

QA Maintenance and Inspection Vizion DR+ Detector Guide

For safety reasons, be sure to turn OFF the power of each instrument when the performed inspection indicates power to be off. Failing to power off instrument when requested may result in electric shock.

When the instrument is cleaned, be sure to turn OFF the power of each instrument, and unplug the power supply cord from the AC outlet. Never use benzene, thinner or any other flammable cleaning agents, as this may result in fire or electric shock.

The instrument must be repaired by a qualified engineer only. Failure to do so may result may result in fire, electric shock, or accident.

I. Environment of Use and Storage

Do not install the instrument in a location with the conditions listed below. Otherwise, it may result in failure or malfunction, fall or cause fire or injury.

- Close to facilities where water is used.
- Where it will be exposed to direct sunlight.
- Close to air-conditioner or ventilation equipment.
- Close to heat source such as a heater.
- Prone to vibration.
- Insecure place.
- Dusty environment.
- Saline or sulfurous environment.
- High temperature or humidity.

Do not place the storage case or instrument in a location with the conditions listed below.

- Where the cable of the sensor unit will be strongly pulled when the sensor unit is put into the case, otherwise, the cable may be damaged, resulting in fire or electric shock.
- Where someone might get their foot caught in the cable of the sensor unit is put in the case. Otherwise they could trip over, resulting in injury

II. Power Supply

- The instrument's cables are long, do not tangled during use.
- Be careful not to get your feet caught in the cabling.
- Always connect the three-core power cord plug to a grounded AC power outlet.

III. Handling

- Do not spill liquid or chemicals onto the instrument.
- In cases where the patient is injured, do not allow the instrument to become wet with blood or other body fluids, as doing so may result in fire or electric shock. In such situation, protect the instrument with disposable covering as necessary.
- Wipe the CFRP plate of the sensor unit with ethanol or glutaraldehyde solution to disinfect it each time a different patient uses the instrument, in order to prevent infection.

For safety reasons turn off the power of each instrument when not in use.

IV. Maintenance and Inspection

- For safety reasons, be sure to inspect the instrument before using it. In addition, carry out a regular inspection at least once a year.
- The instrument must be repaired by a qualified engineer only. If it is not repaired properly, it may cause fire, electric shock or accident.

V. Maintenance

- Maintenance should be done by service provider
- If the Detector Panel is defective, the detector will be returned as is to the manufacturer for repair
- Clean the equipment with a dry soft cloth, or a soft cloth lightly moistened with mild detergent solution. Do not use any type of solvent, such as benzene
- This equipment and accessories are to be disposed of safely after the life span of them and national regulation must be observed.
- For safety reasons, be sure to inspect the instrument before using it. In addition, carry out a regular inspection at least once a year.
- Arrange the detector and power supply link cable to prevent the damage of the cable's rubber tube. For example, do not press the cable under the legs of the table or the people.

VI. Inspection

In order to ensure that the instrument is used safely and normally, be sure to inspect the instrument before use. If any problem is found during the inspection, take measures indicated. If the problem still cannot be corrected, contact a ViZion DR+ Dealer representative or distributor.

It is recommended that a record of the inspection be kept by making copies of the check lists in this section, or making a separate check list.

For safety reasons, be sure to turn OFF the power of the detector when the following inspections are about to be performed. Otherwise, it may result in electric shock

VII. Daily Inspection

➤ Before Turning ON the Power

	Inspection	Result		
		Date / /	Date / /	Date / /
Cable	Check that cables are not damaged or cover of cables is not torn.	Good/ Bad	Good/ Bad	Good/ Bad
	Check that the plugs and locks of connectors are not loose.	Good/ Bad	Good/ Bad	Good/ Bad
Detector	Check that the cover or parts are not damaged and not loose.	Good/ Bad	Good/ Bad	Good/ Bad

➤ After Turning ON the Power

- Perform the following inspection with the detector power supply.
- Check Power LED after power on

	Inspection	Result		
		Date / /	Date / /	Date / /
General	Check the Power LED			

- Check Link LED when panel is connected to PC and PC is power on

	Inspection	Result		
		Date / /	Date / /	Date / /
General	Check the Link LED			

VIII. Monthly Inspection

Perform the following inspection periodically at least once a month. Contact a VIZION DR+ Dealer representative or distributor if there is any problem.

Phantom Inspection:

1. Visually check the performance of the instrument by performing exposures using a phantom or a resolution chart in 4 corners of the image and in the center of the image. Figure 1
2. Record the maximal distinguishable resolution.
3. If maximal distinguishable resolution is less than 3.4, repeat the calibration.

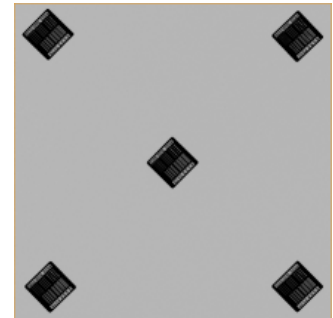


Figure 1

Data	Middle	top of left	top of right	bottom of left	bottom of right
Installation					

Flat field Inspection:

Check the performance of the instrument by performing the following **Flat Field Inspection of ViZion DR+ Instructions** and document the Date and Results.

Date:

Results:

Flat Field Inspection of ViZion DR+ Instructions

1. Flat field inspection should be done on a monthly basis.
2. The flat field image should have pixel values within 10% of the median pixel value.
3. A deviation of more than 10% or visible artifact may denote the need for recalibration.

Consult with a manufacture representative or service technician if pixel values deviate more than 10%.

NOTE: If generator or X-ray tube power deviates from the original flat field KvP, SID or mAs previous pixel values will vary from previous flat field image values.

1. Disable ViZion DR enhancement
 - a. Select *Options* from the acquisition screen. Figure 2
 - b. Select the *Post-Processing* tab from the configuration screen.

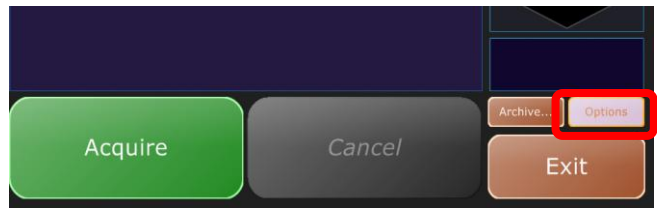


Figure 2

- c. Disable (uncheck)
 - Enable Auto Shutter
 - Enable Enhancement
 - Enable Auto W/L
 - d. Select the *Developer* Tab from the Configuration screen. Figure 4
 - e. Enable (check)
 - Show Pixel Value

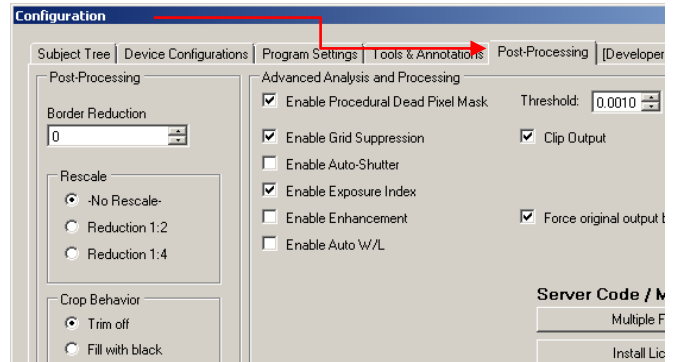


Figure 3

2. Expose Flat Field Images
 - a. 80 kVp, + or - 5 MAS @ 120SID
 - b. 70 kVp, + or - 5 MAS @ 120SID
 - c. 60 kVp, + or - 5 MAS @ 120SID

3. Inspect Pixel Values of Flat field image. Move the mouse pointer over the images to display different pixel values

- a. Mean _____
- b. Median _____
- c. Average _____

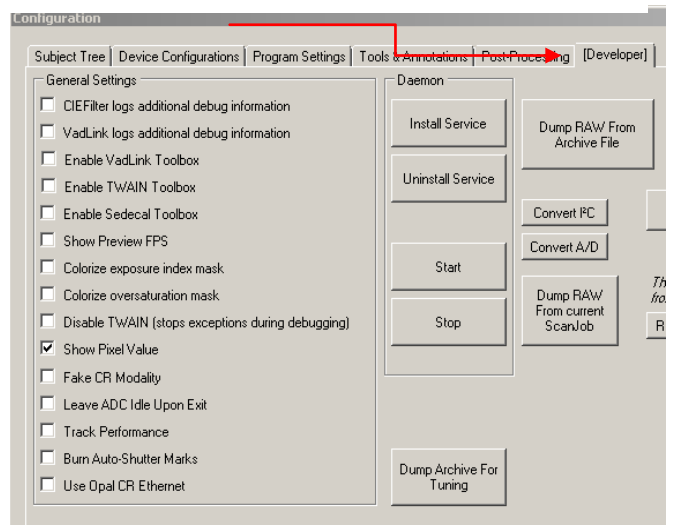
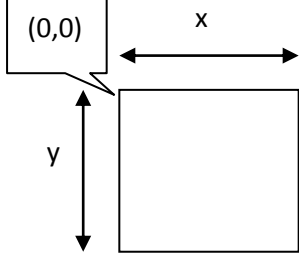


Figure 4

4. Inspect Flat Field Image for visible artifacts (W/W should be 10% of W/L of Flat Field Image)

Description of the artifact(or drawing)	
Artifact Position (drawing+coordinates)	 <p>X: Y:</p>
Artifacts reappear on every image?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If no, does it correspond to particular conditions or does it appear randomly?	<input type="checkbox"/> Particular conditions <input type="checkbox"/> Random
In case of particular conditions, describe these conditions (X-ray conditions, environmental conditions, system operating conditions, ...)	