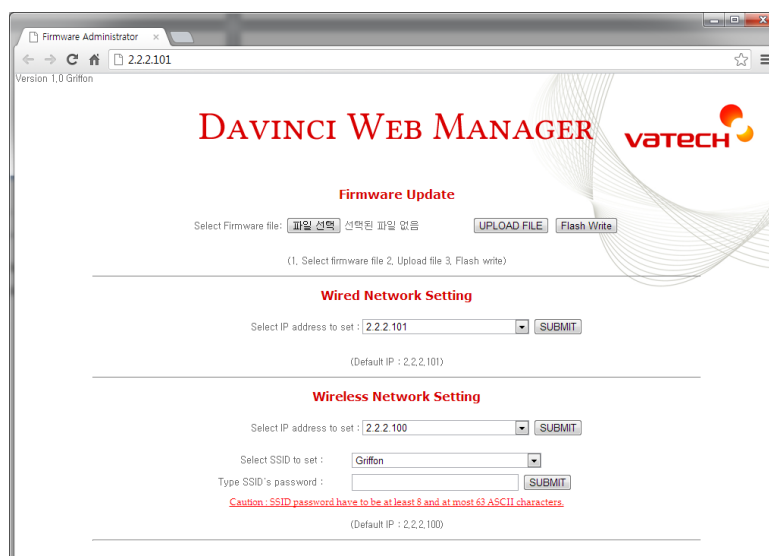


Using Web Manager (IP, SSID Change / Upgrade FW)

Change IP Address of Detector

- A. Turn on Detector and connect to PC
(wired connection is recommended)
- B. After detector boot up, Launch web-browser
(Optimized for Chrome/Internet Explorer)
- C. Connect to “http://[Detector’s IP]“



- D. Select IP address to change from drop-down menu

Wired Network Setting

Select IP address to set

(Default IP : 2,2,2,101)

Wireless Network Setting

Select IP address to set

Select SSID to set :

Type SSID's password :

Caution : SSID password have to be at least 8 and at most 63 ASCII characters.

(Default IP : 2,2,2,100)

- E. Click “SUBMIT”
- F. Restart detector(Turn Off then On)

Change SSID and PSK(Pre-Shared Key)

- A. Turn on Detector and connect to PC
(wired connection is recommended)
- B. After detector boot up, Launch web-browser
(Optimized for Chrome/Internet Explorer)
- C. Connect to “http://[Detector’s IP]”
- D. Select SSID to set
(This value should match to Router’s setting)

Wired Network Setting

Select IP address to set :

(Default IP : 2,2,2,101)

Wireless Network Setting

Select IP address to set :

Select SSID to set :

Type SSID's password :

Caution : SSID password have to be at least 8 and at most 63 ASCII characters.

(Default IP : 2,2,2,100)

- E. Type Pre-Shared Key to set (Password)
(This value should match to Router's setting
Default:project302)

Wired Network Setting

Select IP address to set :

(Default IP : 2,2,2,101)

Wireless Network Setting

Select IP address to set :

Select SSID to set :

Type SSID's password :

Caution : SSID password have to be at least 8 and at most 63 ASCII characters.

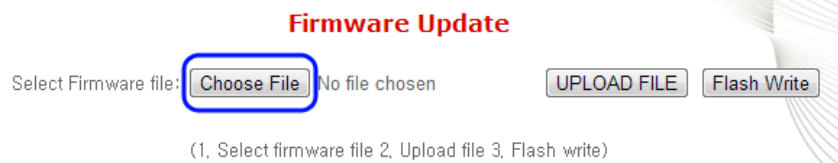
(Default IP : 2,2,2,100)

- F. Click "SUBMIT"
G. Restart detector(Turn Off then On)

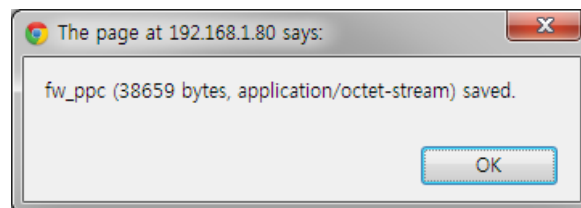
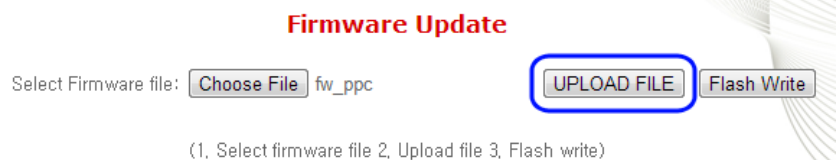
Upgrade Firmware

- A. Turn on Detector and connect to PC
(wired connection is recommended)

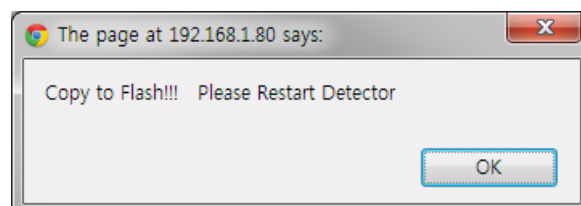
- B. After detector boot up, Launch web-browser
(Optimized for Chrome/Internet Explorer)
- C. Connect to “http://[Detector’s IP]“
- D. Select firmware file by click “Choose File” button.
(Released file is named ‘fw_ppc’)



- E. Click ‘Upload File’ button



- F. Click ‘Flash Write’ button



- G. Restart detector(Turn Off then On)

Calibration



X-ray detector should be used at stable state within driving temperature range. Acquire the X-ray images after power on and 5 minutes warming up to obtain high quality images.

General Principle

Notation

Calibration can be done by image acquisition S/W. The gain-offset correction (under calibration) will be done with one dark, at least one bright and object frame.

Parameter	Description
Offset	Dark image, acquired image without X-ray exposure
Bright	Acquired image with X-ray exposure
Object	Bright image with object, will be calibrated
Gain	Gain of imaging system, offset subtracted image
Offset correction	Offset subtract
Gain correction	Compensate gain variance of pixel



The calibration range of bright is can be select by which exposure level is maximum level that user want to use. If the maximum level of user want to use is '20000' in this case the level is contained in Bright point of '4'(refer 'Table 5 : Median value'). The meaning is you don't have to make bright point for '5' and '6'(In this case, it will be does not working if you get image on higher level than maximum bright point.)

Bright Calibration Point

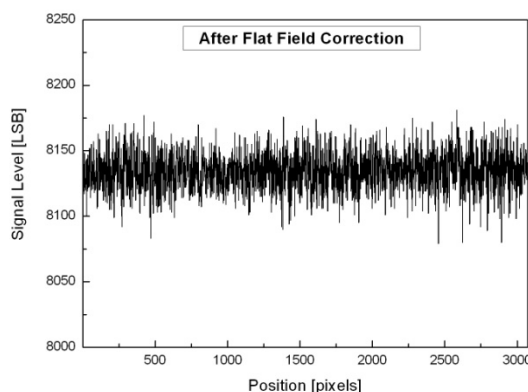
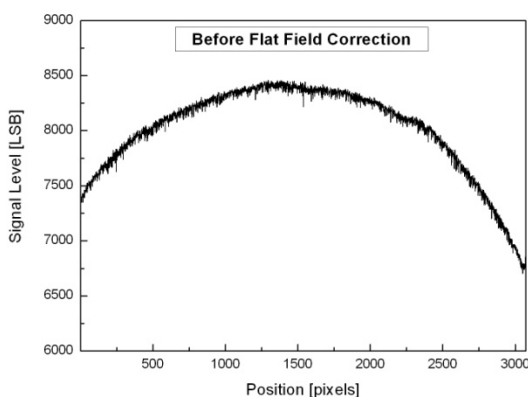
To gain correction, bright frame and dark frame should be acquired. The dark frame is needed only one frame. The bright frame is recommended to be acquired more than 8 different levels of median values of bright frames. The X-ray source condition will be recommended the tube energy level of 70kVp with variable tube current and exposure time. To acquire at least 3 frames at same condition will be recommended. The median values of bright frames are below.

(Additional 21mm Al filter is recommended for calibration)

Point	1	2	3	4	5	6	7	8
Median Value [LSB]	500~1500	4500~5500	9500~10500	14500~15500	19500~20500	24500~25500	29500~30500	34500~35500

The Purpose of Bright Calibration

The center of the non calibrated image is brighter than the edge due to hill effect of X-ray exposure. Generally, the intensity of X-ray flux at center region of exposed area is higher than surroundings due to the X-ray expose like cone shape. A calibration process is used to compensate for this effect. Generally, called it 'Flat Field Correction'(Bright calibration).

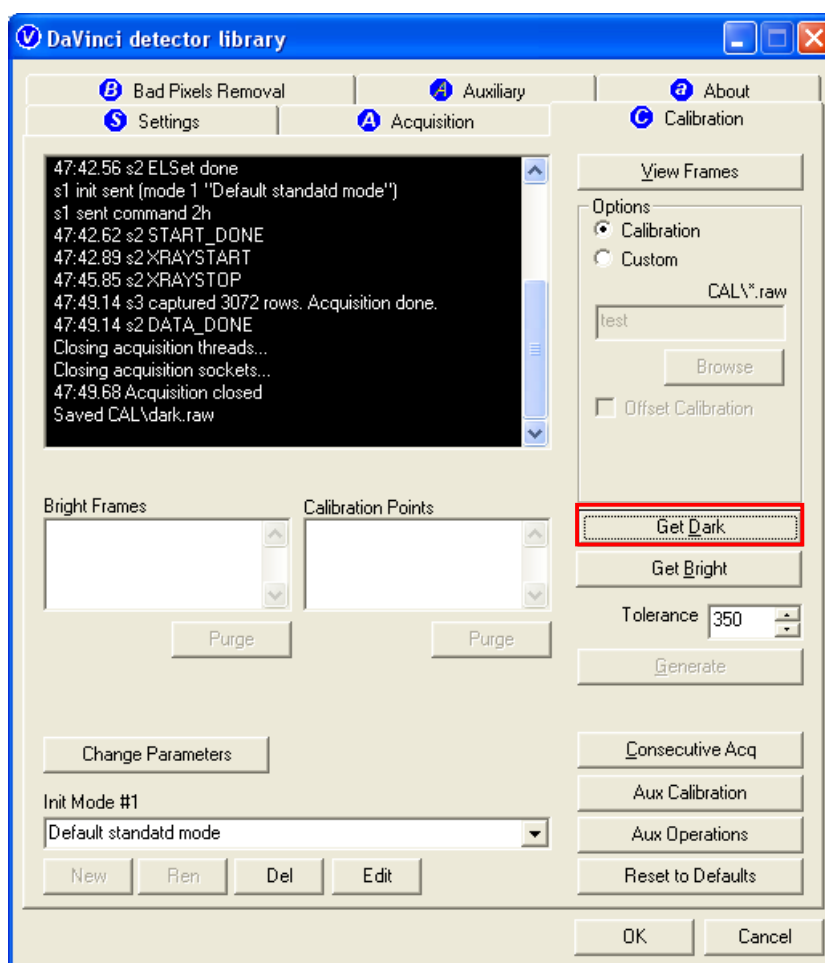


Calibration

Describe the calibration step by step.

1st Step

Move to “Calibration” tap, and push “Get Dark” button. Acquire dark frame, the “dark.raw” will be generated at “\cal\” folder.

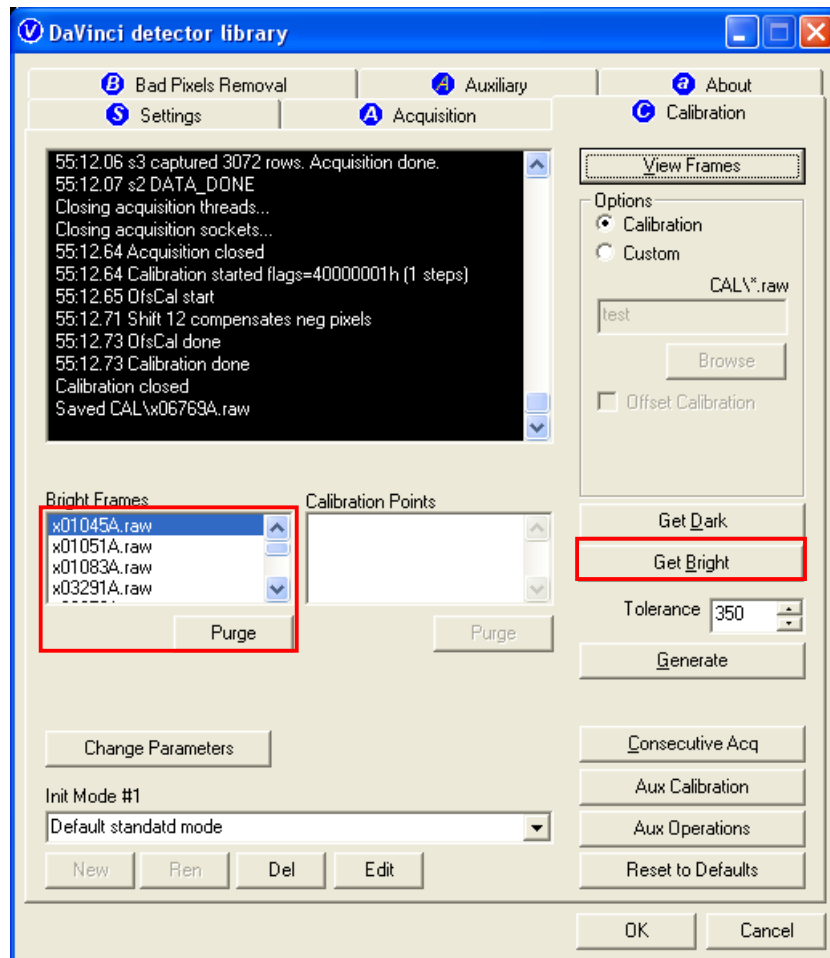




Click button [Get Bright]. It will produce *frame* with name %CAL% xNNNNNA.raw, where NNNNN is median pixel's value within current *image* borders after offset calibration (cut frame edges are never used during calibration). Suffix 'A' (it also could be 'B', 'C' etc) avoids casual coincidence of file names.

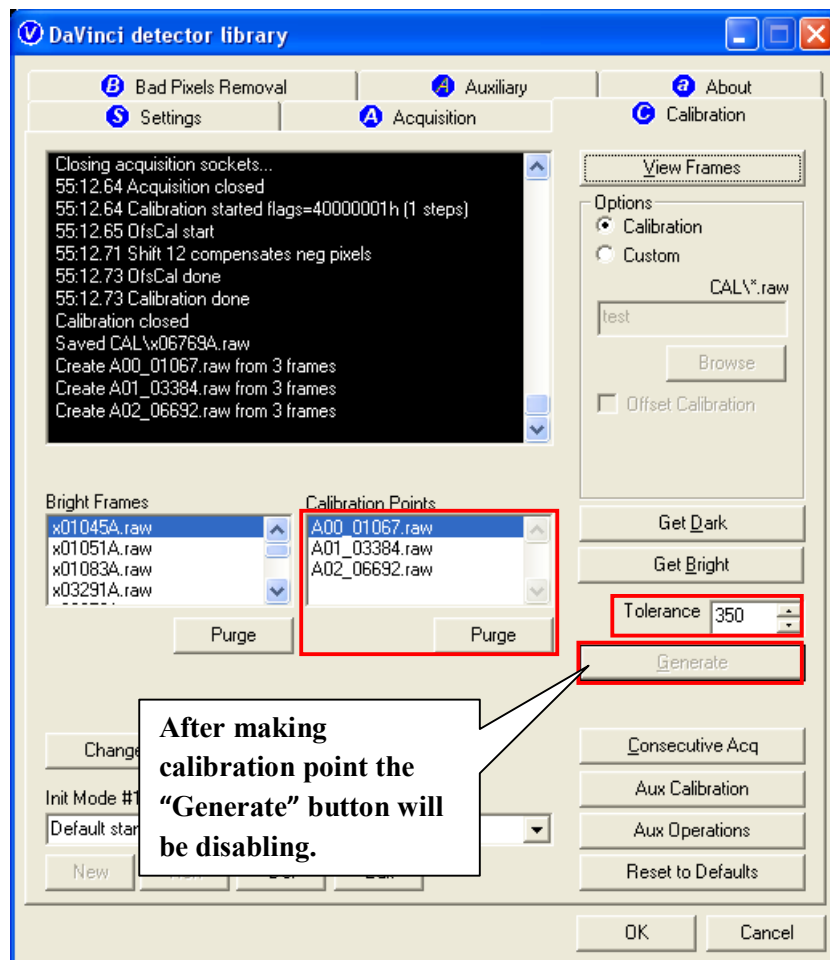
2nd Step

Push "Get Bright" button at different six of X-ray condition. The X-ray condition should be set or tested before, same as the level of '1.2'. Push "Get Bright" button at least 3 times at same condition, and then the offset subtracted bright (gain) is generated which of filename is "xNNNNNA.raw(Refer to NOTE)



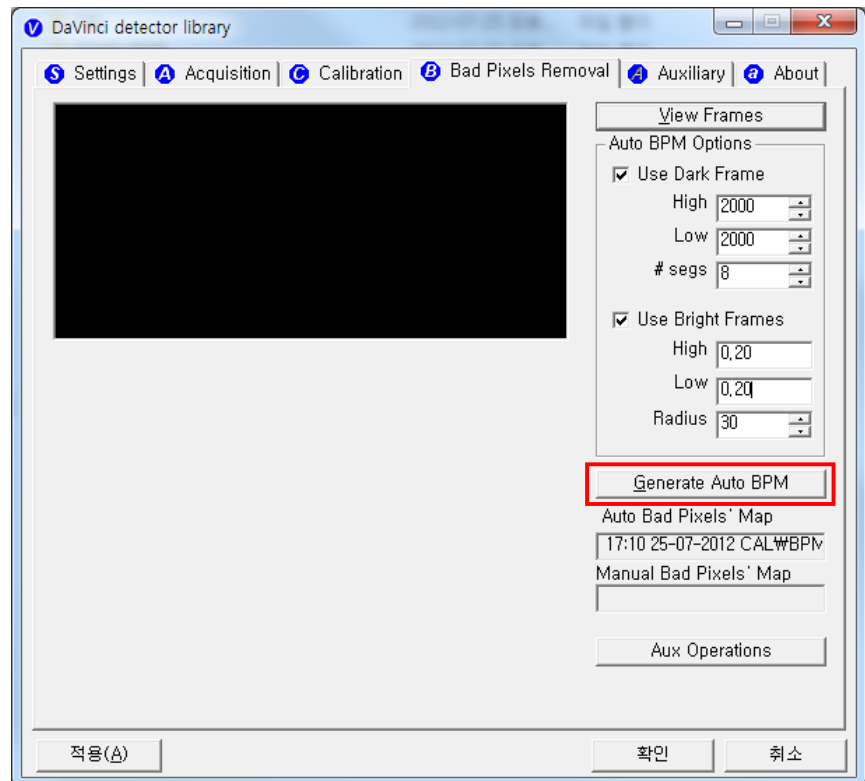
3rd step

After 2nd step, the “Generate” button will be activated. Click the button “Generate”, and then calibration point will be generated which of file name is “A ‘# of point’_ ‘median value of generated point’” like file of bright frame. The acquired bright frames within tolerance value which is variance of median level of acquired bright frames will be averaged and generated to a calibration point. The tolerance value can be edited.



4th step

After 3rd step, Change Bad Pixels Removal Tab, Click the button “Generate Auto BPM”, and then Defect Map will be generated which of file name is “BPM.raw “ at the “cal\” folder.



5th step

For additional Defect correction, if “BPMM.raw” is existed at the install CD, copy to the “\cal\” folder.

6th step

On Acquisition Tab. Check the box “Offset Calibration”, “Gain Calibration”, and “Bad Pix Map” for activate to each calibration and Bad Pixels Removal. Otherwise, it will does not working when going to pre-processing .

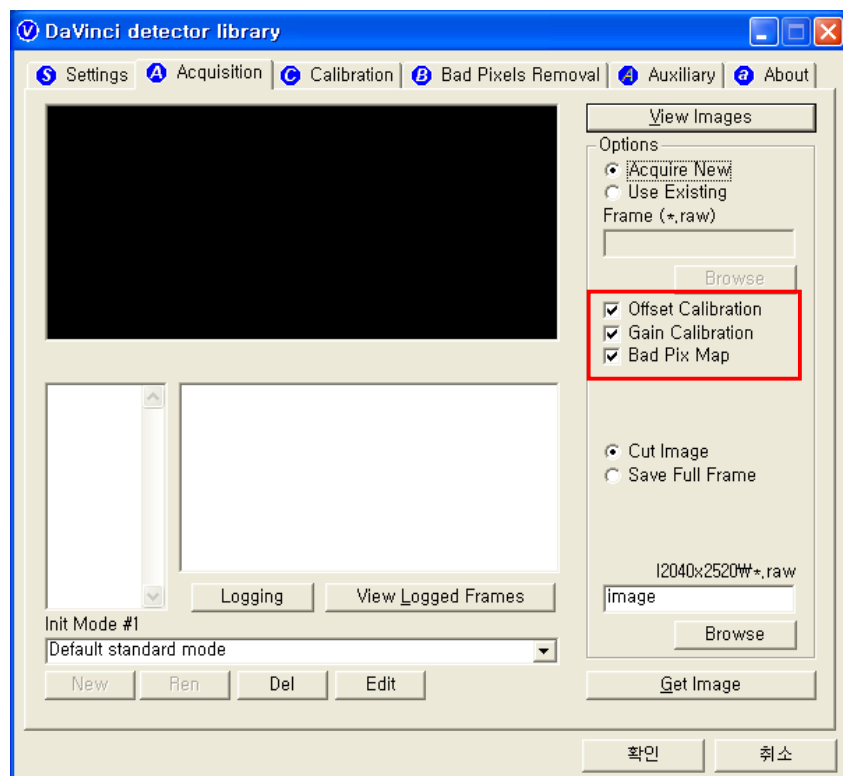


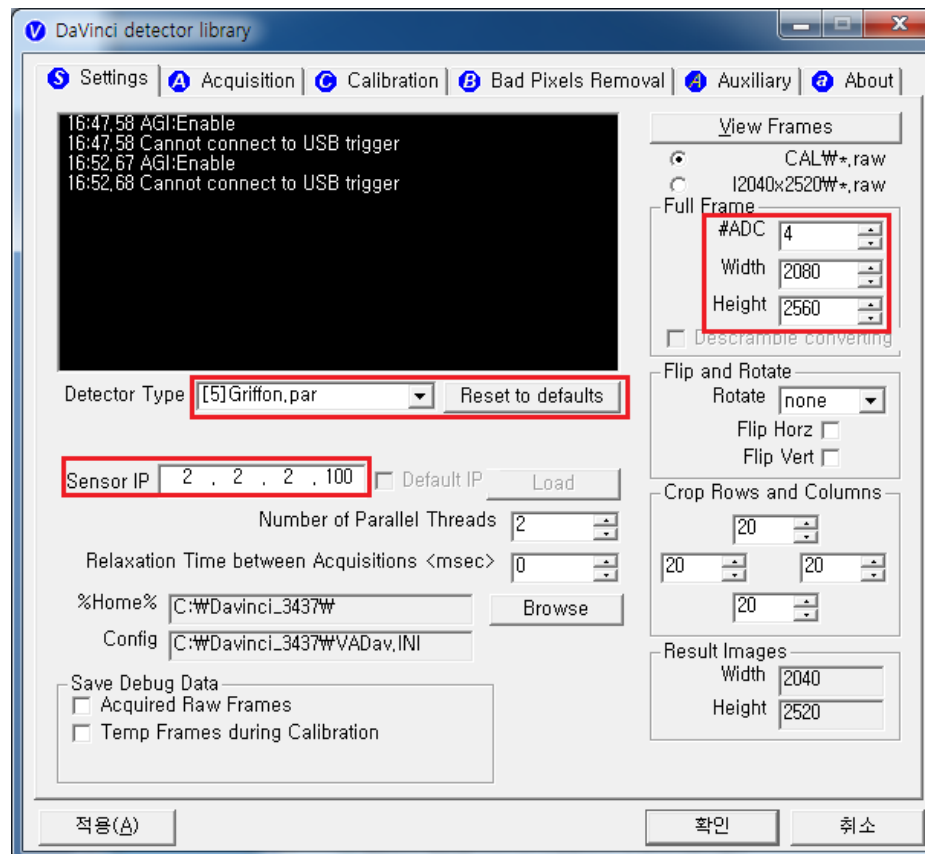
Image Acquisition Test

Program setup

To acquire images, run _vadav.lnk program.

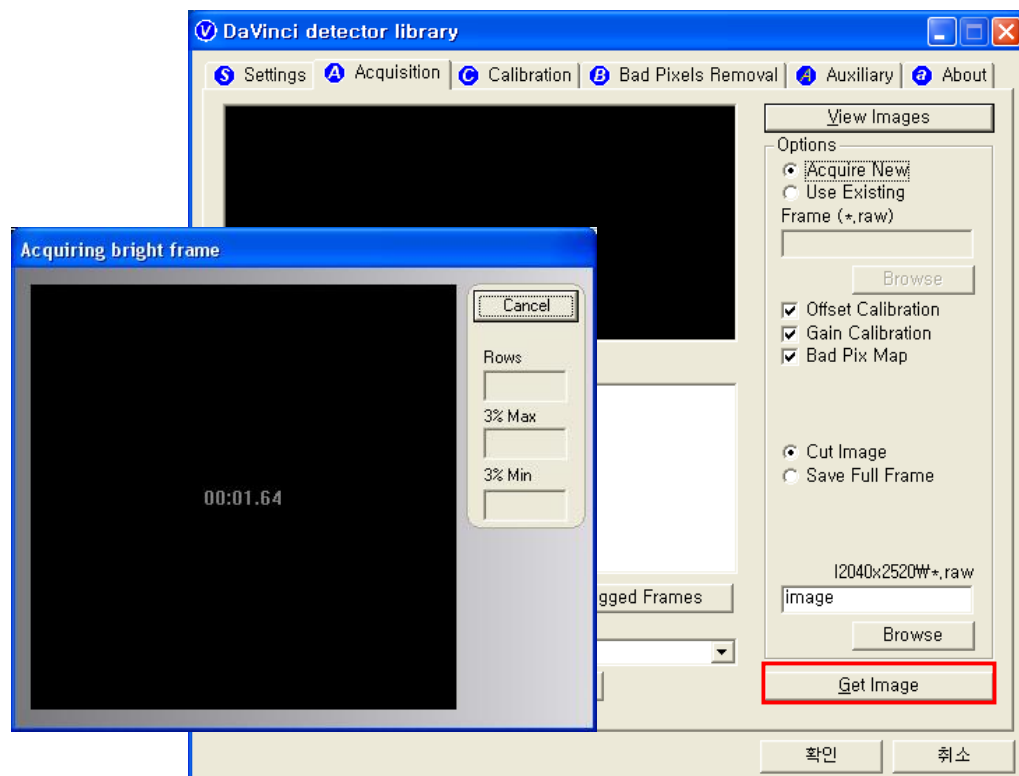
Please set the following figures

- Detector's IP : Wireless - 2.2.2.100 Wire – 2.2.2.101
- Detector's number of ADC : 4
- Detector's size of image : 2080 X 2560



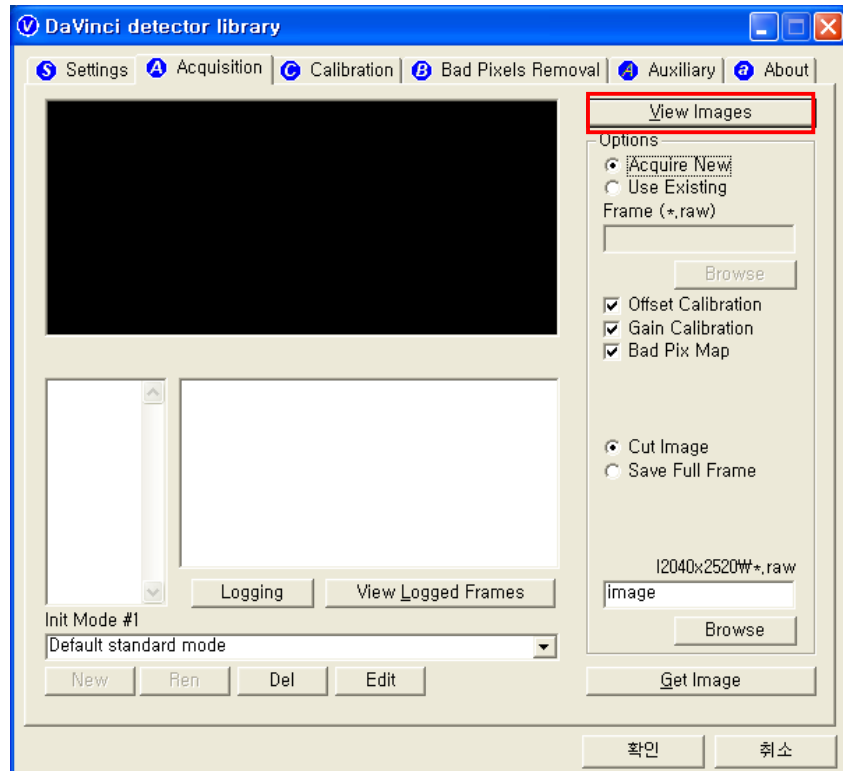
Get Image

On Acquisition tab, click the “Get Image” button to get image. After click the button, you can see pop-up window, which is display window time and process of acquiring image.

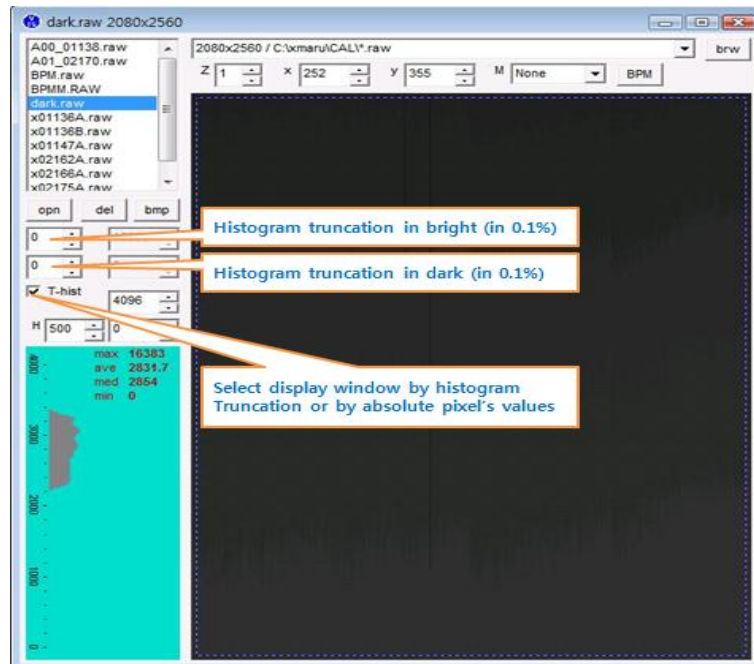


View Images

Frame- and image-files have extension “raw” and contain pixel data in signed 16-bits little-endian format. One could view those files in Photoshop or another image editor.



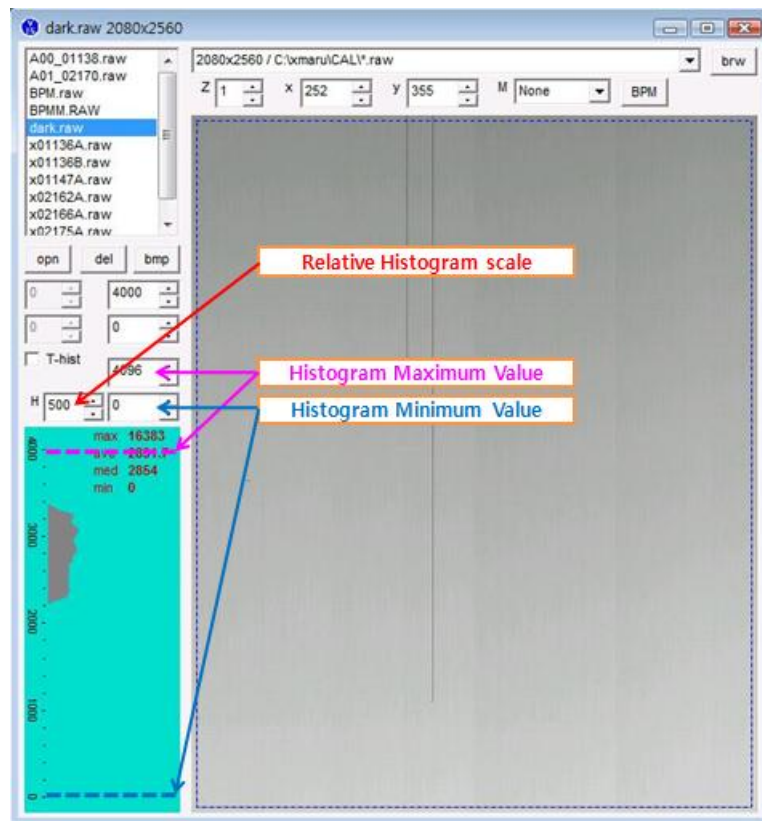
Common controls and displayed statistics



- Pixel_Min – minimum pixel value in frame- or image- data
- Pixel_Max – maximum pixel value
- Pixel_Black – if a pixel \leq Pixel_Black then it is displayed as black (RGB 0, 0, 0)
- Pixel_White – if a pixel \geq Pixel_Black then it is displayed as black (RGB 255, 255, 255)

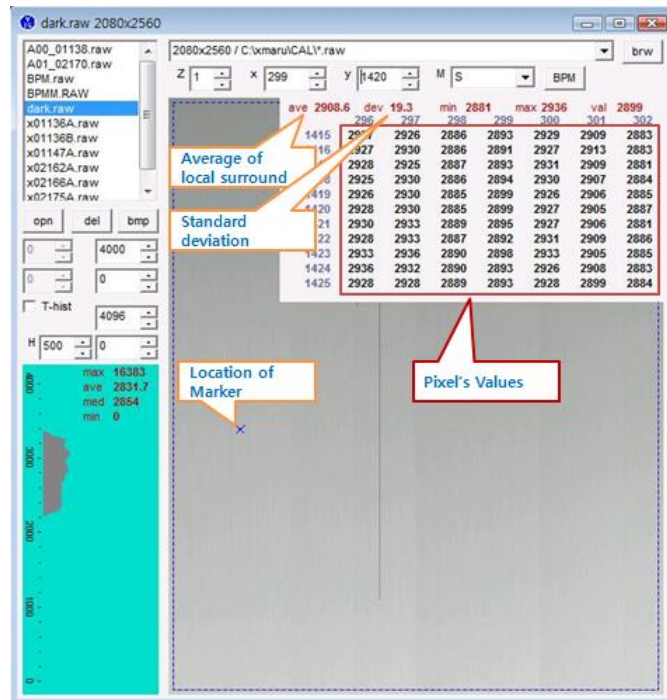
Histogram's presentation

Relative Histogram Scale $[H]=1000$ means that the distance depicted as “H” on the drawing matches 1% of total number of pixels. Respectively $[H]=100$ means that “H” matches 0.1% of pixels and $[H]=500$ means that “H” matches 0.5% of pixels.



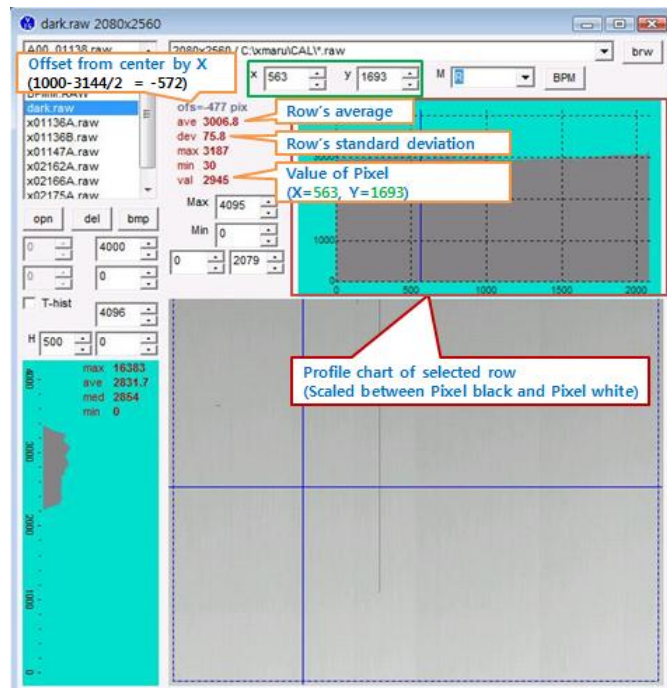
Marker type “S”

Displays local surround of selected location



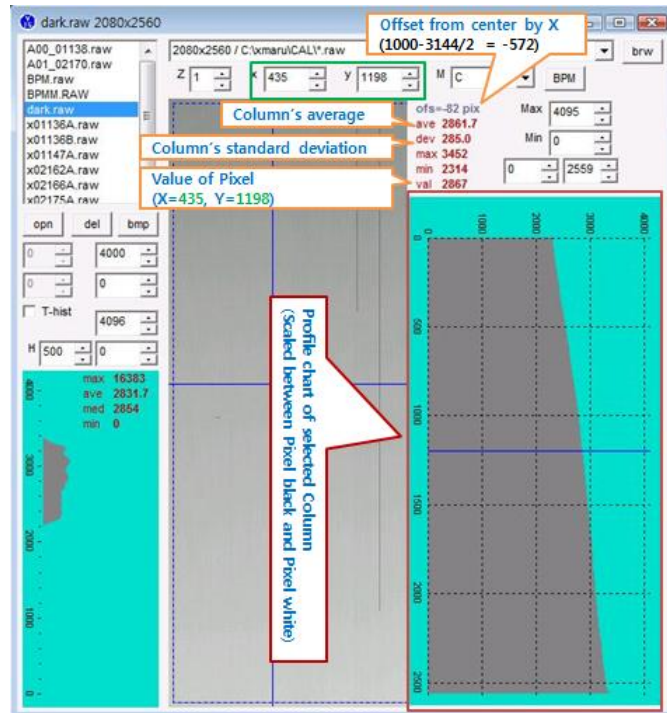
Marker type “R”

Display profile chart of a row.



Marker type “C”

Display profile chart of a column.



Operation

Recommend

X-ray detector should be used at stable state within driving temperature range.

Acquire the X-ray images after power on and 5 minutes warming up to obtain high quality images.

Switching power on / off

- All connection should be done, before turn on the power.
- Press the power button by more than 3 sec, when power on/off.
- The green light of the LED indicator on the detector is on, the detector power is on.
- The blue light of the LED indicator on the detector is blinking, the detector is getting prepared to work and initialize.
- After power off, separate the battery.

Storage

Store the sensor unit in clean and dry place. Ensure that storage place should be not affected by dust or liquids.

Information



Do not touch signal input, signal output or other connectors, and the patient simultaneously. External equipment intended for connection to signal input, signal output or other connectors, shall comply with relevant IEC Standard.

Safety standard

This equipment has been tested and found to comply with the limits for medical devices in IEC 60601-1-2:1994. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

This equipment generate, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. 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 following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other devices are connected.
- Consult the manufacturer or field service technician for help (e.g., IEC 60950-1 for IT equipment and IEC 60601-1 series for medical electrical equipment.)

In addition, all such combination system shall comply with the standard IEC 60601-1 and/or IEC 60601-1 harmonized national standard or the combination. If, in doubt, contact qualified technician or your local representative.

- Type of protection against electric shock: Class I equipment
- Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529: IPX0, ordinary equipment
- This equipment is not suitable for use in the presence of flammable anesthetic s or oxygen.
- Mode of operation: continuous operation

Radio Frequency compliance information

FCC/IC Notice (U.S.A and CANADA)

- **FCC Part 15 Subpart C §15.247 and IC RSS-210 Issue 7**
FCC Part 15 Subpart E §15.407 and IC RSS-210 Issue 7

- **FCC ID: QIIRY1012WCA**

5.15- 5.25 GHz band is restricted to indoor operations only.

Host device of the approved module shall be marked with the following item:

Contains Transmitter Module FCC ID: PPD-AR5BHB116

Compliance with FCC requirement 15.407(c)

Data transmission is always initiated by software, which is then passed down through the MAC, through the digital and analog baseband, and finally to the RF chip. Several special packets are initiated by the MAC. These are the only ways the digital baseband portion will turn on the RF transmitter, which it then turns off at the end of the packet. Therefore, the transmitter will be on only while one of the aforementioned packets is being transmitted. In other words, this device automatically discontinues transmission in case of either absence of information to transmit or operational failure.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

FCC CAUTION

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.

When installing it in a mobile equipment

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines in Supplement C to OET65. This equipment has very low levels of RF energy that it deemed to comply without maximum permissive exposure evaluation (MPE). But it is desirable that it should be installed and operated keeping the radiator at least 20cm or more away from person's body (excluding extremities: hands, wrists, feet and ankles).

Electromagnetic Compatibility Information

Guidance and manufacturer's declaration - electromagnetic emissions

The EUT is intended for use in the electromagnetic environment specified below. The customer or the user of the EUT should assure that it is used in such an environment.		
Immunity Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The EUT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF Emissions CISPR 11	Class A	The EUT is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Complies	The EUT is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	The EUT is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes

Guidance and manufacturer's declaration - electromagnetic immunity

The EUT is intended for use in the electromagnetic environment specified below.


The customer or the user of the EUT should assure that it is used in such an environment.

The EUT is intended for use in the electromagnetic environment specified below. The customer or the user of the EUT should assure that it is used in such an environment.			
Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV Contact ±8kV air	±6kV Contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ± 1kV for input/output lines	±2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (<95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (<95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EUT image intensifier requires continued operation during power mains interruptions, it is recommended that the EUT image intensifier be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity

The EUT is intended for use in the electromagnetic environment specified below.

The customer or the user of the EUT should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80MHz</p> <p>3 V/m 80 MHz to 2.5GHz</p>	<p>$V_1=3V_{rms}$</p> <p>$E_1=3V/m$</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the EUT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance :</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80\text{MHz to } 800\text{MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800\text{MHz to } 2.5\text{GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol :</p> 

NOTE 1) At 80MHz and 800MHz, the higher frequency range applies.

NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EUT is used exceeds the applicable RF compliance level above, the EUT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EUT.

^b Over the frequency range 150kHz to 80MHz, field strengths should be less than $[V_1]$ V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EUT

There is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EUT can help Prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EUT as recommended below, according to the maximum output power of the communications equipment.

Separation distance according to frequency of transmitter [m] IEC 60601-1-2			
Frequency of Transmitter	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz
Equation	$d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
Rated maximum output power of transmitter [W]	$V_1 = 3V_{rms}$	$E_1 = 3V/m$	$E_1 = 3V/m$
	Separation Distance (meters)	Separation Distance (meters)	Separation Distance (meters)
0.01	0.116	0.1166	0.2333
0.1	0.368	0.3687	0.7378
1	1.166	1.1660	2.3333
10	3.687	3.6872	7.3785
100	11.660	11.6600	23.333
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1) At 80MHz and 800MHz, the separation distance for the higher frequency range applies.			
NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EUT is used exceeds the applicable RF compliance level above, the EUT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EUT.			
^b Over the frequency range 150kHz to 80MHz, field strengths should be less than [V1] V/m.			

Name	Shield Type	Length	Notes
Link cable	Shielded	6 m	Provided with wiring unit.
P-interface cable	Non-shielded	8 m	Provided with X-ray interface unit.
USB cable (A to B)	Non-shielded	1.8 m	Provided with AGI unit.
AC power cord (220V)	Shielded	1.8 m	Provided with charger unit.


Immunity and Compliance Level

Immunity test	IEC 60601-1-2 Test Level	Actual Immunity Level	Compliance Level
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz	3Vrms	3Vrms
Radiated RF IEC 61000-4-3	3Vrms 80MHz to 2.5GHz	3V/m	3V/m

Guidance and manufacturer's declaration - electromagnetic immunity

The EUT is intended for use in the electromagnetic environment specified below.

The customer or the user of the EUT should assure that it is used in such an electromagnetic environment.

Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms 150 kHz to 80MHz	The EUT must be used only in a shielded location with a minimum RH shielding effectiveness nad, for each cable that enters the shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location.
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m 80MHz to 2.5GHz	Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3V/m. ^a Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 2) It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the EUT is used exceeds 3V/m, the EUT should be observed to verify normal operation.

If abnormal performance is observed, additional measures may be necessary, such as relocating the EUT or using a shielded location with a higher RF shielding effectiveness and filter attenuation.

Maintenance

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

Maintenance

- Maintenance of the detector should be done by an authorized 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.
- This equipment must only be connected to a supply mains with protective earth.



When the instrument is going to be cleaned, be sure to turn OFF the power of each instrument, and unplug the power cable from the AC outlet. Otherwise, fire or electric shock may result.

Cleaning

Cover

Clean the cover by the left warning box, if it is dirty.

CFRP of Detector

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. If you are using disinfectant other than those specified above, or you are mixing another disinfectant with ethanol, please also consult a specialist, because they may harm the CFRP plate.



Inspection

In order to ensure that the instrument is used safely and normally, please be sure to inspect the instrument before use. If any problem is found during the inspection, please take measures indicated in this chapter. If problem still cannot be corrected, please contact Rayence 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.

Inspection chart

Inspection	User	Vendor	Cycle
Check that cables are not damaged or cover of cables is not torn	O		Daily
Check that the plugs and locks of connectors are not loose	O		Daily
Check that the cover or parts are not damaged and not loose	O		Daily
Check the LED indicator	O		Daily
Check the bad pixel map		O	Half year
Check the performance of the instrument by performing exposures using a phantom or a resolution chart		O	Yearly

Disposal or Recycling

Follow local governing ordinances and recycling plans regarding the disposal or recycling of device components.



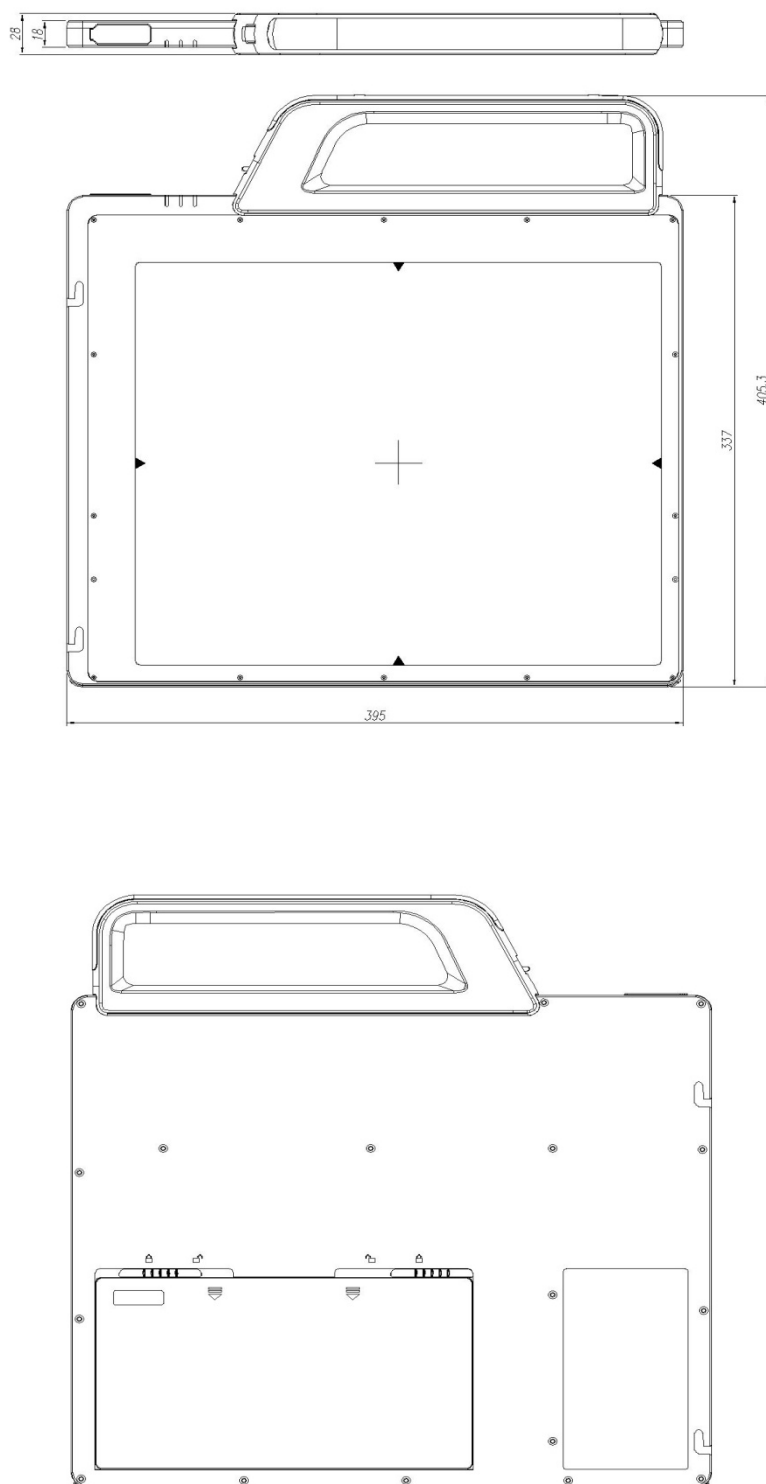
Disposal of old Electrical & Electronic Equipment

(Application in the European Union and other European countries with separate collection system.) This symbol indicates that this product shall not be treated as household waste. Instead, it shall be handed over to the applicable collection point for the recycling of electrical and electronic equipment. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. For more detailed information about recycling this product, please refer to local governing ordinances and recycling plans.

Appendix

Dimension

[unit : mm]





Medical Image Processing Unit

1012WCA



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