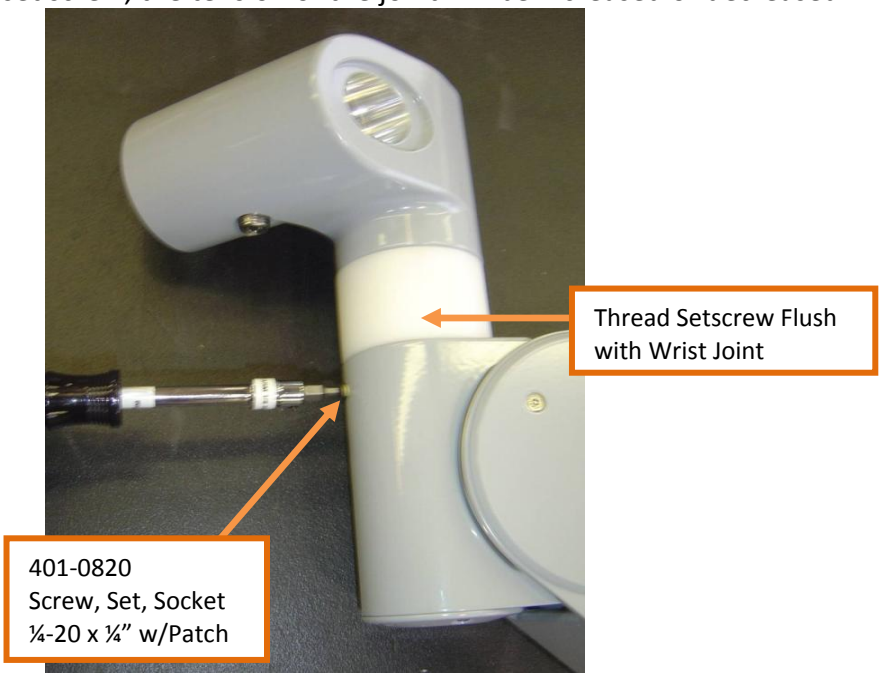
1. Close all windows, and Right Click next to the mouse pad, and select “User Preferences”.
2. Click on the drop down arrow at the “Edge” location, and select “Low”.
3. Click on the drop down arrow at the “MultiB and Filter” location, and select “Off”.
4. Click on the drop down arrow at the “LIH NR” location, and select “8”.
5. Click on the drop down arrow at the “DVR NR” location, and select “2”.
6. Verify the “Flip Enable” is checked.

3.2.9 Flex arm tension adjustments

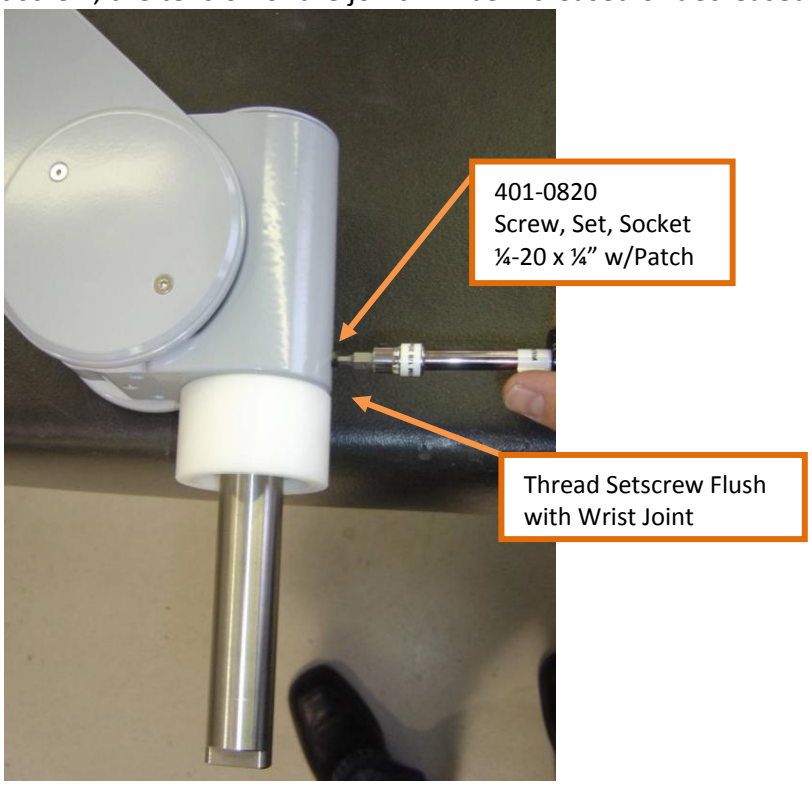
Tools:
(1) 1/8” Allen Wrench
(1) 1/4” Allen Wrench

By adjusting this set screw, the tension on the joint will be increased or decreased

By adjusting this set screw, the tension of the joint will be increased or decreased.



By adjusting this set screw, the tension of the joint will be increased or decreased



4 SYSTEM SET-UP

4.1 DICOM Setup

DICOM setup is performed through the “system configuration” menu. To access this menu, right-click anywhere on the screen, and select the “system configuration” option. A password is required to access this menu – OrthoScan can supply this upon request. Enter this password into the password dialog box (refer to figure 8.1) and press return on the keyboard.

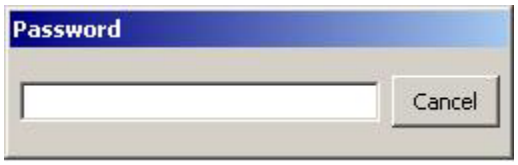


Figure 8.1: Password dialog

Once the password has been accepted, the system settings dialog box will appear (see figure 8.2).

Modality Setup

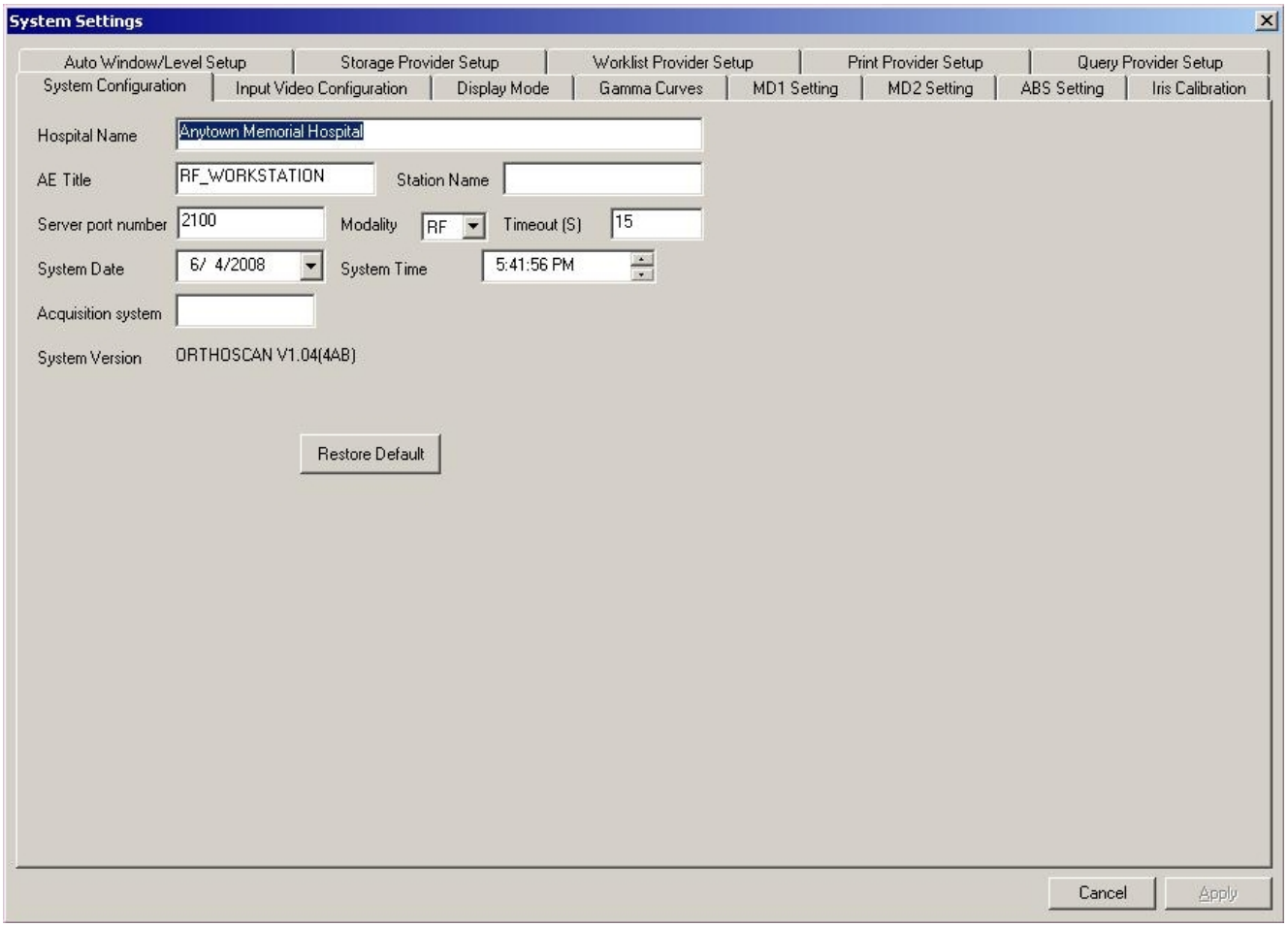


Figure 8.2: system settings dialog box

The “hospital name” field corresponds to the Institution Name (0008,0080) tag in the DICOM header field.
The “AE title” is the AE title assigned to the OrthoScan mini c-arm.
The “Station Name” field corresponds to the Station Name (0008,1010) tag in the DICOM header field

The “Modality” field corresponds to the Modality (0008,0060) tag in the DICOM header field.
After making changes, click the Apply button at the bottom left to save the changes.

Storage Provider Setup

Click the storage provider setup tab.

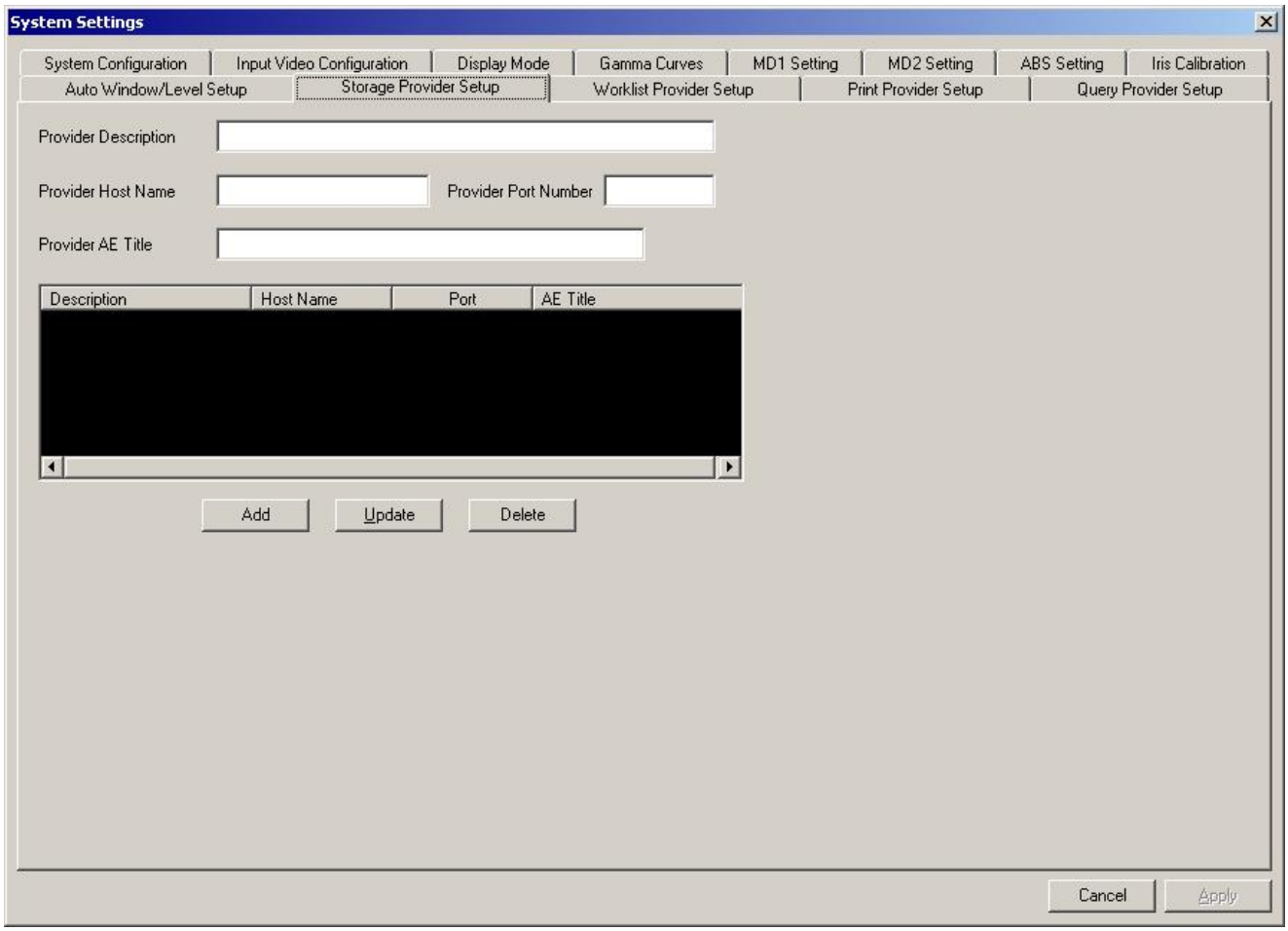


Figure 8.3: storage provider setup tab

“Provider Description” is a descriptive name for the server, e.g. “Anytown PACS Server”.
“Provider Hostname” is either the hostname or IP address of the storage commitment provider. Note: entering a hostname will only work if DNS has been configured on the c-arm.
“Provider Port Number” is the port number used on the storage commitment provider.
“Provider AE Title” is the AE title of the storage commitment provider.

After entering the data into the fields, press the “Add” button to save the data. Multiple storage commitment providers can be setup and stored.

Worklist Provider Setup

Click the storage provider setup tab.

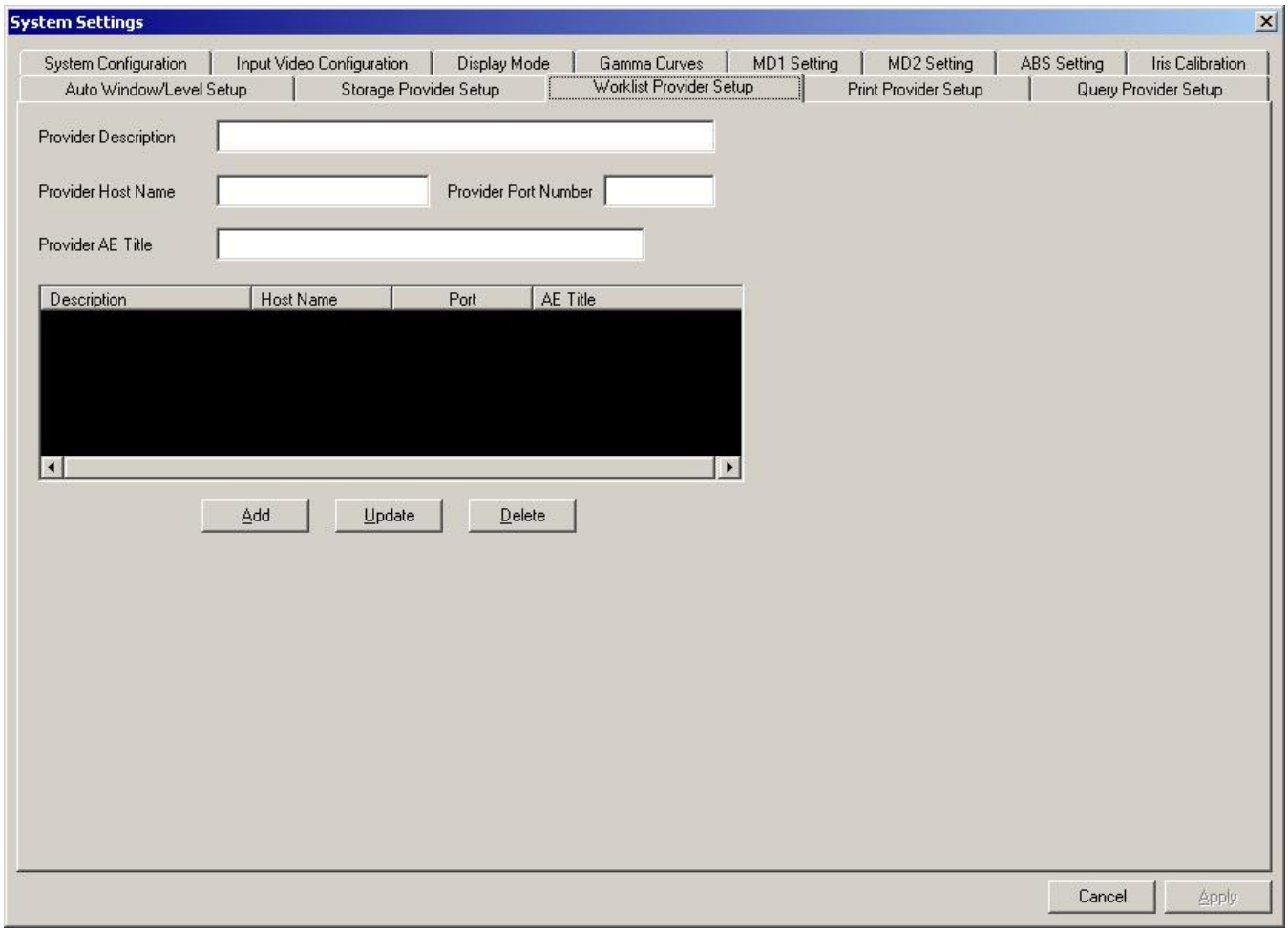


Figure 8.4: storage provider setup tab

"Provider Description" is a descriptive name for the worklist server, e.g. "Anytown Worklist Provider".
"Provider Hostname" is either the hostname or IP address of the worklist provider. Note: entering a hostname will only work if DNS has been configured on the c-arm.
"Provider Port Number" is the port number used on the worklist provider.
"Provider AE Title" is the AE title of the worklist provider.

After entering the data into the fields, press the "Add" button to save the data. Multiple worklist providers can be setup and stored.

DICOM Print Provider Setup

Click the storage provider setup tab.

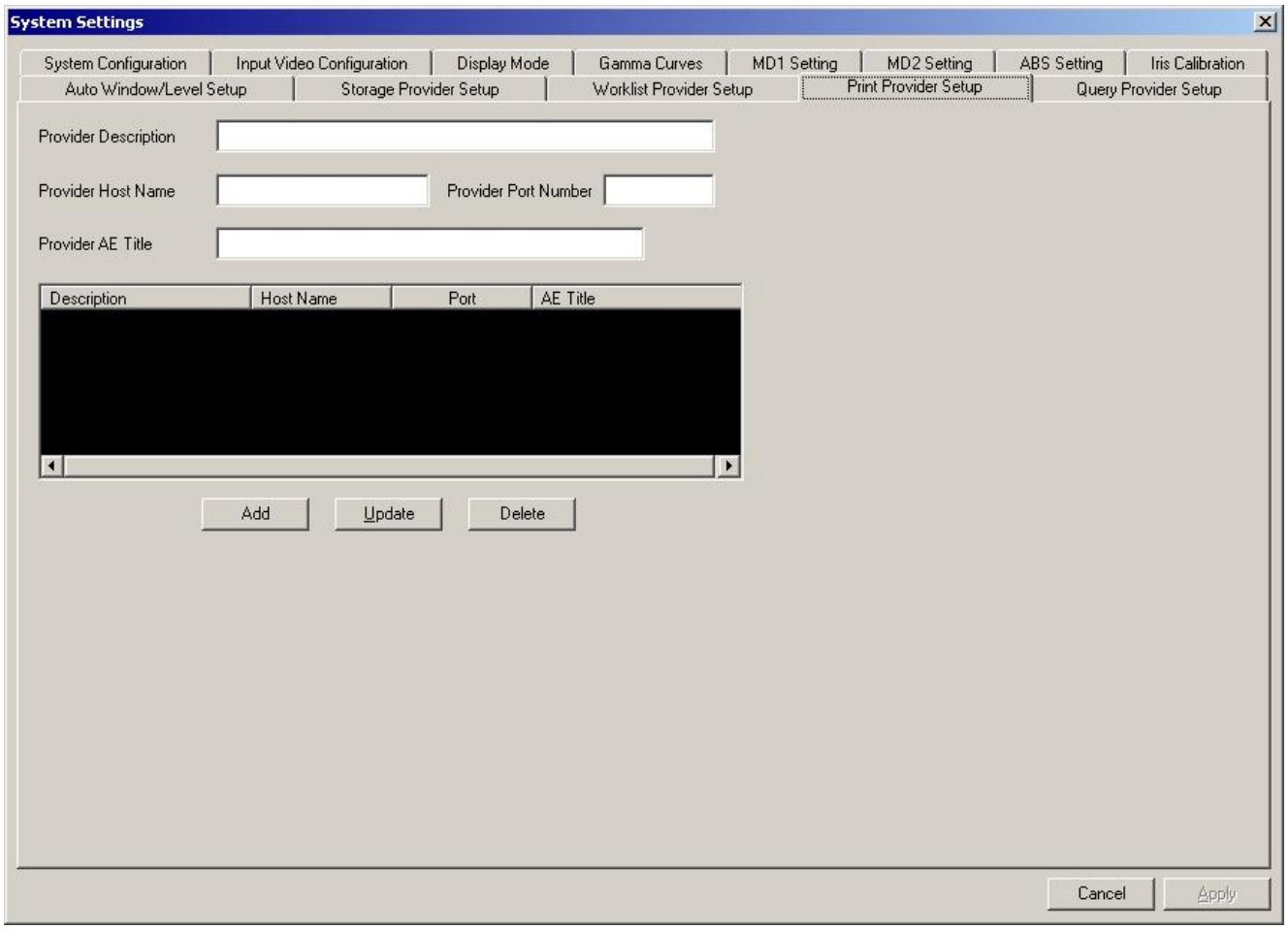


Figure 8.5: print provider setup tab

"Provider Description" is a descriptive name for the print service provider, e.g. "Anytown Blue Film Printer".
"Provider Hostname" is either the hostname or IP address of the print service provider. Note: entering a hostname will only work if DNS has been configured on the c-arm.
"Provider Port Number" is the port number used on the print service provider.
"Provider AE Title" is the AE title of the print service provider.

After entering the data into the fields, press the "Add" button to save the data. Multiple print service providers can be setup and stored.

5.1 Appendix A

Image Calibration

Purpose

This document describes how to correctly and safely perform an alignment and adjustment of the Collimator on an assembled OrthoScan HD–Flat Detector. It is important that you read through this entire document to be familiar with the procedure, equipment and safety precautions before proceeding.

Scope

Only trained and authorized personnel shall perform the following procedure of Image Calibration. All OrthoScan HD–Flat Detector must undergo this process.

Related Documents

010-0108 Image calibration Worksheet

Authorities and Responsibilities

Only trained authorized personnel shall perform the following alignment and adjustments procedures. A radiation detection badge shall always be worn throughout this procedure. Proper radiation protective garments may also be worn when needed.

Definitions

There are various symbols used throughout this document to indicate important steps in the procedure. Table 1.3 defines these symbols and describes their meaning.

Symbol	Description
	This symbol indicates that safety equipment or clothing is required for this step.
	Radiation hazard.
	Electrical hazard.

Table 1.3: Symbol Definitions

5.2 Procedure

Safety

The calibration and testing involves many significant dangers. However, by following these safety precautions, wearing the correct safety clothing and using the correct safety equipment, you can significantly reduce the risk to yourself.

The main dangers you will face are:

- high voltages
- exposure to lead
- radiation exposure
- dangers associated with using tools

Before proceeding with any part of the procedures, take the time to familiarize yourself with the steps involved, and make yourself aware of any potential hazards.

When working with high voltage (anything above 50v), always ensure that you have informed the people working around you. Ensure they are aware of what to do in case of an emergency. This is for your safety and theirs – you benefit from having someone available should something go wrong, and they benefit by making sure that they keep a safe distance from what you are working on.

Lead is a poisonous material, and oral ingestion can cause long-term mental health effects. Therefore, always wear latex gloves when working with lead, and wash your hands when you are finished. Always clean tools and equipment, and the surface you were working on, after you finish working with lead. Never put your hands near your mouth until you have washed your hands.

Radiation exposure may not be eminent the moment of exposure but can cause many health effects. Before continuing, please be aware of your surroundings. Ensure that you maintain a safe distance from others that may be passing to avoid exposure. A radiation badge should always be worn when performing x-ray calibration procedures.

Before using any tool or equipment, make sure you are aware of how to use them correctly and safely.

The following safety equipment and clothing should always be available in the near vicinity.

- latex gloves
- lead apron
- safety glasses

In addition to this, you should always wear a radiation exposure tracking badge while working with radiation.

If you are ever in doubt about how to proceed, or unsure about what safety precautions to take, ask a supervisor or colleague. Never sacrifice the safety of yourself or those around you.

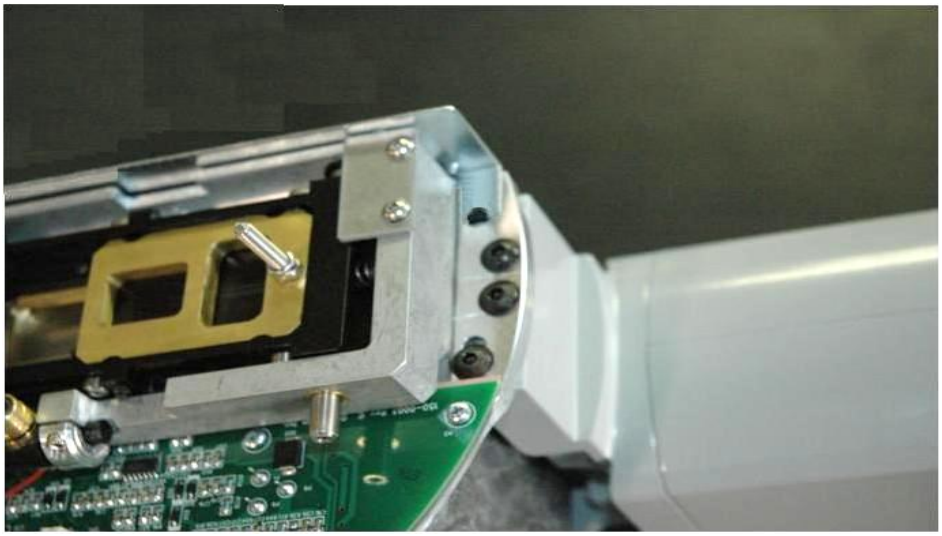
5.3 Preparation of Collimator

Objective:
To properly align Collimator in image field of view

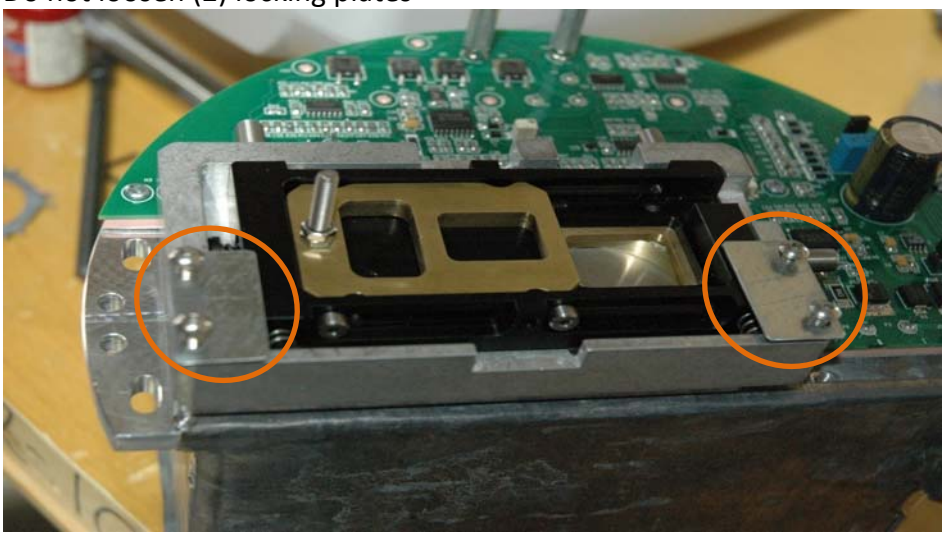
Parts:
1. Qty: 1 OrthoScan C-Arm ready for Image Calibration

Tools:
1. 5/64” Allen Key
2. 7/64” Allen Key

Procedure:
1. Rotate the C-arm so that the HVPS is at the bottom with the collimator upside down.



Do not loosen (2) locking plates



5.4 Collimator Alignment

Objective:

To properly and correctly perform the Collimator Alignment.

Parts:

1. Qty: 1 OrthoScan C-Arm ready for Collimator Alignment

Tools:

1. 5/64” Allen Key
2. 7/64” Allen

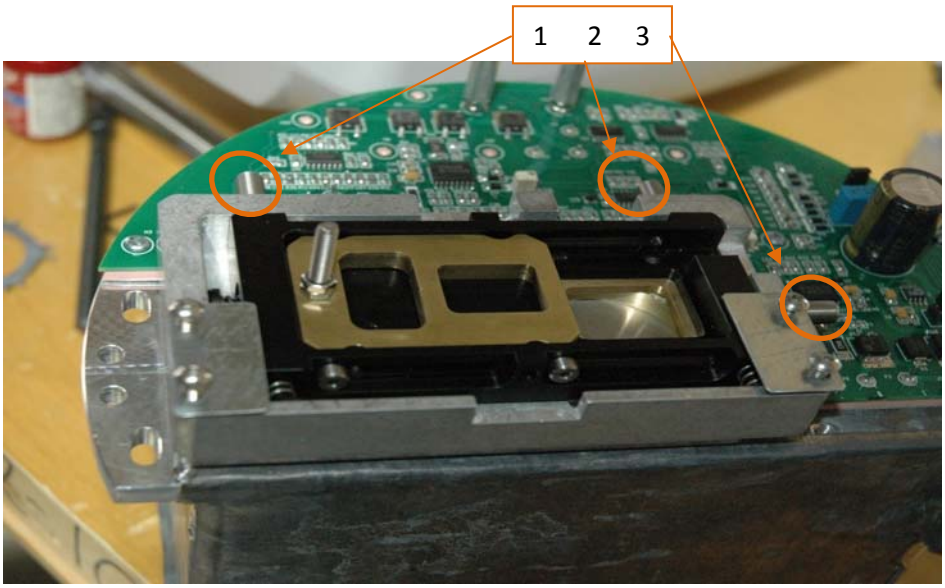


Fig 2-2-3

Procedure:

1. Turn C-Arm unit ON by pressing the momentary green switch once. Wait for system to boot up and the OrthoScan Screen displayed. **Note: Keep all metal tools away from the HVPS Control CCA and cables.**
2. Before taking an image the following should always be observed of the Collimator Assembly:
   - The locking screw indicated by a circle in Figure 2.2-3 should always be snug and not too tight to allow movement of the Intermediate Collimator.
   - Collimator Clamps are snug against the Intermediate Collimator.
   - All set screws indicated by rectangles in Figure 2.2-3 should always be snug and resting against the Intermediate Collimator sidewalls.
   - Collimator Slide is locked in its position, engaging the ball plungers in either Normal or or Mag mode.

3. Take an image by momentarily pressing the foot switch.
4. Using the image displayed on screen determine what adjustment is needed to eliminate any black sections of the image.
5. Turn Unit OFF by pressing green monetary switch once. **Note: Do not attempt to adjust set screws while machine is powered ON.**
6. Adjust the Intermediate Collimator by loosening and/or tightening the set screws and locking screw. Simple adjustment steps are explained in Table 2.3.

Table 2.3: Basic Adjustments

7. Turn Unit back ON.
8. Repeat step 3.If required repeat steps 4 – 5 until the image displayed has no black sections or is within specification limits.

9. While imaging, rotate the image using the Image Rotate Keys and ensure that all frames are free of black sections. If necessary repeat steps 3-6.
10. Rotate C-arm back to its original position with flat detector at the bottom and HVPS at the top.
11. Repeat step 3. If necessary steps 4 -7 may need to be repeated.
12. Repeat steps 3-12 in Mag mode with the slide moved forward.
13. Once all black sections are eliminated or are within specification limits in both Normal and Mag mode, ensure all screws are fully tightened.

14. While imaging, ensure all rotation angles are free of black sections. Further adjusting may be needed, as tightening all screws may tweak the position of the Intermediate Collimator slightly.
15. Turn unit off.

Unit has completed the Collimation procedure

6 SYSTEM QC DOCUMENTATION

6.1 Radiation QC Document (060-0001)

Machine Serial Number: _____

Detector Test Equip ID_____ **Cal Due Date**_____

Base Test Equip ID_____ **Cal Due Date: NA**

Non-Boost Maximum EER & Half Value Layer

Indicated kV	Observed kV	Acceptable Range (kV)	Observed mR/s	Maximum Range (mR/s)
75		69.8 – 78.8		83.3 mR/s

Half value layer in mmAl:

Minimum allowable =0.0444 x (observed KV above) – 0.6556 = _____

Recorded HVL = _____ Results: PASS / FAIL (circle one)

NOTE: This value must be ≥ the minimum limit calculated above.

Range Testing

Use the manual kV/µA buttons to select the indicated kV steps and record the observed kV and mR/s values in the table below.

Indicated kV	Non-Boost Observed kV	Boost Observed kV	Acceptable Range (kV)	Non-Boost Observed mR/s	Boost Observed mR/s	Acceptable Range (mR/s)
56			52.0 - 59.9			1.4 – 1.9
66			61.4 - 70.6			2.5 – 3.4
75			69.8 - 78.8			3.7 – 5.1
78			72.5 – 80.0			6.1 – 8.8

Repeatability

Use the manual kV/µA buttons to select the 66kV step. Make 4 successive exposures and record the observed kV values in the table below.

Mode	Exposure 1	Exposure 2	Exposure 3	Exposure 4	Acceptable Range (kV)
Non-Boost					61.4 – 70.6
Boost					61.4 – 70.6

Leakage and Scatter

Survey Meter Test Equip ID_____ **Cal Due Date**_____

Tube leakage at 1m _____mR/hr. Maximum 10mR/hr

Scatter at 1m _____mR/hr. Maximum 10mR/hr

Unit Passed: _____ **Tested By:** _____

Date _____/_____/_____ Time _____:_____

6.2 Radiation QC Procedure

Purpose

This document describes how to perform the window level calibration & radiation QC test.

Symbols

Table 1.0 defines these symbols and describes their meaning.

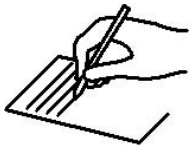
Symbol	Description
	This symbol shows that something needs to be recorded on the datasheet.
	Radiation hazard.

Table 1.0: Symbol Definitions

Reference Documents

Radiation QC Test Form: 060-0001

Hazards, Safety and Safety Equipment

During this procedure a dosimeter badge shall be worn. In addition, safety clothing is optional such as a lead apron may be worn for additional protection.

Prior to performing the tests, ensure that all test equipment has been calibrated.

Radiation QC Document 060-0001 (datasheet)

The datasheet is used to record data collected during this operation, including test results, test instruments used and calibration information regarding the test instrumentation.

Where a change may be required to a previous recorded entry, score out (single line) the original information, write the new information beside it. Initial and date the change.

Where a failure occurs and a repair is performed after the start of testing, repeat the test and record the second data on a new datasheet. Record the repair on the Defect Record and attach as permanent record in the DHR. Do not discard the old datasheet, but retain it with the DHR.

Test Equipment

Verify all instrumentation and test equipment used to perform the following operation is calibrated and record the testing device and calibration information on the radiation test document (060-0001).

You will need the following test equipment items:

Operation	Manufacturer	Model	Description
Radiation QC Test	Unfors	Xi (or equivalent)	Multifunction X-ray meter
Radiation QC Test	Unfors	NA	Unfors Test fixture (P0042)
Scatter/ Leakage	Fluke	451B-RYR (or equivalent)	Ion Chamber Survey Meter
Scatter/ Leakage	Various	NA	Tape measure or meter stick
Window Level Calibration	Various	NA	Large Phantom (P0078)

Table 2.0: Required Test Equipment

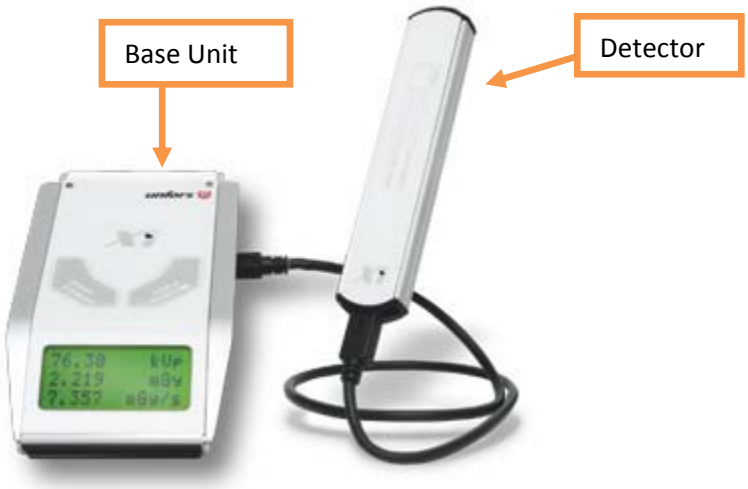


Figure 3.1: Unfors Xi Multifunction X-ray Meter

1. **Non-Boost Maximum Entrance Exposure Rate (EER) and Minimum Half Value Layer (Test Table #1)**

   a. Verify test equipment is within calibration due date.
   b. Affix the UNFORS test wand to centered location at the source window (tube enclosure) to intercept the center of the beam of the Entrance AKR. Refer to Figure 3.2.
   c. Connect the Detector to the Base unit via the cable in the Unfors Kit.
   d. Set the Base Unit on a stable surface a sufficient distance from the source but close enough for the cable to reach the Unfors Test Fixture.

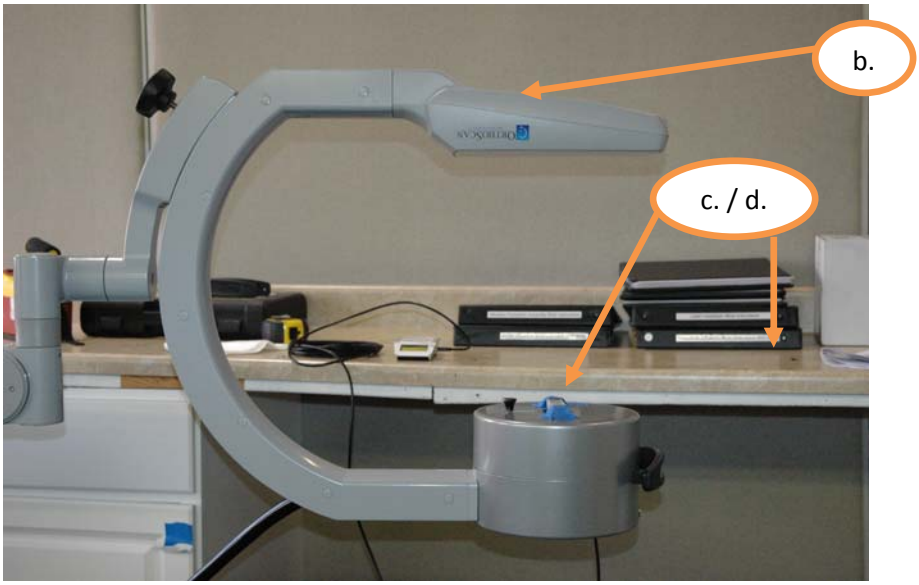


Figure 3.2

Note: Ensure when placing the Detector in the test fixture that you do not pull the Base Unit.

   e. Attach the Power Cord to the unit under test and to a power outlet.
   f. Attach the footswitch and turn the unit ON.
   g. Set the collimator to Normal" mode.
   h. Turn on Unfors Base Unit with setting on R/F High. Wait for Unfors Meter to zero adjust.
   i. Using the manual kV/µA buttons set kV to 75kV.
   j. Display image by momentarily pressing the footswitch (~11 seconds).
   k. Record observed kV & mR/s on Radiation QC Document (P/N: 060-0001).
   l. Perform calculation: 0.0444 x (observed kV value) – 0.6556. This is the minimum allowable HVL in mm Al.
   m. Record the calculated minimum allowable HVL value & observed HVL on the Radiation QC Document (P/N: 060-0001).
   n. Refer to Test Table 1 Select Pass or Fail.

Specifications Table:

Test Table 1

Indicated kV	Acceptable Range (kV)	Max. Acceptable Limit (mR/s)
75	69.8 – 78.8	83.3 mR/s

2. Acceptable Range of Observed kV values and mR/s (Test Table #2)

a. Utilize the same UNFORS equipment as recorded in section 2.
b. Center the wand into position on the image intensifier or flat detector as appropriate. Refer to figure 3.3 for the set up of flat detector-based (FD) systems.
c. Turn on Unfors Base Unit with setting on R/F Low and wait for Unfors Meter to zero adjust.

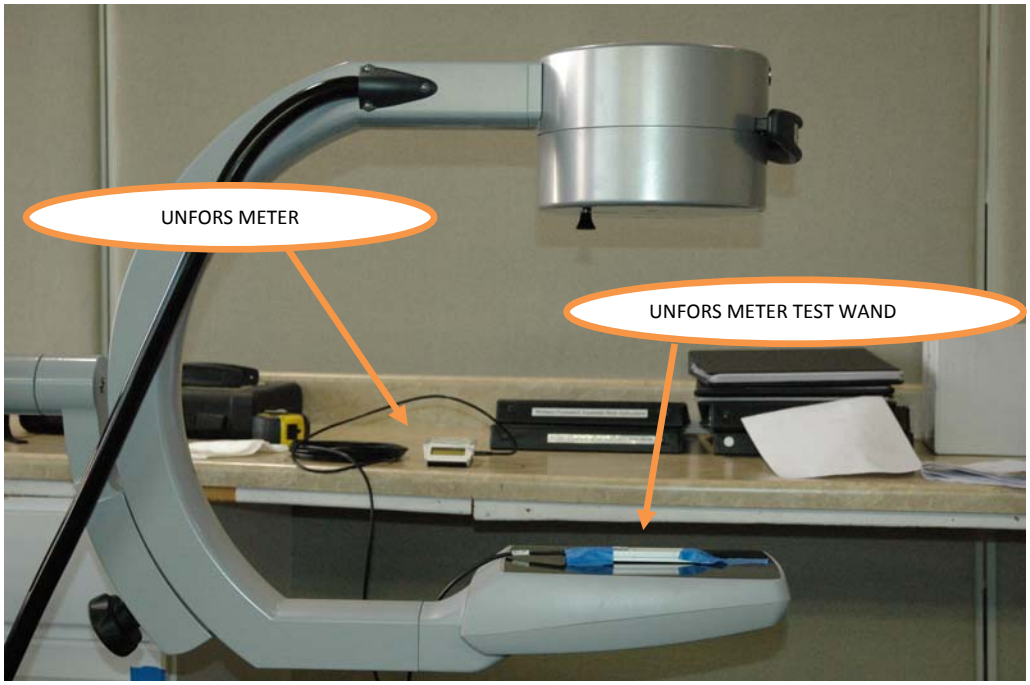


Figure 3.3

d. In non-boost mode, using the manual kV/µA buttons set kV to 56kV.
e. Display image by momentarily pressing the footswitch (~11 seconds).
f. Verify the kV reading stays within the acceptable range in Test Table 2 of the targeted kV.
g. Release the footswitch and wait for the Unfors Meter to calculate the average, which shall appear on the screen after it zero adjust.
h. Record the displayed value of kV and mR/s on the Radiation QC Document (P/N: 060-0001).
i. Repeat steps c, d and e for each value indicated in the specifications table.
j. Verify repeatability: Using the manual kV/µA buttons, set kV to 66kV.
k. Repeat steps f, g, & h for four consecutive exposures.
l. Activate Boost Mode and repeat steps e, f, g, h and i.
m. If displayed values remain within the acceptable ranges provided, the unit passes.
n. If any displayed value falls outside the kV acceptable range, remove the centering fixture and place the UNFORS wand directly on the imaging assembly fiber window (centered). Repeat steps e, f, g, h and i.
o. If displayed values remain within the acceptable ranges provided, the unit passes.
p. If any displayed value falls outside the kV acceptable range, reject the unit per the nonconforming material procedure.
q. Turn the Unfors Base Unit OFF and remove the Detector and Unfors Test Fixture from unit.
r. Return Unfors Kit to case.

Specifications Table:

Test Table 2

Indicated kV	Acceptable Range (kV)	Acceptable Range (mR/s)
56	52.0 – 59.9	1.4 – 1.9
66	61.4 – 70.6	2.5 – 3.4
75	69.8 – 78.8	3.7 – 5.1
78 (Boost Mode)	72.5 – 80.0	6.1 – 8.8

3. Maximum Leakage Value Test

a. Verify test equipment is within calibration due date and record the equipment information on the Radiation QC Document (P/N: 060-0001).
b. Using the manual kV/µA buttons, set kV to 75kV.
c. Turn ON the Fluke Meter 451B-RYR (or equivalent).
d. Measure a distance of one meter (use the 1 meter board or floor markings) from the Source End (center of X-ray focal point).
e. Open shutter of the Fluke Meter. Position meter to be level with x-ray source enclosure & orientate meter as shown in Figure 3.4.
f. Depress footswitch while observing Leakage from the Source until it settles at its peak (~ 30 seconds).
g. Verify the leakage value does not exceed the rejection limit defined in Test Table 3.
h. Record the value in the Leakage section of the Radiation QC Document 060-0001.

Figure 3.4

Test Table 3

Test	Acceptable Range (mR/s)
Tube leakage at 1m	Maximum 10mR/hr
Scatter at 1m	Maximum 10mR/hr

4. Maximum Scatter Value Test

a. Using the same test equipment, set-up and distance as the leakage test, position meter to be level with the Flat Detector. Refer to figure 3.5.

b. Use the technique factor setting of 75kV.

c. Turn ON the Fluke Meter.

d. Depress footswitch while observing Scatter until it settles at its peak.

e. Verify the scatter value does not exceed the rejection limit defined in Test Table 3.

f. Record the value in the scatter section of the Radiation QC Document 060-0001.

Figure 3.5

Test Table 3

Test	Acceptable Range (mR/s)
Tube leakage at 1m	Maximum 10mR/hr
Scatter at 1m	Maximum 10mR/hr