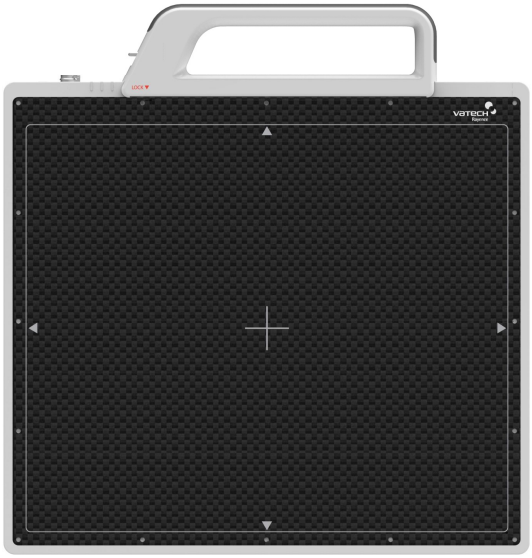
Release Version 1.0.0

Medical Image Processing Unit

1417WGA

User Manual



Attention

For improvement of product performance, supplementation, or follow-up of information; the contents of this manual are subject to change without separate prior notice.

Please note that our company has neither responsibility for any accidents nor obligation to do free repair service for any damage of the equipment due to user's mistake, which resulted from failure to follow the contents in this manual. Make sure to be familiar with the safety precautions and usage procedures. Also note that the product may slightly differ from the contents of this manual depending on specification.

The following marks are used for the effective use of the product in this manual.

Attention, consult accompanying documents.

This is used to emphasize essential information. Be sure to read this information to avoid incorrect operation.

This indicates hazardous situation which, if not heeded, may result in minor or moderate injury to you or others, or may result in machine damage.

This indicates a potentially hazardous situation which, if not heeded, could result in death or serious injury to you or others.

Federal Law restricts this device to sale by or the order of a radiologist or any other practitioners licensed by the law of the state in which that person practices to use or order the use of the device.

Contents

Introduction

Overview

The 1417WGA is a wireless digital X-ray flat panel detector that can generate images of any part of the body. The wireless LAN((IEEE 802.11a/g/n) communication feature improves the operability, and high-speed processing. This X-ray imaging system consists of a scintillator directly coupled to an a-Si TFT sensor. It makes high-resolution, high-sensitive digital images.

Intended use

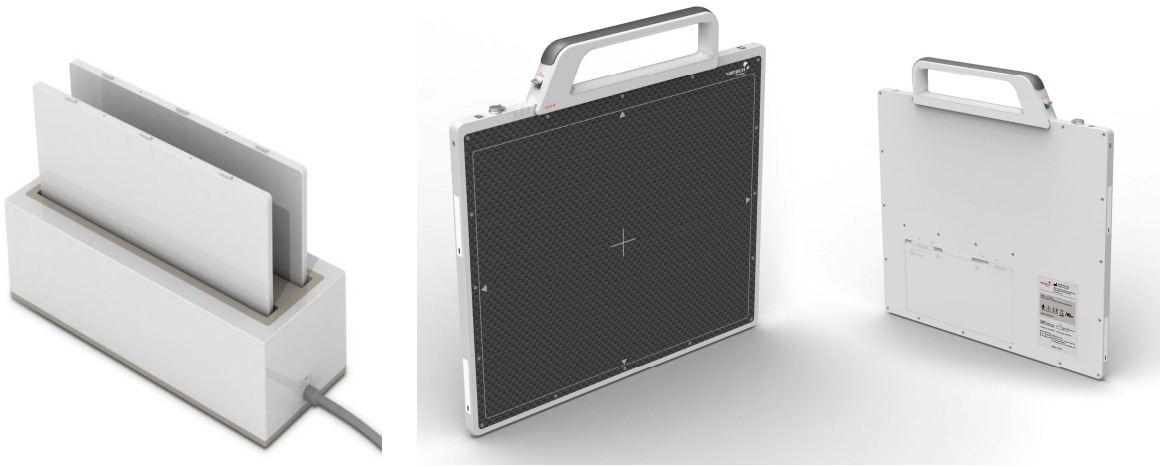
For U.S.A.

1417WGA Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for human anatomy including head, neck, spinal column, arm, leg and peripheral (foot, hand, wrist, fingers, etc.). It is intended to replace film based radiographic diagnostic systems and provide a case diagnosis and treatment planning for physicians and other health care professionals. Not to be used for mammography.

For European Union

This device provides digital X-ray imaging for diagnosis of disease, injury, or any applicable health problem. The image is obtained as the result of imaging X-rays passed through the human body with an X-ray flat panel detector and importing a digital signal output from the detector into the image processor.

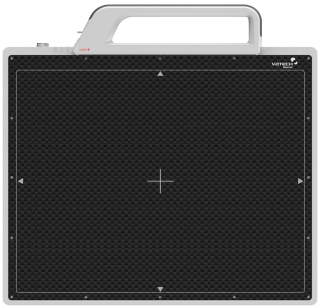
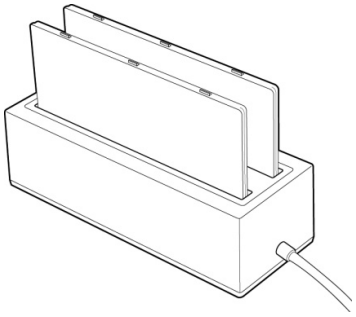
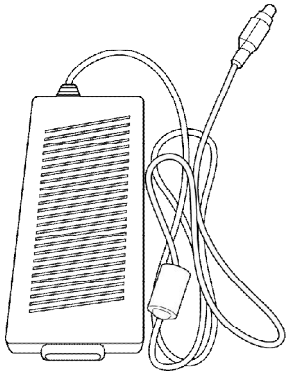
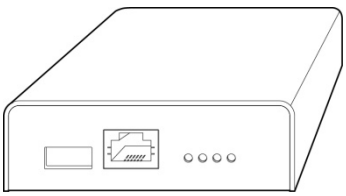
Product features



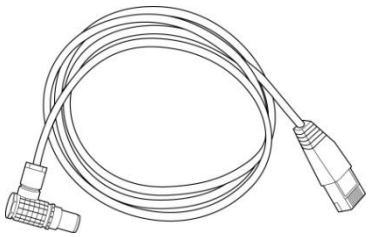
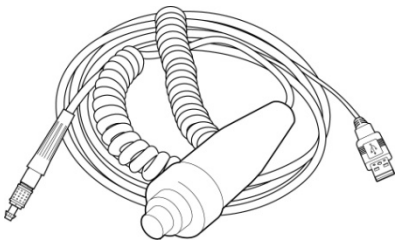
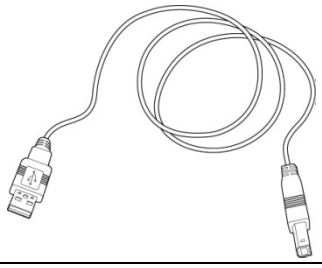
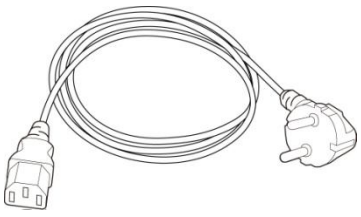
- Wi-Fi (802.11a/g/n)
- Based on a-Si TFT active matrix
- Compact (15.9mm thickness) and light weight (Typ. 3.6kg)
- Limiting Resolution : 3.9 lp/mm
- 14-bit digital output
- Easy integration

Product components

- Medical Image Processing Unit

Photo	Item	Part Name	Quantity
	Detector	SD1417WGA	1
	Handle	-	1
	Battery pack	RB37WH	2
	Battery charger	RC120W	1
	Charger adapter	PMP120-13-3	1
	AGI	RA001A	1

- Cables

	Item	Part Name	Length	Quantity
	Link cable	VRH076A	6m	1
	P-Interface cable	VRH017A	8m	1
	USB cable(A to B)	VRH078A	1.8m	1
	AC Power cord	VRH018A/019A	1.8m	1

- Installation CD
    - Manual
    - Detector Library

- Option
    - Additional Battery
    - Charger for the Car
    - Cover Bag
    - AP package

Components Description

The detector is designed to capture radiographic images.

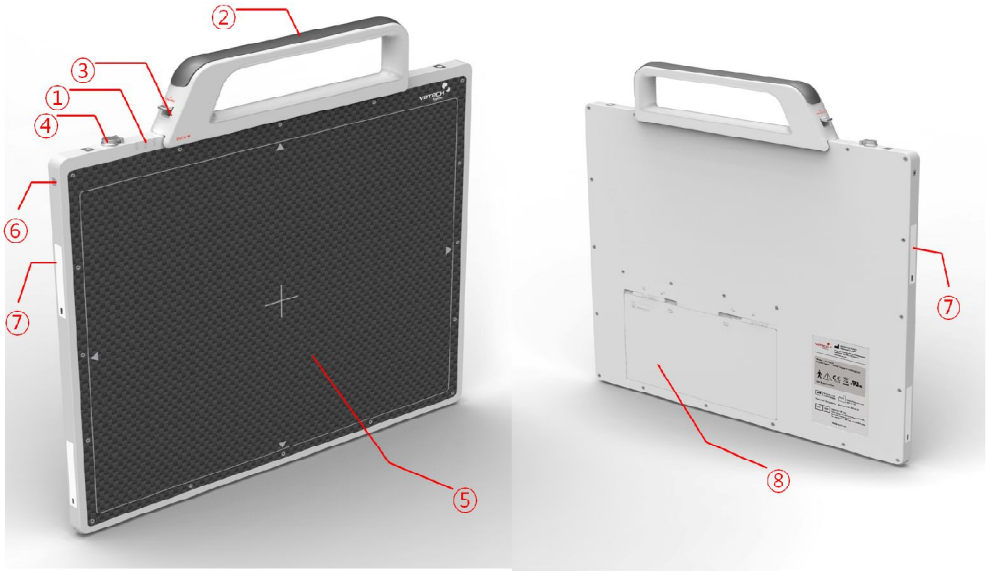
Captured images are transmitted to PC using the wireless/wired connection.

The SparkLAN WPEA-121N 802.11 a/b/g/n half mini PCI-e module is implemented. It supports 2T2R (2 transmit 2 receive) MIMO technology, which delivers throughput up to 300Mbps.

1417WGA (FCC ID: QIIRY1417WGA) in the RF module (FCC ID: PPD-AR5BHB116) does not use DFS band.

The module adopts the latest 802.11n Dual-Band technology (2.4Ghz and 5Ghz). The transmitter of the module is powered by host equipment(Detector). The antennas are 2 printed-dipole antennas.

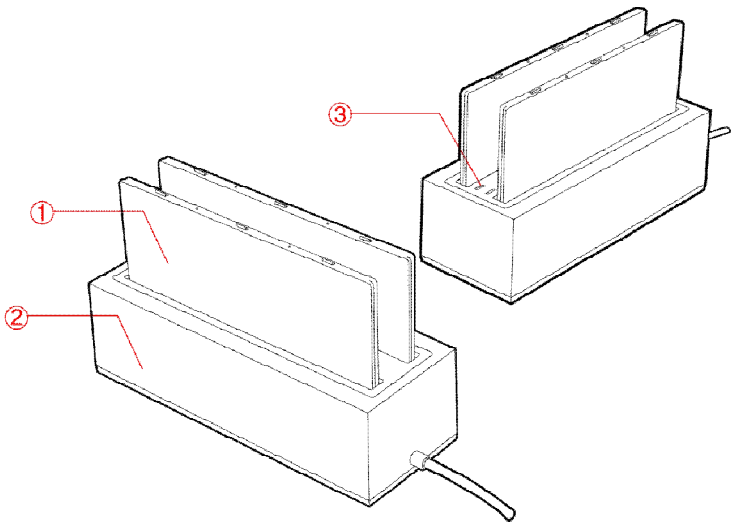
(1) Detector



1. **LED indicator:** The LED indicates the state of detector.
   i. **Green on :** Power on.
   ii. **Blue blinking :** Wireless Connection.
   iii. **Orange on :** Low battery.
2. **Handle :** Hold this handle when carrying the sensor unit. It is removable.
3. **Handle unlock-lever :** This is an unlock-lever to remove handle.

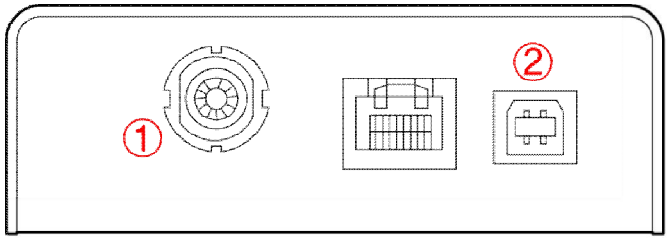
4. **Link cable connector :** This is a connector for Wire communication and power supplying. Connect the detector to PC and SMPS(not provided) using Link cable.
5. **CFRP(Carbon Fiber Reinforced Plastic) :** The part of the patient's body to which an image is to be taken should be placed against this plate.
6. **Power button :** Power on / Power off switch.
7. **Shock sensor :** Detector has built-in 4 Shock sensors. It detects and records impact and mishandling of fragile
8. **Battery unlock-lever :** This is an unlock-lever to remove battery.

(2) Battery & Charger



1. **Battery :** Lithium ion battery. The number of times being acquired image is 600 images(@ cycle time : 15s). The batteries last 2.5 hours and are rechargeable.
2. **Charger :** Two port cradle type.
3. **LED indicator :**
    i. **Orange on :** charging
    ii. **Green on :** Charging is completed.

(3) AGI



1. **Trigger connector:** This is a connector for synchronization between detector and generator. Connect the AGI to the generator using P-interface cable..
2. **USB connector:** This is a connector for communication between AGI and PC. Connect the AGI to the PC using USB cable.

Warning

Environment of Use and Storage

Follow the specified process of operational instructions written in this manual for the safety of the users and patients.

Does not use or store the instrument near any flammable chemicals such as thinner, benzene, etc. Also, this instrument is not a category AP or APG equipment. If chemicals are spilled or evaporate, it may result in fire or electric shock through contact with electric parts inside the instruments. Also, some disinfectants are flammable. Be sure to take care when using them.

Connection

Do not connect the instrument with anything other than specified. Otherwise, it may result in fire or electric shock.

Handling

Always be sure to keep checking the condition of the system and the patient to ensure they are normal during the use of the instrument. If any problem is found, take appropriate measures, such as stopping the operation of the instrument, as required.

Never disassemble or modify the product as it may result in fire or electric shock. Also, since the instrument incorporates parts that may cause electric shocks and other hazardous parts, touching them may cause death or serious injury.

Do not hit or drop the instrument. The instrument may be damaged if it receives a strong jolt, which may result in fire or electric shock if the instrument is used without being repaired.

When Problem Occurs

Should any of the following occur, immediately turn OFF the power of each instruments, unplug the power supply cord from the AC outlet, and contact Rayence representative or distributor.

- When there is smoke, odd smell or abnormal sound.
- When liquid has been spilled into the instrument or a metal object has entered through an opening.
- When the instrument has been dropped and it is damaged.

Maintenance and Inspection

For safety reasons, be sure to turn OFF the power of each instrument when the inspections indicated in this manual are going to be performed. Otherwise, it may result in electric shock.

When the instrument is going to be cleaned, be sure to turn OFF the power of each instrument, and unplug the power supply cord from the AC outlet.

The instrument must be repaired by a qualified engineer only. If it is not repaired properly, it may cause fire, electric shock, or accident.

Caution

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, 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.
- Freezing or condensation.

Do not place the storage case 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. Otherwise they could trip over, resulting in injury

Handling

Do not spill liquid or chemicals onto the instrument or, in cases where the patient is injured, allow it 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.

Turn off the power of each instrument for safety when they are not going to be used.

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.

Modifications

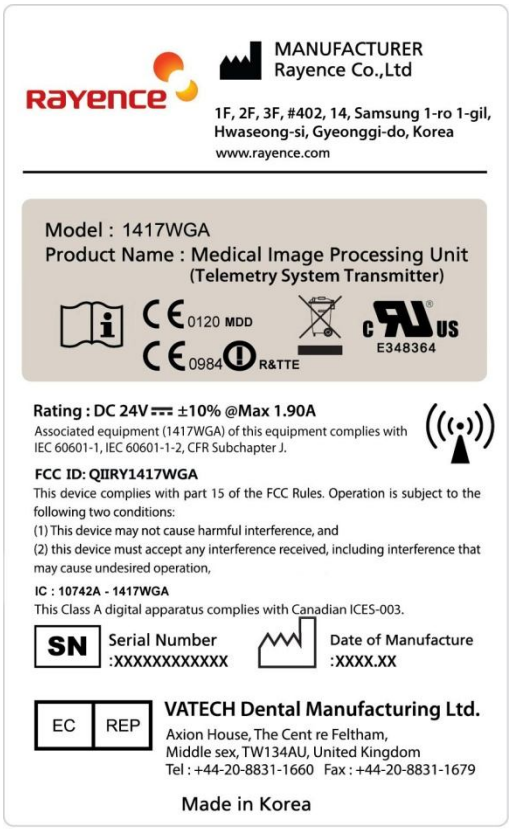
Any changes or modifications in construction of this device which are not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Marking and labeling symbols

Symbols	Meaning
	Caution : “Attention, see instructions for use”
	Manufacturer
	Date of manufacture
	Serial number
	WEEE : Waste Electrical and Electronic Equipment
	Authorized representative in the European Community
	CE symbol grants the product compliance to the European Directive for Medical Devices 93/42/EEC as a class Ⅱa device. Authorized by **Notified Body SGS (code no.:0120) of British**
	non-ionizing radiation

Labels

Detector label



Battery label

Battery sticker

Notes for Using the Detector

Preparing

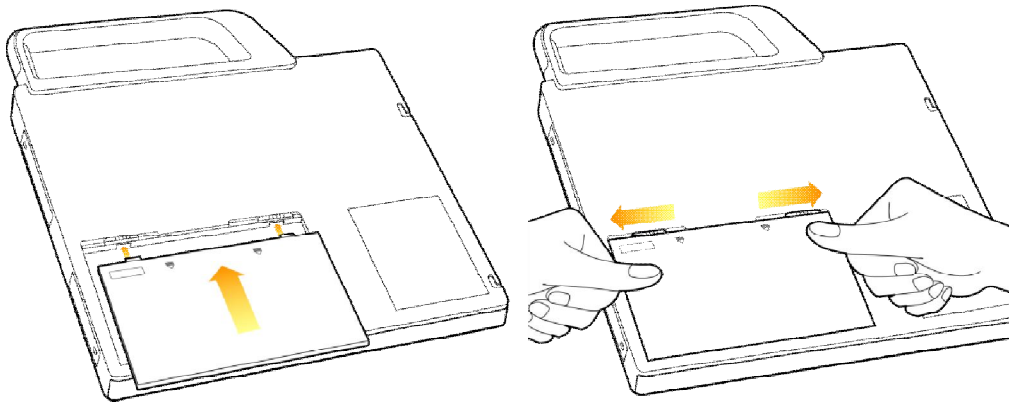
Fully charge the battery pack. Charge the battery on the day of examination or on the previous day.

- Battery slowly discharges even of not in use. The battery pack may have expired if it discharges immediately after being fully charged. You can purchase an optional battery pack to replace an exhausted one.
- Be sure to fully charge the battery before use.

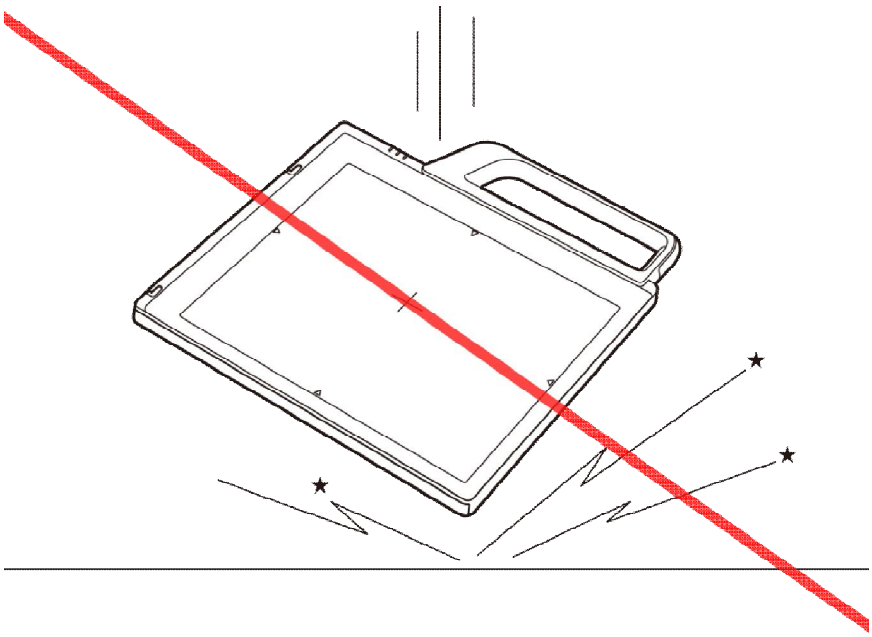
  ※ The battery charger, RC120W is designed for the dedicated battery pack.

  ※ When the detector will not be used for some time, remove the battery pack.

Attach the battery pack. Align the claw on the battery pack and the groove on the battery bay. Insert the battery pack fully. Push down the battery pack. Slide the lock lever toward (lock) side and lock it.

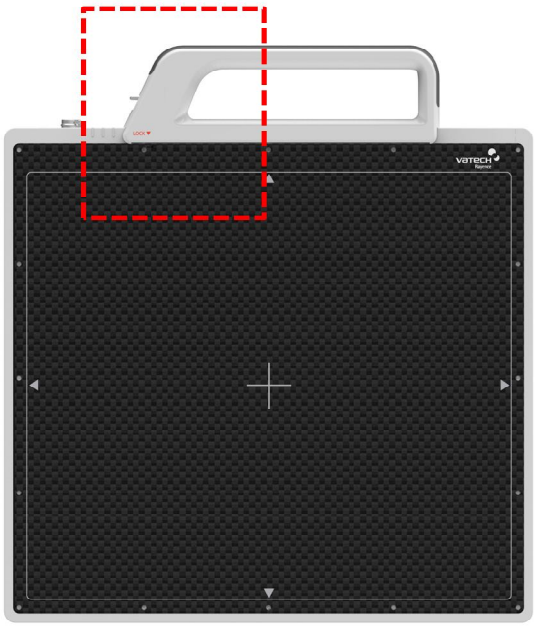


Handling



Handle the instrument carefully, as it may be damaged if something is hit against it, dropped, or receives a strong jolt.

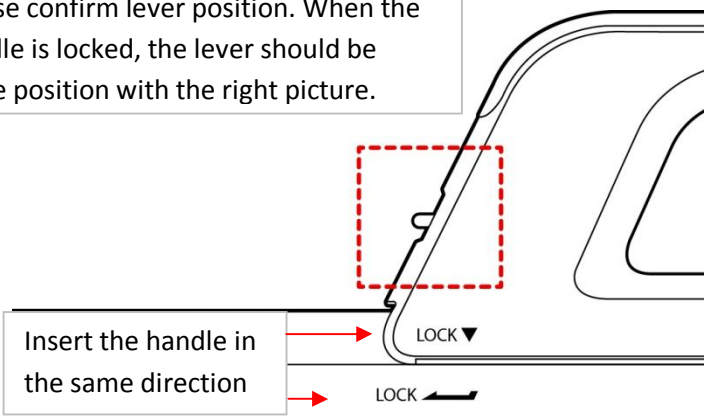
Handle Assembly



※ Insert the handle always in the same direction.

- Handle Assembly

Please confirm lever position. When the handle is locked, the lever should be same position with the right picture.



CAUTION If the handle is not locked, the detector can be dropped.

Before Exposure

Be sure to check the equipment daily and confirm that it works properly.

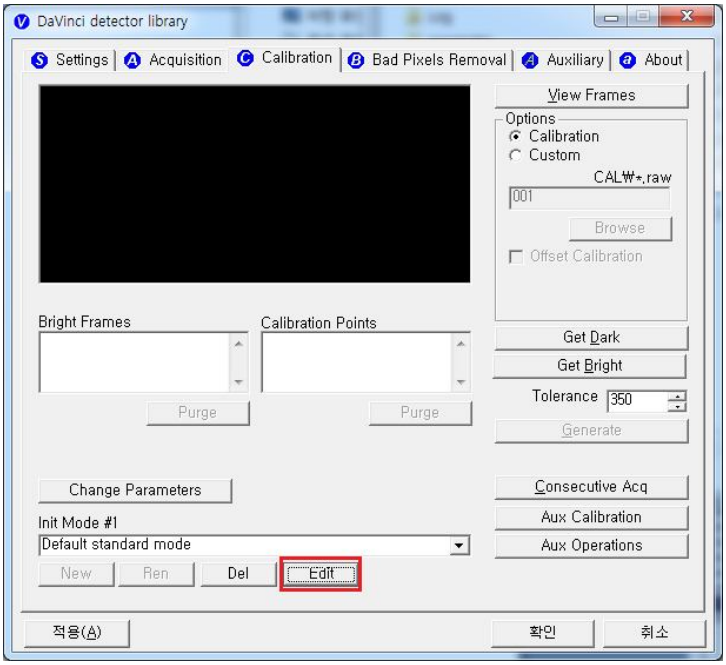
Sudden heating of the room in cold areas will cause condensation to form on the instrument. In this case, wait until condensation disappears before performing exposure. If the instrument is used with condensation formed on it, problems may occur in the quality of the instrument. When an air-conditioner is going to be used, be sure to raise/lower the temperature gradually so that a difference in temperature in the room and in the instrument does not occur, to prevent forming of condensation.

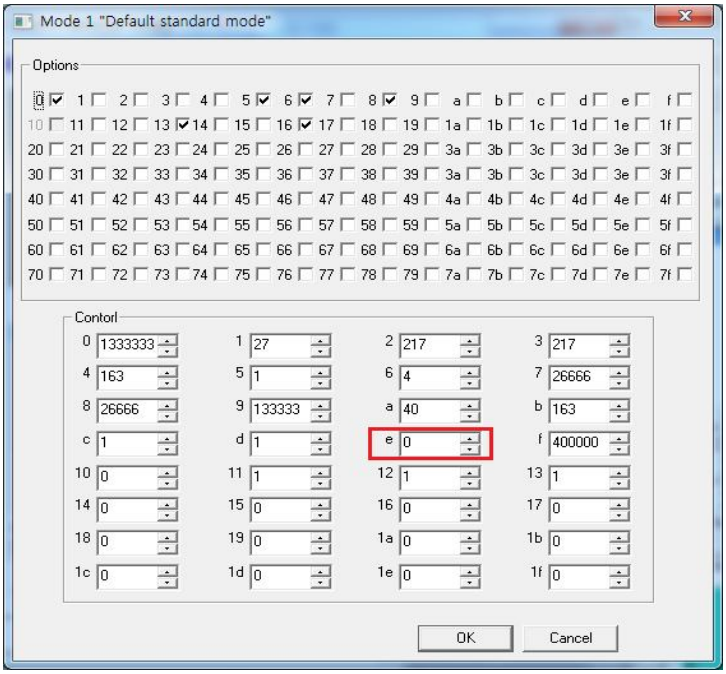
During Exposure

Do not use the detector near devices generating a strong magnetic field. Doing so may produce image noise or artifacts.

Do not apply excessive weight to the sensor unit. Otherwise, the sensor may be damaged.

- Sleep Mode/Wake up





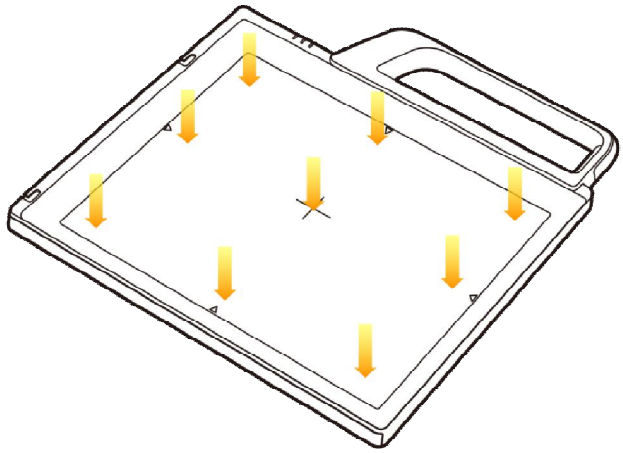
CAUTION Do not change parameters except “Control e”

Control “e” parameter : sleep time

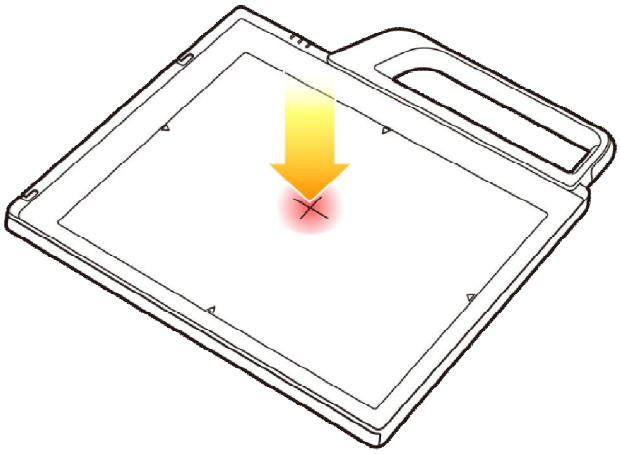
- 0 : disabled (default)
- 1 : 1 sec
- 2 : 2 sec …
- 600 : 600 sec

- If you set sleep time, the detector goes to the sleep mode after “N” sec after acquiring image
- If you want to wake up the detector, Press the power button(less than 1 second)

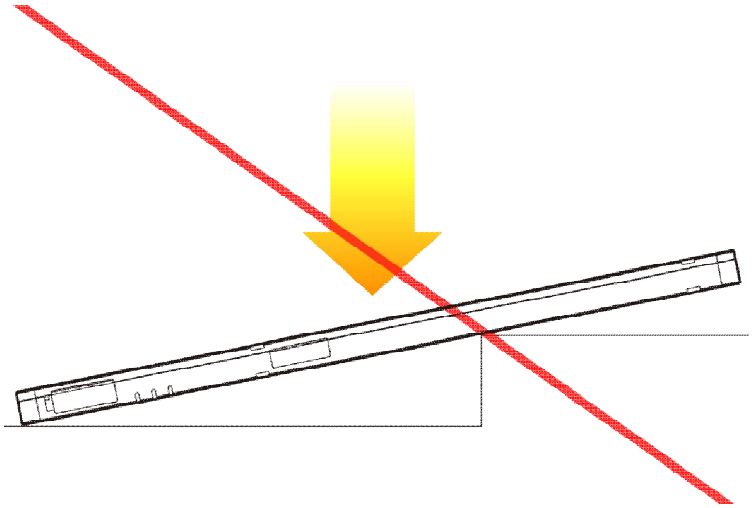
Limit of Load



Uniform load: 150 kg over the whole area of sensor window.



Local load: 100 kg on an area 40 mm in diameter.



Be sure to use the sensor unit on a flat place so it will not bend.

Otherwise, the sensor may be damaged.

Disinfection and Cleaning

Do not spray the detector directly with disinfectants or detergents.

Do not use anything other than neutral detergent for cleaning the cover of the instrument. Otherwise, the coating will be corroded.

Others

Be sure to reconnect the cables to the proper connectors. Otherwise, the instrument may malfunction or may be damaged.

Technical Features

Mechanical Features

Size	450 x 417 x 15.9 mm
Weight	3.6 kg (not incl. Handle)
Encapsulation Material	Mg
Window Material	Carbon fiber plate with 1.2 mm thickness

Electrical Features

Detector

Sensor Type	Amorphous Silicon with TFT (Single Panel)
X-ray Converter	Gd_2O_2S:Tb
Total Pixel Number	2816 × 3328 pixels
Active Pixel Area	35.8 cm × 42.3 cm
Active Pixel Number	2270 × 3280 pixels
Pixel Pitch	127 μm
Limiting Resolution	Max. 3.9 lp/mm
Energy Range	40 - 150 kV
A/D Conversion	14 bits
Frame Rate	240 fph
Preview Time	< 3.0 sec
Charge Integration Time	upto 4 sec
Max. Linear Dose	Typ. 70 μGy @ SID 1500 mm
Saturation Dose	Typ. 80 μGy @ SID 1500 mm
Data Interface - Wireless - Wired	 Wi-Fi (802.11a/g/n) Gigabit Ethernet

- Under RQA5 condition (70kVp, 21mmAl)
- Preview time may vary by complex factors

Battery

Size	232.5 x 132.8 x 7 mm
Weight	Typ. 0.3 kg
Input	12.5 VDC
Output	11.1 VDC
Charging time	Typ. 2.5 hours
Capacity	Typ. 3400 mAh
The number of times being acquired image	600 images

The Battery level can be displayed on the LED status of battery.

If the battery level goes down under 25%, please charge the battery

Display	Battery level
	75~100 %
	50~75 %
	25~50 %
	0~25 %

Charger

Size	267.5 x 100 x 77 mm
Weight	Typ. 0.86 kg
Input	20 VDC
Output	11.1 VDC

Adapter

Size	160 x 76 x 43.7mm (cable length: 1.28m)
Weight	Typ. 0.92 kg
Input	100~240 VAC, 47~63 Hz, 1.4~0.6A
Output	20 VDC, Max 6.0A

Wireless Spec

Standard	802.11a/g/n compliance
Peak Rate	300Mbps
Frequency	2.4 GHz / 5 GHz
Bandwidth	20MHz/40MHz
MIMO	2x2

※ Recommended Maximum operable distance : 7m
(From the Access Point)

※ 5150~5250 MHz band is restricted to indoor operations only. (for FCC)
5150~5250 MHz band is restricted to indoor operations only. (for CE)
5150~5250 MHz is indoor use only. (for Japan)

Environmental requirement

Storage condition

Item	Min.	Typ.	Max.	Unit	Note
Temperature	-20		55	℃	
Humidity	10		80	% H.R.	
Pressure	70		106	kPa	
Shocks (Wrapping condition)		10G (25G)			16ms, 1000times, in 6directions, non-Driving
Vibrations (Wrapping condition)		2G (10G)			10-150Hz, 10Sweeps, 1min/Octave, XYZ axis

Operation condition

Item	Min.	Typ.	Max.	Unit	Note
Temperature	5		35	℃	
Humidity	30		75	% H.R.	
Pressure	70		106	kPa	

※ Regularly changed parts : Battery (warranty 6 months)

PC Requirements

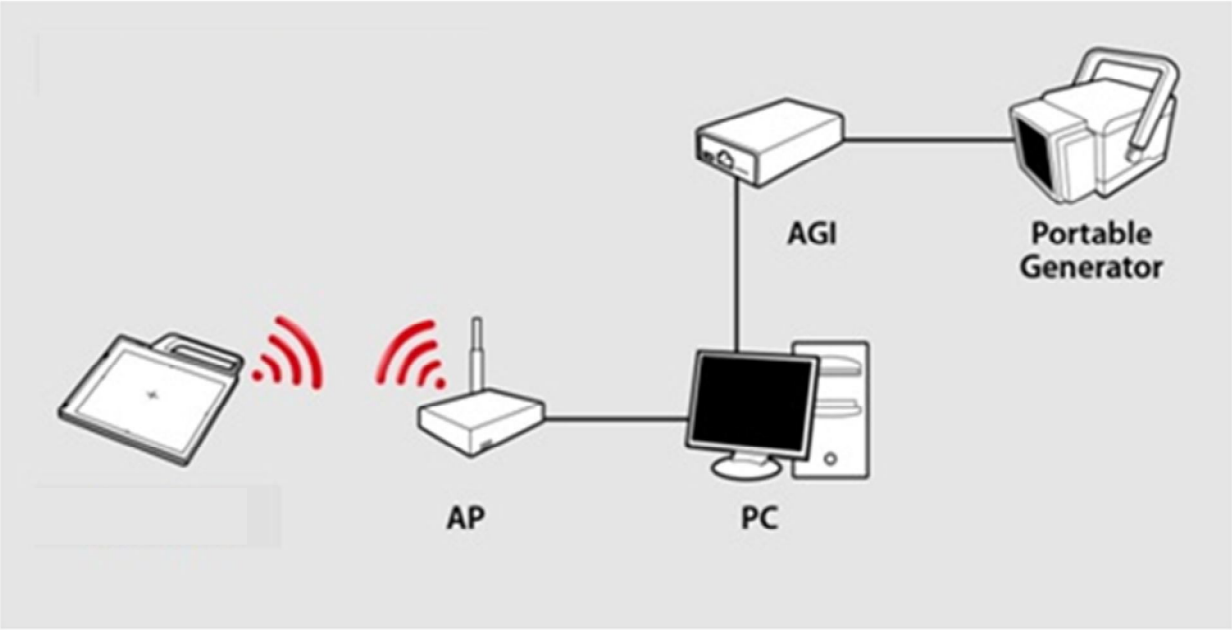
- Processor : At least Intel Pentium IV HT with 2.8GHz, Intel Core Duo / Core 2 or comparable AMD Dual Core processor
- At least 2 GB RAM
- At least 40 GB hard disk for the software, in addition to the required archive capacity for image storage
- Upper that Intel® Gigabit Network card
- Graphics card/monitor : Resolution of at least 1,280 x 1,024 pixels in True Color mode
- OS : Windows XP, vista, 7(32/64 bit)

Installation

WARNING Portable Imaging processing unit must be installed in a way that enables the user to achieve optimal use

The Detector is composed of sensitive electronic parts and components. It is recommended to use the product in a clean place and to exercise caution to ensure that it is not affected by dust or liquids. It is recommended to Use a dry and soft cloth to clean the detector housing.

General interface



※ The 1417WGA(incl. WLAN module) is as Client, and AP(Access Point) needs to be bought by local end-user. Since the AP is set up as the locally available frequency, the module just uses the frequency received from AP.

Connection

Power Connection

A. Connect the battery pack or power cable to the equipment.

B. Connect the USB cable from your PC to AGI.

※ Be sure to sure only the dedicated battery pack, RB37WH for 1417WGA.

Wireless Communication

A. AP Router(Line sharer) setting

- SSID : Griffon
- Internal network
    - IP address : 2.2.2.1
    - Subnet mask : 255.255.255.0
    - Dynamic IP allocation range : 2.2.2.2~2.2.2.254
- Pre-Shared Key(Password) : project302
    - Authentication methods : WPAPSK or WPA2PSK
    - Password methods : TKIP/AES
- AP IP : 2.2.2.1
- Channel (Frequency)
    - Avoid crowded channel
      (Using wireless detector under crowded channel result in low performance)
    - If available, Use 'Auto-Channel Selection' function of router to find optimal channel

B. Reception Indicator

Link LED flickering

Blink Speed : Slow – Low link quality

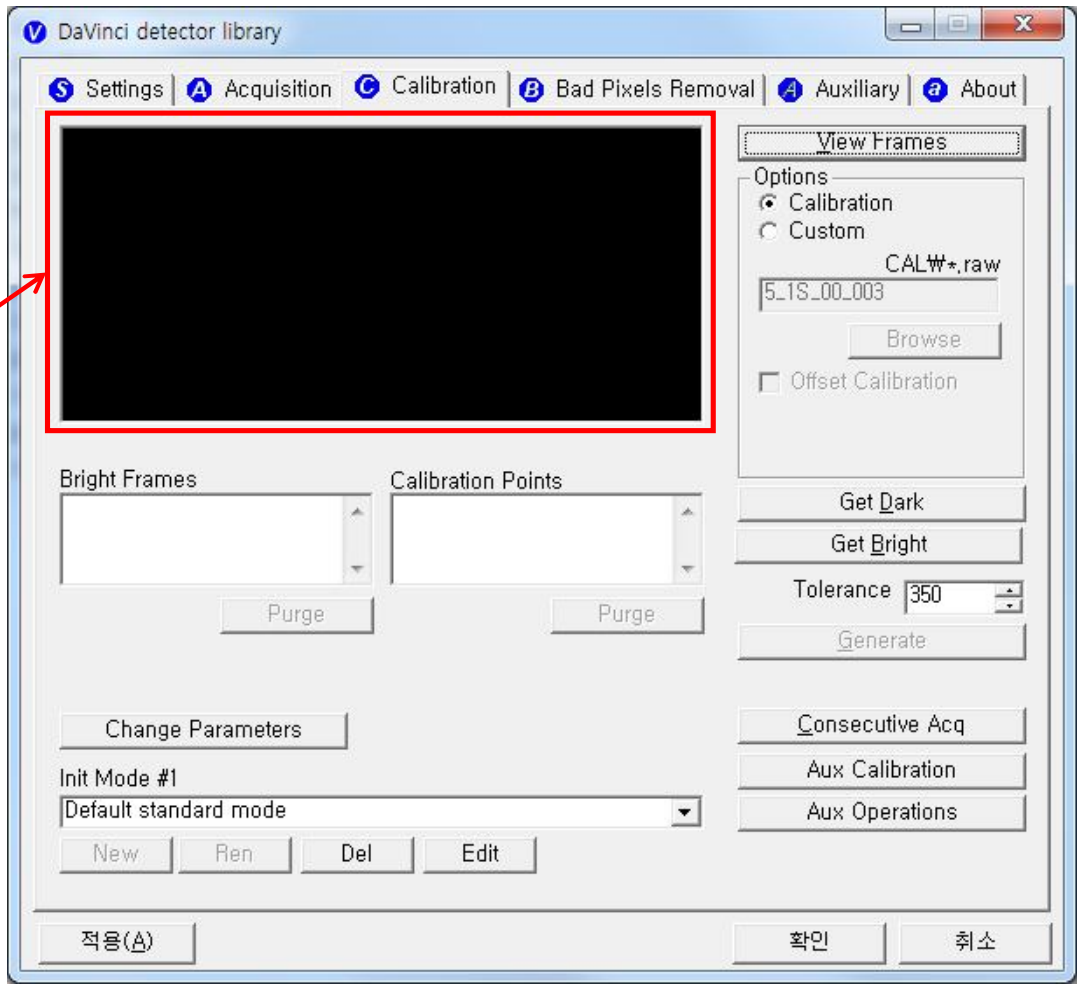
Fast – High link quality

C. Checking Link Quality

- After wireless connection is established, perform ‘Get Bright’ in ‘Calibration’ tap.

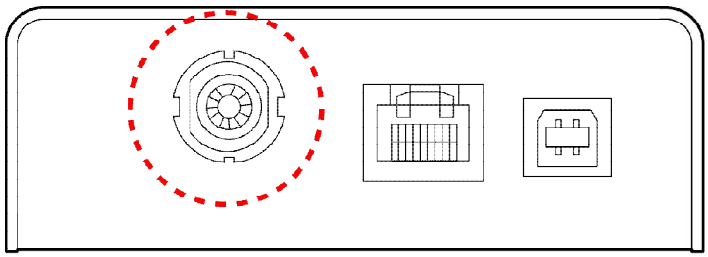
- Check the value named ‘Wireless Signal’ in black log screen.
Wireless Signal = Link Quality (Max. 100)

The value ‘Wireless Signal’ will be displayed here



Trigger Connection

A. Connect the P-interface cable to the generator

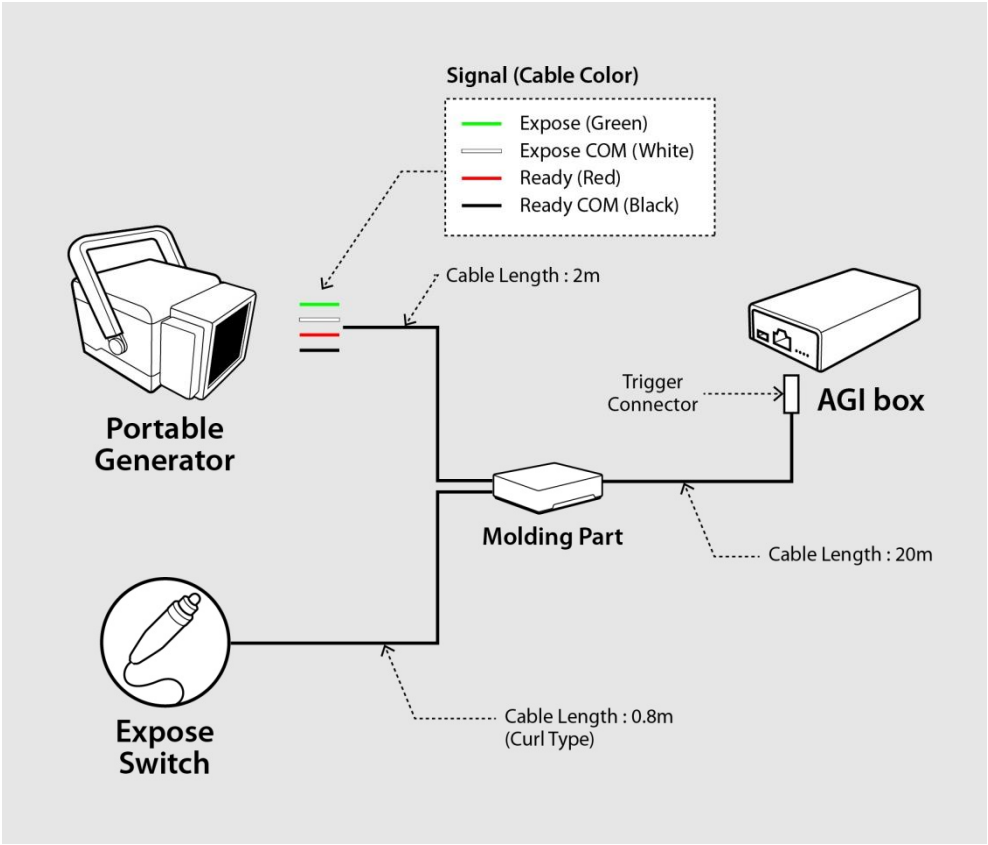


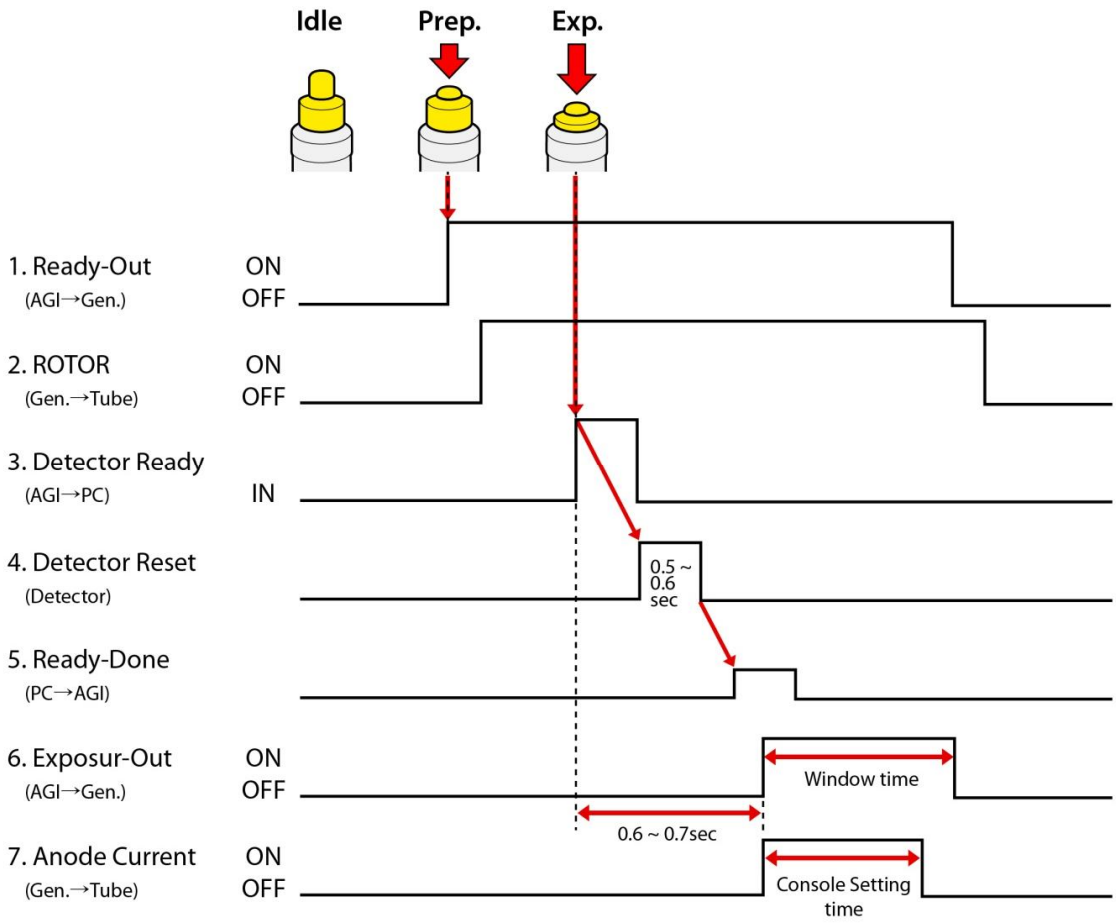
CAUTION Make assurance doubly sure SIGNAL RATING before connection.

X-ray Generator Connection

Connect the P-interface cable between the AGI box and X-ray generator.

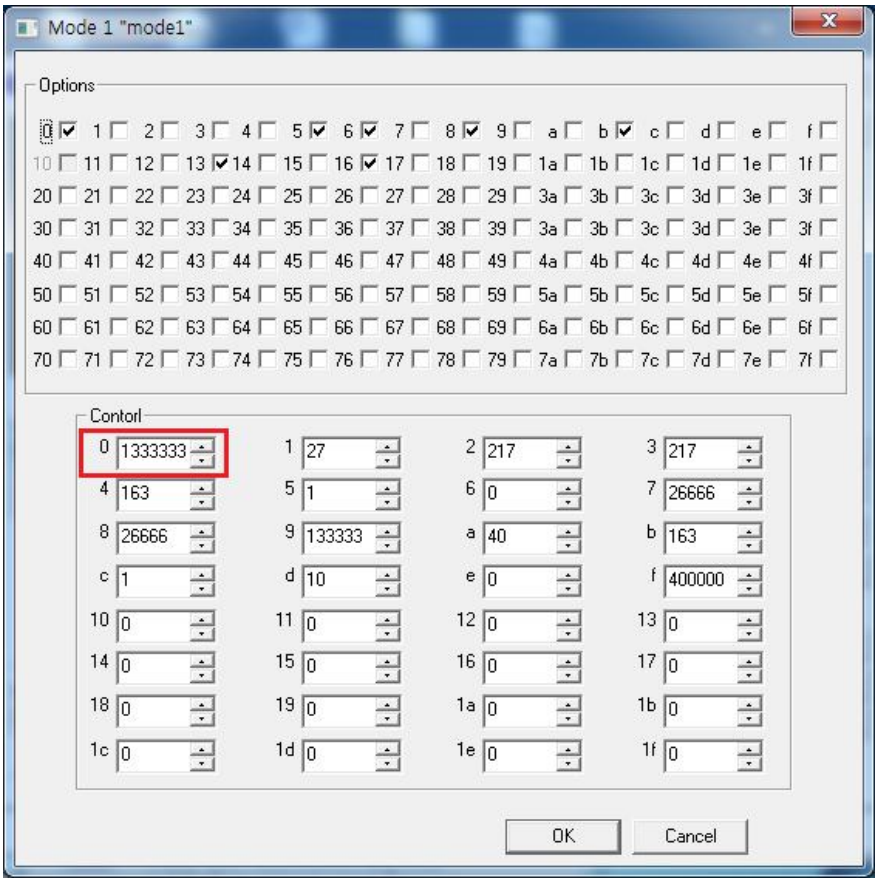
A. Wired Mode 1 : P-interface cable mode





The window time can be changed. Refer to the following pictures

NOTE Exposure Time(*clk) 1333333 is designate to 0.5sec



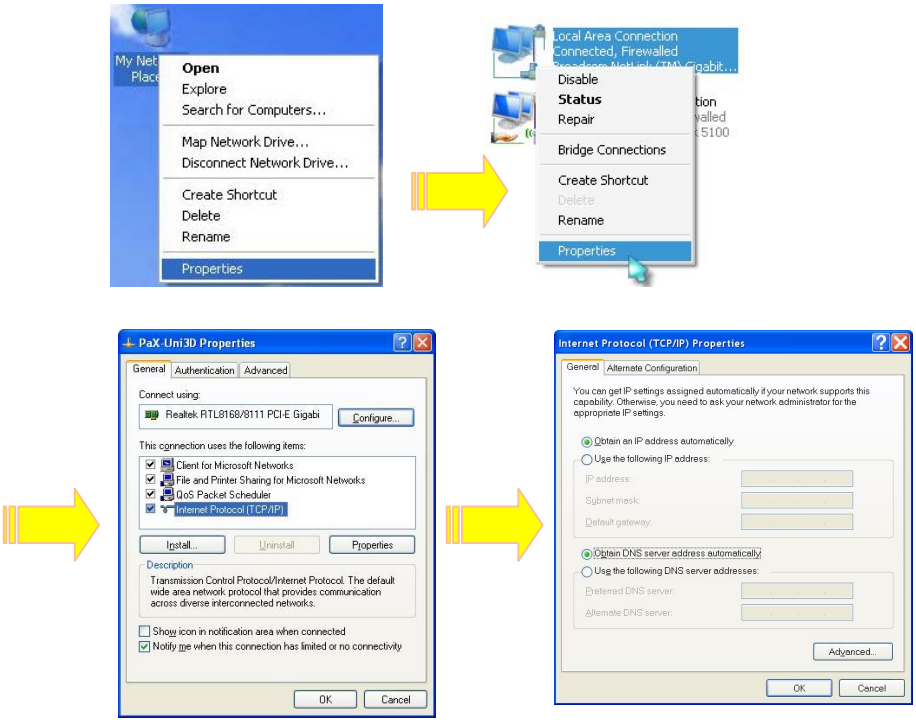
IP set up

[My Network Places] → [Properties] → [Local Area Connection]

→ [Properties] → [Internet Protocol (TCP/IP)]

→ [Use the following IP address]

IP address : Obtain an IP address automatically



IP address : Obtain an IP address automatically

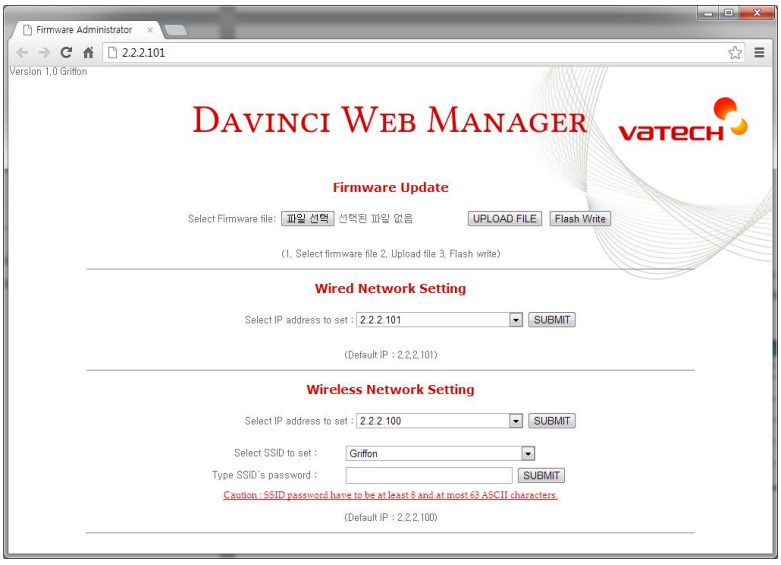
Using Web Manager (IP, SSID Change / Upgrade FW)

Change IP Address of Detector

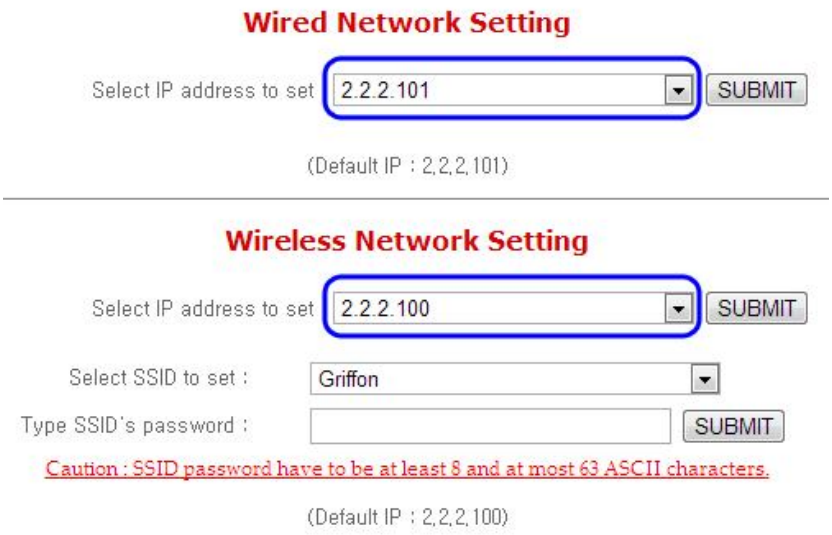
A. Turn on Detector and connect to PC
(wired connection is recommended)

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



E. Click “SUBMIT”

F. Restart detector(Turn Off then On)

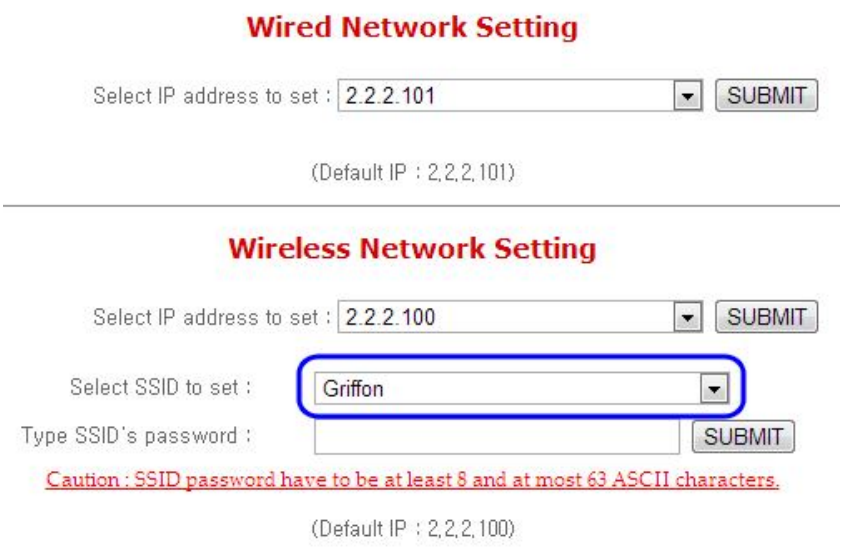
Change SSID and PSK(Pre-Shared Key)

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

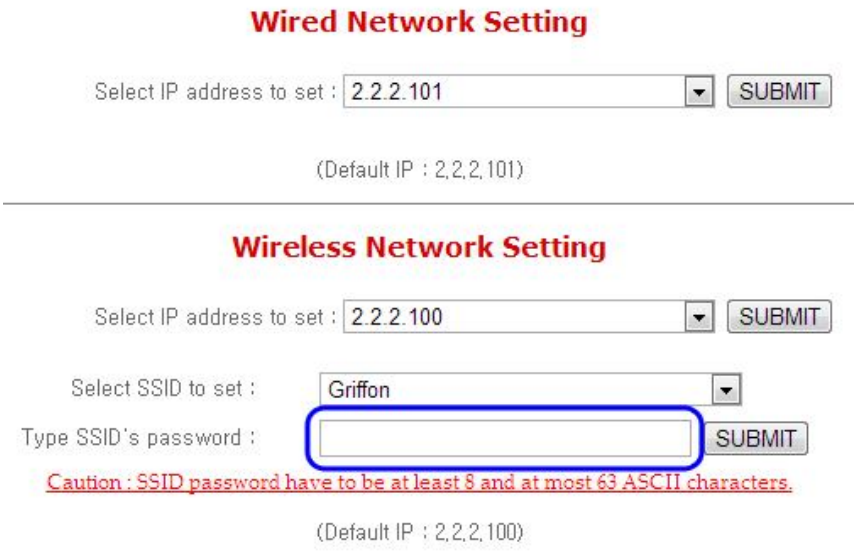
B. After detector boot up, Launch web-browser
(Optimized for Chrome/Internet Explorer)

C. Connect to “http://[Detector’s IP]“

D. Select SSID to set
(This value should match to Router’s setting)



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



F. Click "SUBMIT"

G. Restart detector(Turn Off then On)

Upgrade Firmware

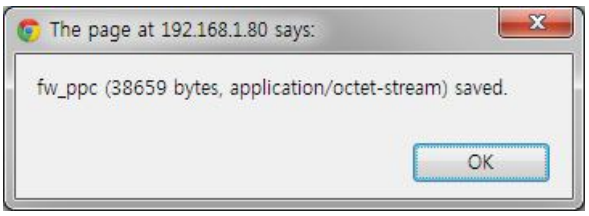
A. Turn on Detector and connect to PC
(wired connection is recommended)

B. After detector boot up, Launch web-browser
(Optimized for Chrome/Internet Explorer)

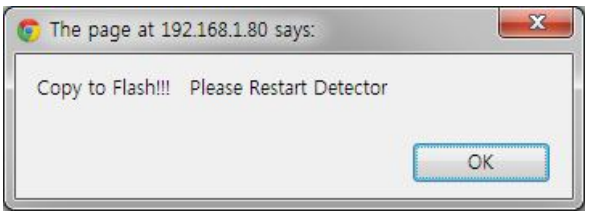
C. Connect to “http://[Detector’s IP]“

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

NOTE 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

NOTE 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

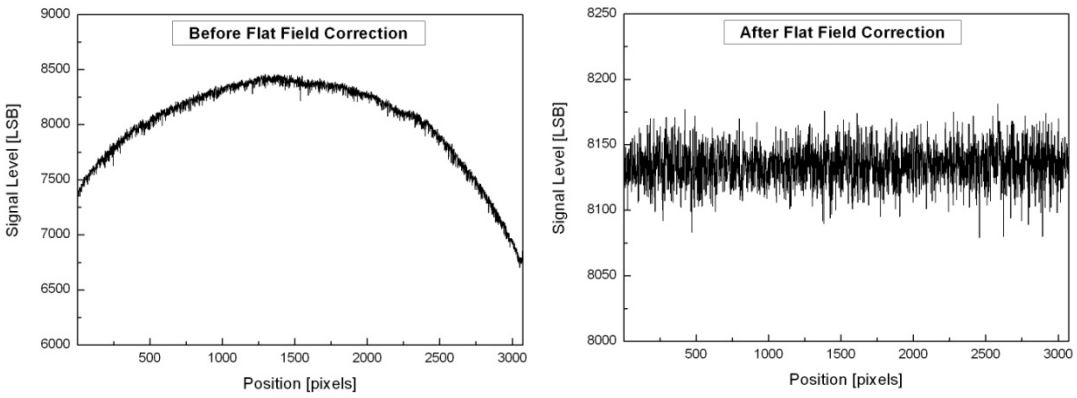
To gain correction, bright frame and dark frame should be acquired. The dark frame is needed only one frame. The bright frame is recommended to be acquired more than 8 different levels of median values of bright frames. The X-ray source condition will be recommended the tube energy level of 70kVp with 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]	850~1150	1850~2150	2850~3150	3850~4150	5850~6150	7850~8150	9850~10150	11850~12150

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).

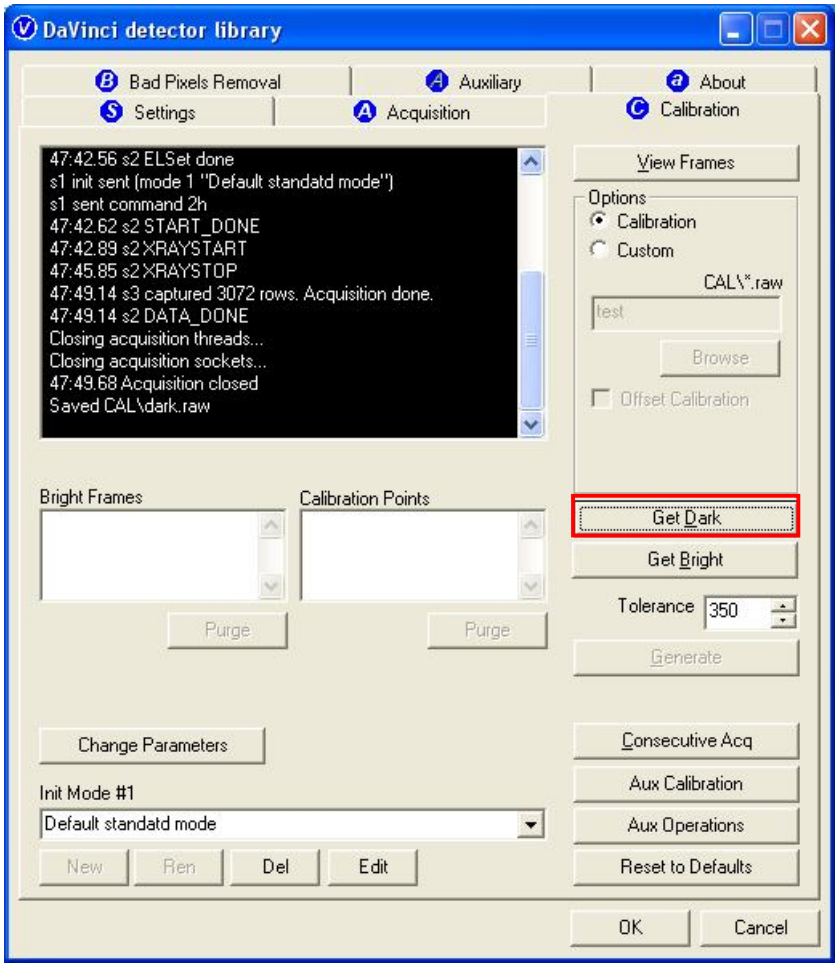


Calibration

Describe the calibration step by step.

1st Step

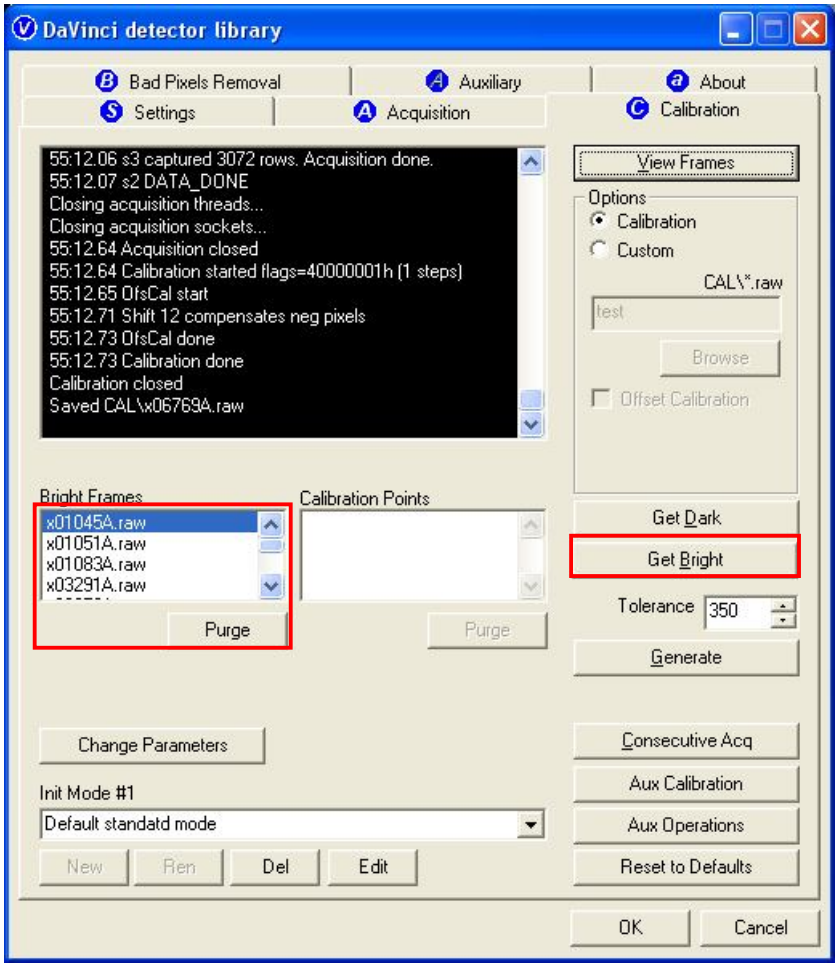
Move to “Calibration” tap, and push “Get Dark” button. Acquire dark frame, the “dark.raw” will be generated at “\cal\” folder.



NOTE 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.

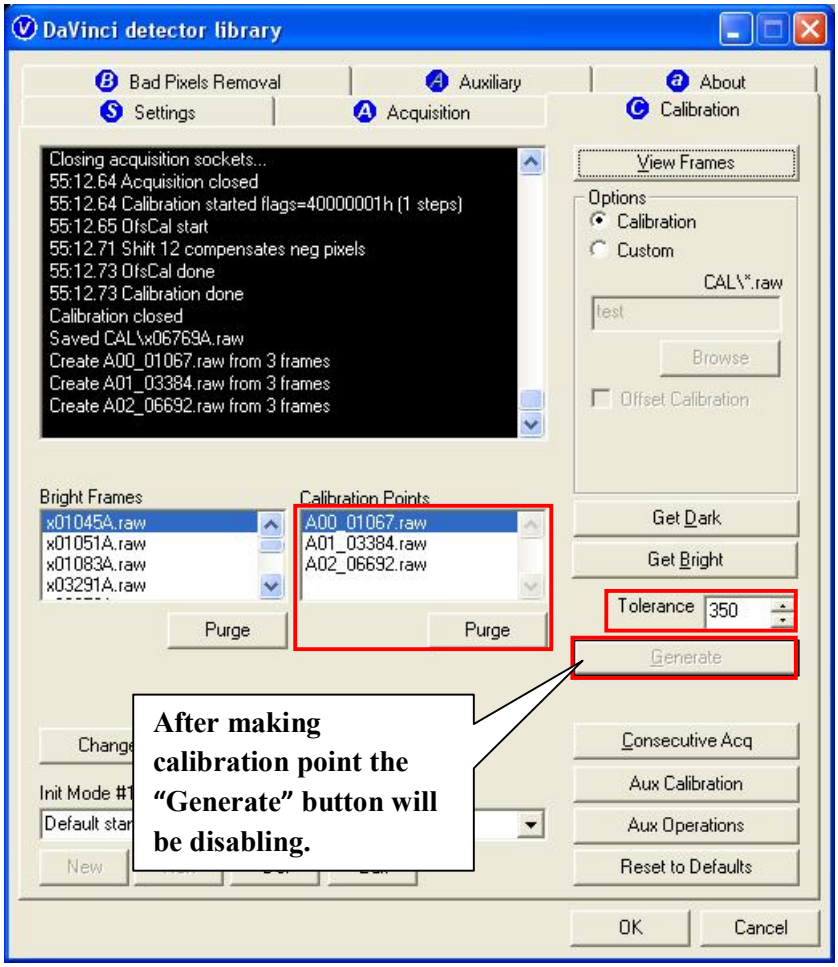
2nd Step

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)



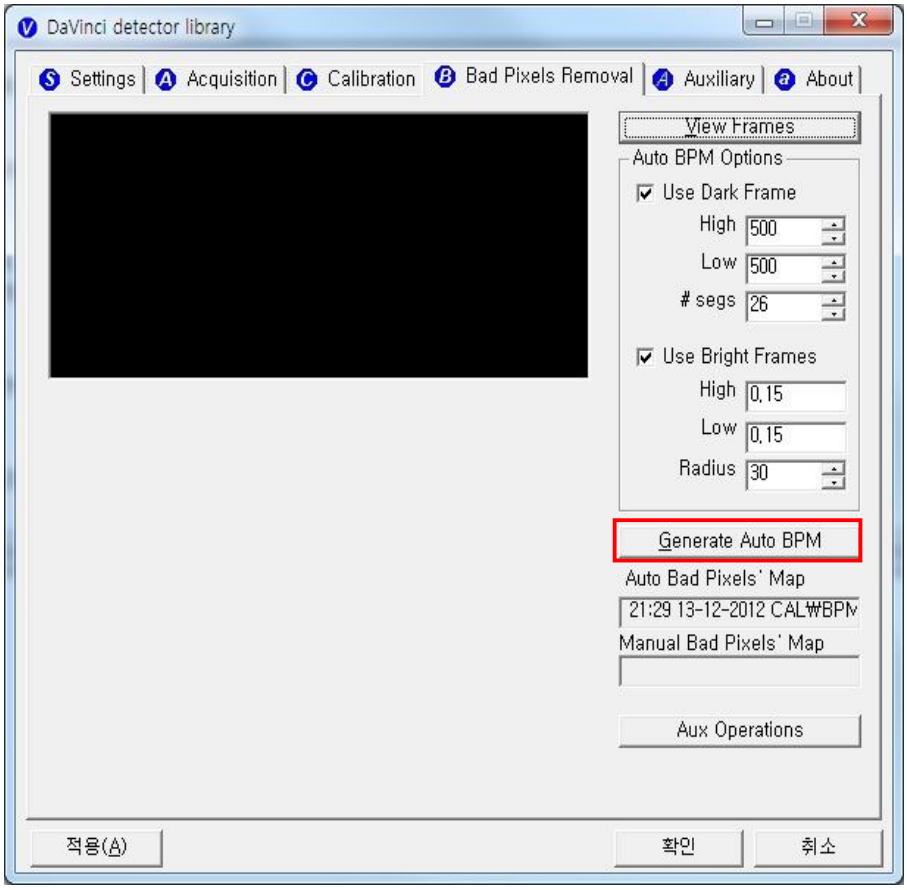
3rd step

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 .

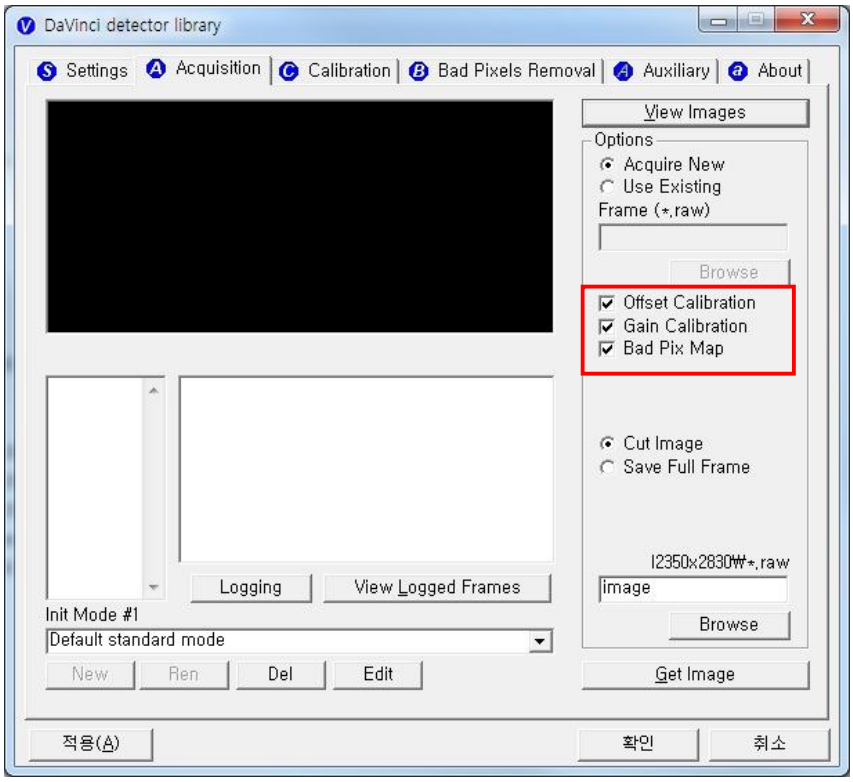


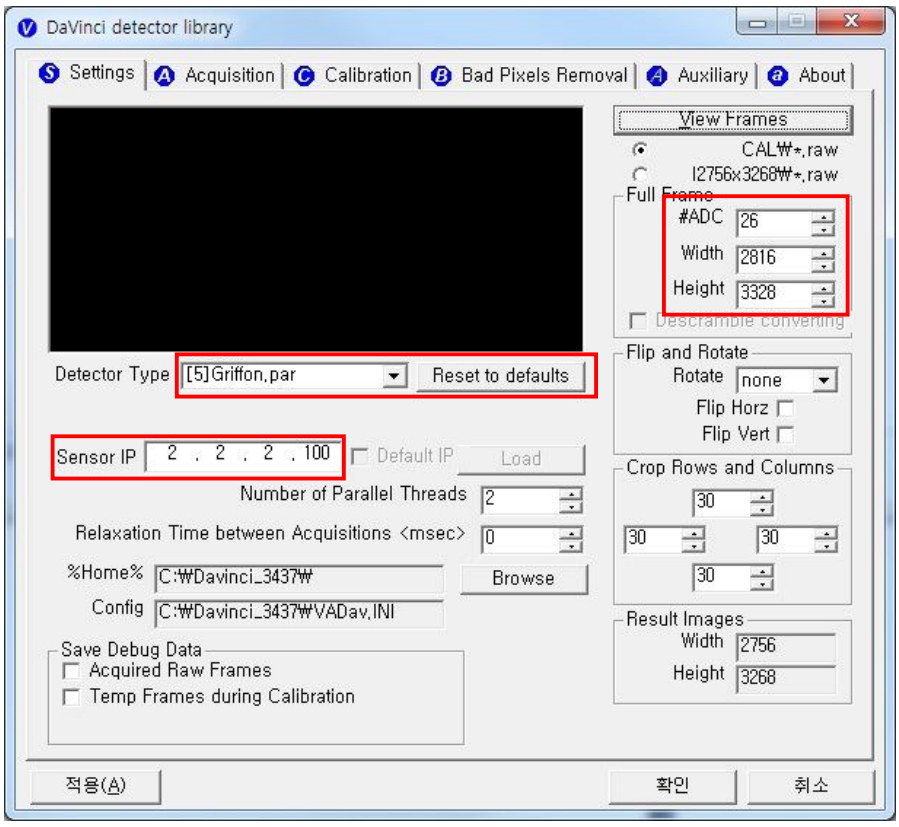
Image Acquisition Test

Program setup

To acquire images, run _vadav.lnk program.

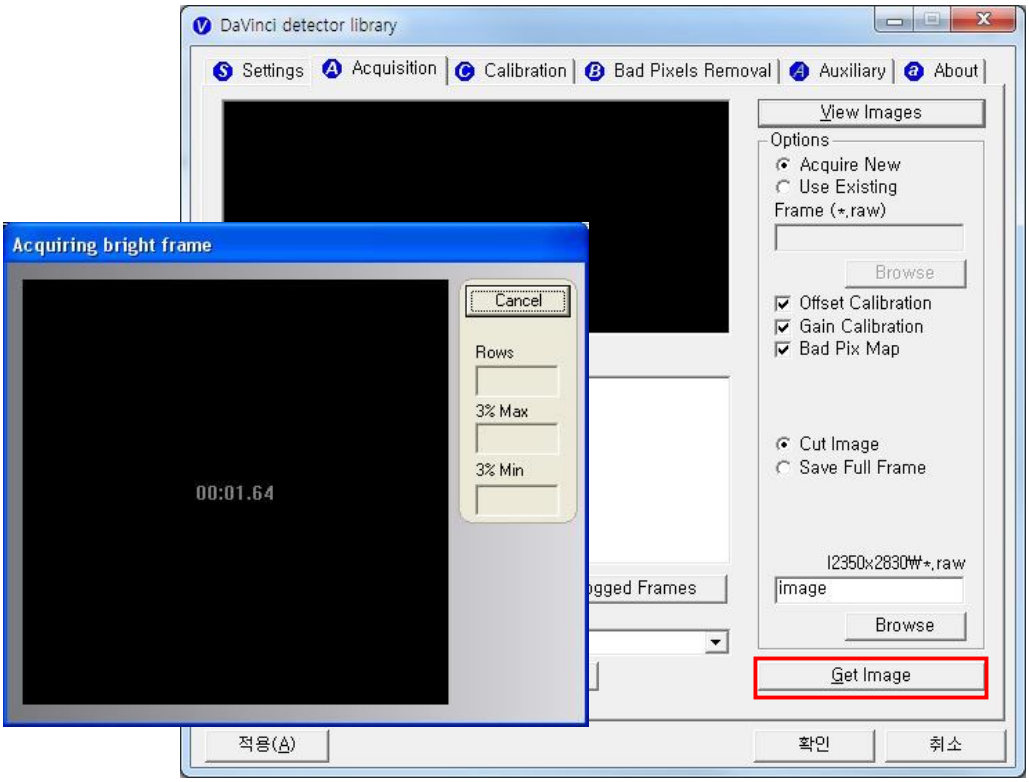
Please set the following figures

- Detector's IP : 2.2.2.100
- Detector's number of ADC : 26
- Detector's size of image : 2816 X 3328



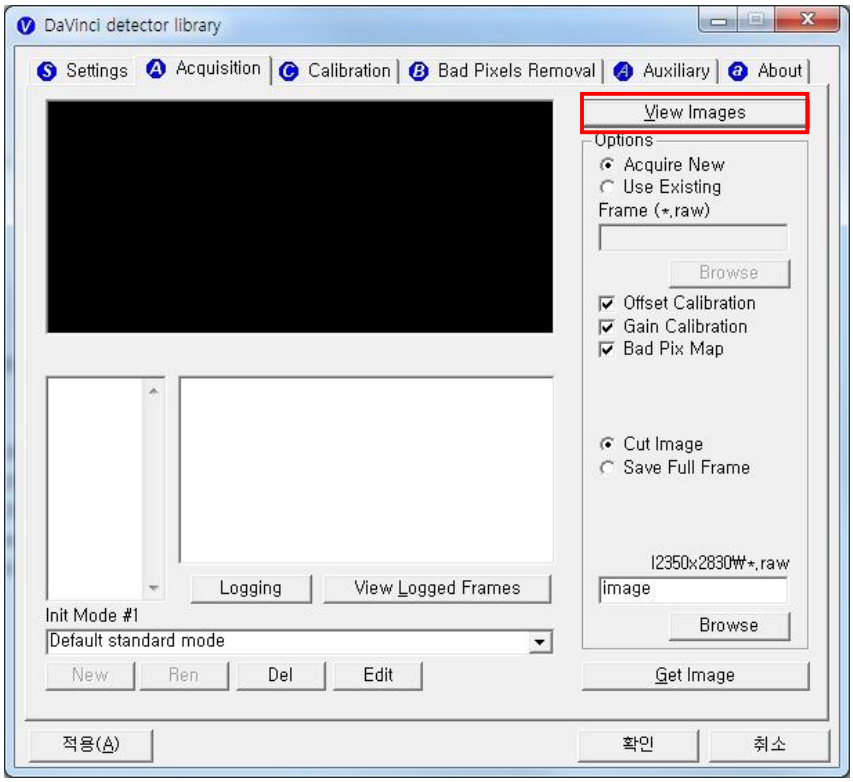
Get Image

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.

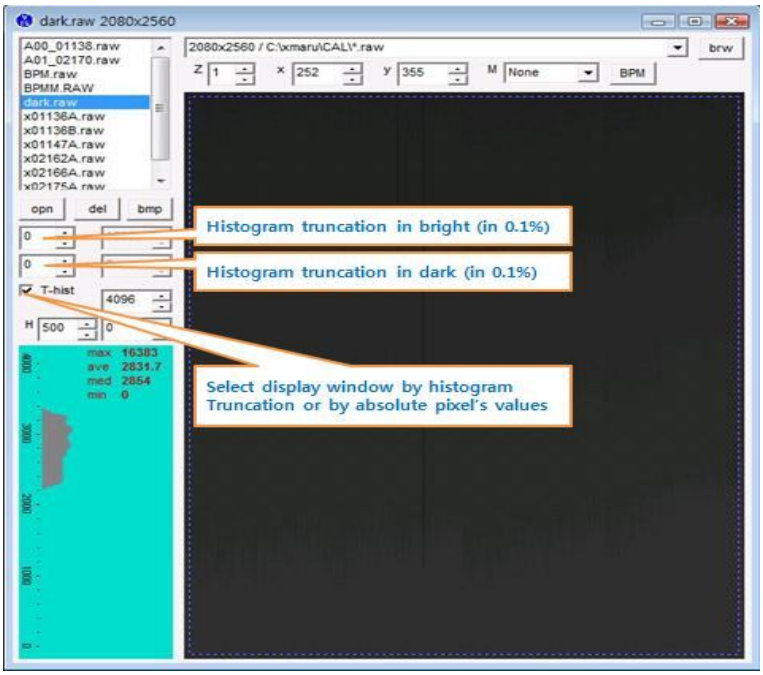


View Images

Frame- and image-files have extension “raw” and contain pixel data in signed 14-bits little-endian format. One could view those files in Photoshop or another image editor.



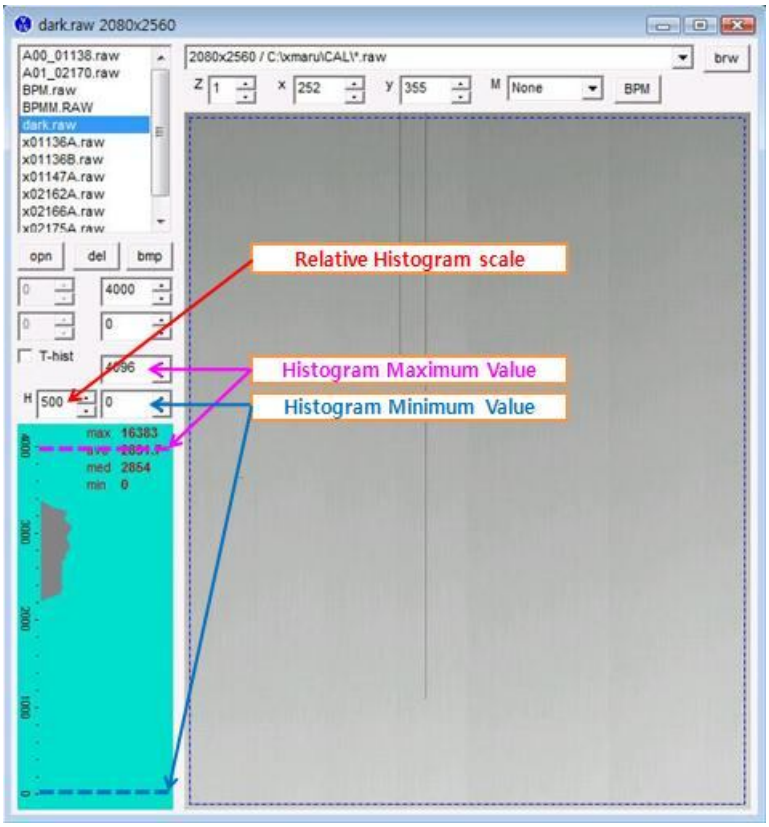
Common controls and displayed statistics



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

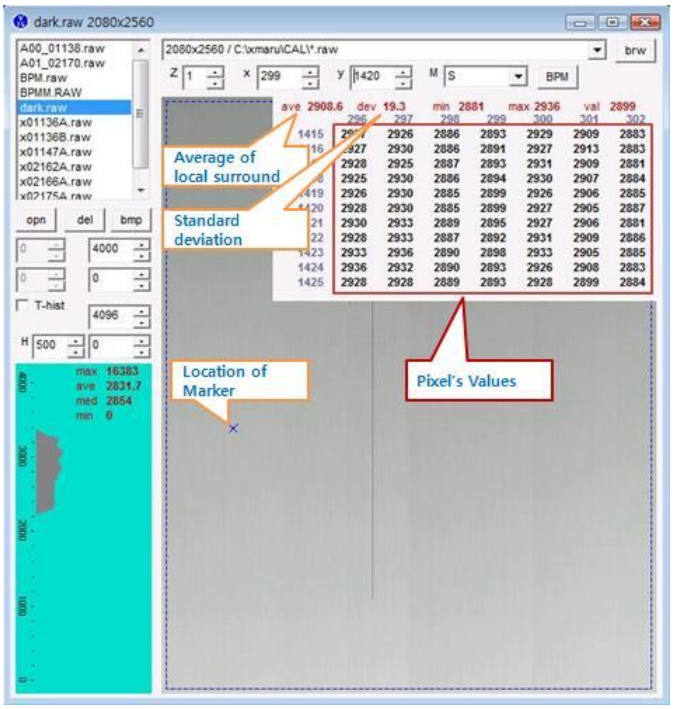
Histogram's presentation

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.



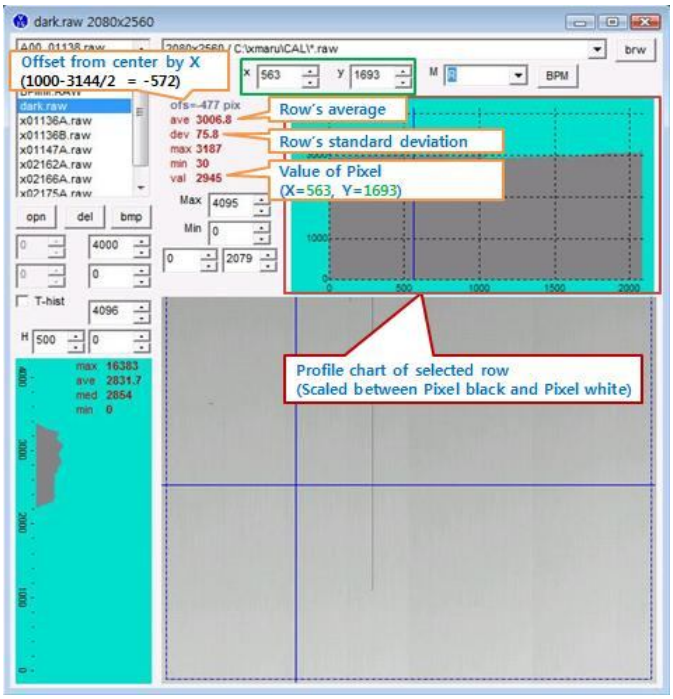
Marker type “S”

Displays local surround of selected location



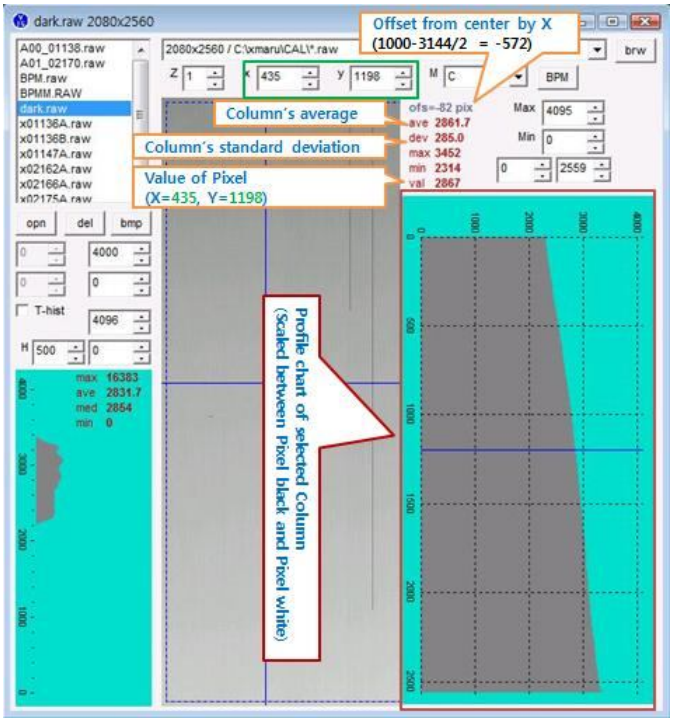
Marker type “R”

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

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 ail 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 ail 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 ail 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
			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.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	V_1=3Vrms	**Recommended separation distance :** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz	E_1=3V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz to 800MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800MHz to 2.5GHz
			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). 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] Interference may occur in the vicinity of equipment marked with the following symbol : 

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=3Vrms Separation Distance (meters)	E_1=3V/m Separation Distance (meters)	E_1=3V/m 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.			

Radio Frequency compliance

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: QIIRY1417WGA**

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 the 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).

To satisfy FCC RF Exposure requirements for mobile and base station transmission devices, a separation distance of 20cm or more should be maintained between the antenna of this device and persons during operation. To ensure compliance, operation at closer than this distance is not recommended.
The antenna(s) used for this transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

-

Maintenance

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.

Cleaning

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.

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.

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.

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

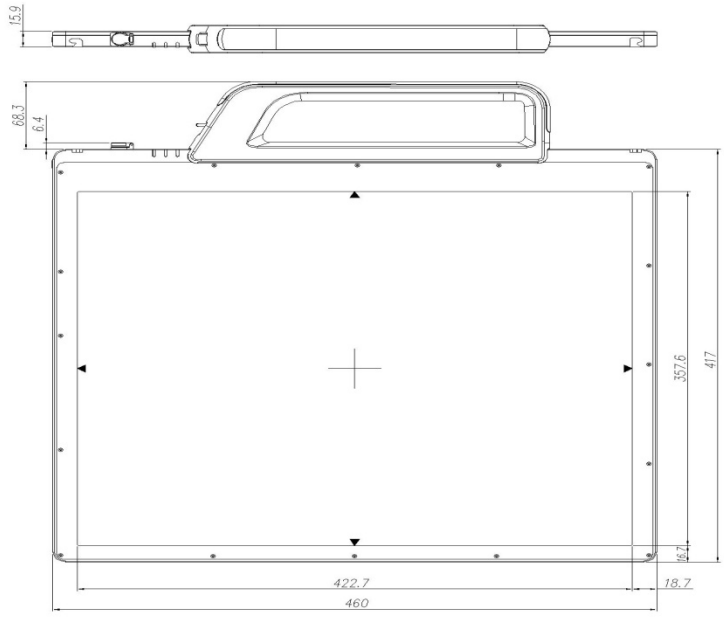
Follow local governing ordinances and recycling plans regarding the disposal or recycling of device components.

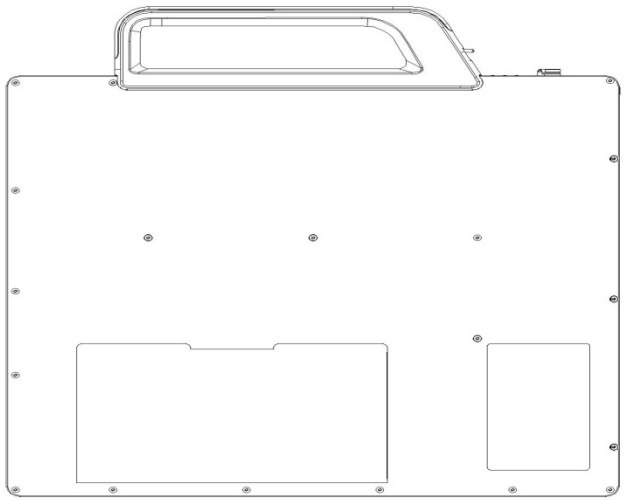
Disposal of old Electrical & Electronic Equipment

(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

1417WGA

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