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SAMSUNG Flat-Panel X-Ray Detector

MODEL NO.: LLX240AB01

User Manual

Samsung Mobile Display Co., Ltd.

This manual is provided for the installation and operation of LTX240AA01-A.

Please read this manual before the detector install and use.

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CAUTION : <u>United States federal law restricts this device to use</u> <u>by or in the order of a physician.</u>

Indication for use

LLX240AB01 Digital Flat Panel X-ray Detector is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.

Samsung Mobile Display Co., Ltd.

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.

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Introduction

Overview

LLX240AB01 is an X-ray image acquisition device that is based on flat-panel. This device should be integrated with an operating PC and an X-ray generator. It can do to utilize as digitalizing X-ray images and transfer for radiography diagnostic.

Product features



Figure 1: LLX240AB01

The surface of housing is made of the metal and X-ray window area is covered with carbon. Inner circuit of detector uses lead to protect it from X-ray and has a structure protecting the inner circuit from X-ray dose under the limits

- Based on a-Si TFT active matrix
- Wide image
- 14-bit digital output
- Easy integration

Product components

Detector (LLX240AB01)



Power Supply (SPS01)

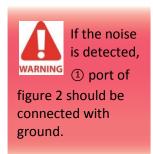


- Cables
 - Detector and power supply link cable (10m)
 - X-ray enable cable (10m)
 - Ethernet cable for communication (10m)
 - AC power supply cord
- Installation CD which contains software for operation and manual
 - Manual (User, Service)



Printed final test report

Components Description



Detector

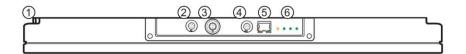


Figure 2: Detector

Number	Description
1	Grounding bolt (There is no extra cable)
2	Main board power connector (DC)
3	AC power connector (AC 100V) (Caution high voltage)
4	X-ray enable connector
(5)	Ethernet port for transmitting the image/command between detector and PC
6	Four LEDs to display the status

Power Supply

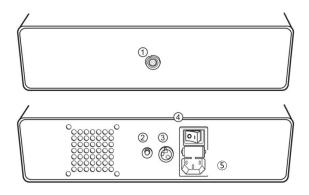


Figure 3: Power supply

Number	Description	
1)	Power connector for detector operating Both direct and alternating current	
2	Light up at 5V operating in power supply	
3	110V / 220V select switch – 110V or 220V select (Within 100~120V, 200~240V range)	
4	Input Power I on / O Power off by main power switch	
(5)	Connect with AC power supply cord Direct current Protective Earth (Ground)	



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.

Power Supply

Power Supply must separate users and patients before connecting cable.

Be sure to turn OFF the power of each instrument before connecting or disconnecting the cables. Also, do not handle them with wet hands. Otherwise, you may get an electric shock that may result in death or serious injury.

Be sure to hold the plug or connector to disconnect the cable.

If you pull the cable, the core wire may be damaged, resulting in fire or electric shock.

Do not cut or process the cables. Also, do not place anything heavy, including the instrument on it, step on it, pull it, bend it, or bundle it. Otherwise, the cable may be damaged, which may result in fire or electric shock.

Do not turn ON the system power when condensation is formed on the instrument. 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 it 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 VATECH 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. Never use benzene, thinner or any other flammable cleaning agents. Otherwise, fire or electric shock may result.

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, 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.
- 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 is put in the case. Otherwise they could trip over, resulting in injury

Power Supply

Because the instrument's cable is long, take care so cables do not get tangled during use. Also, be careful not to get your feet caught in the cable.

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.

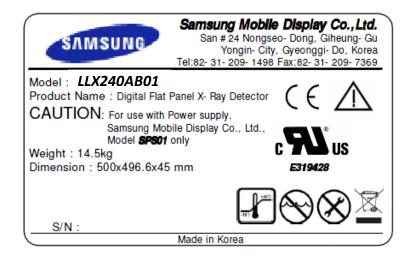
Marking and labeling symbols

Symbols

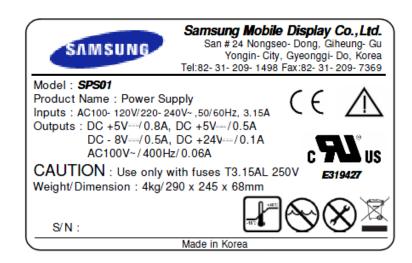
Symbols	Meaning
~	Alternate current
\triangle	Attention
	Protective earth (Ground)
0	Power off (disconnect from the main switch)
	Power on (connect to the main switch)
===	Direct current
\sim	Both direct and alternating current
EC REP	EC Representative
0120	CE symbol grants the product compliance to the European Directive for Medical Devices 93/42/EEC as a class II a device. Authorized by Notified Body SGS (code no.:0120) of British

Labels

- Detector



- Power Supply



Technical Features

Mechanical Features

Dimension and Weight

Component	(W x L x H)	Weight
Detector	500 x 497 x 45mm	13.4kg
Power Supply	288 x 245 x 67 mm	4 kg



Fixation

Position of fixation – Refer to the drawing (Appendix.1)

Electrical Features

Power requirements

AC100-120V/200-240V~50/60Hz, 3.15A

The main power fuse is a 3.15A, 250V~ Type T fuse

(For North America - For 120 Volt applications, use only UL Listed detachable power cord with NEMA configuration 5-15P type (parallel blades) plug cap. For 240 Volt applications use only UL Listed Detachable power supply cord with NEMA configuration 6-15P type (tandem blades) plug cap)

Power supply Connector

Supply power	Input range	Current consumption
DC5V	-0.2V, +0.3V	800mA
DC5V	-0.2V, +0.3V	500mA
DC24V	-1.5V, +0.5V	100mA
DC-8V	±0.5V	500mA
AC100V(400Hz)	±10V(±20Hz)	60mA

X-ray enable cable

LEMO(EGG.1B.308) (PIN)	PIN Description	
1	SPARE	
2	SPARE	
3	READY DONE	
4	READY DONE COM	
5	READY IN	
6	CANCEL IN	
7	12V ~ 24VDC	



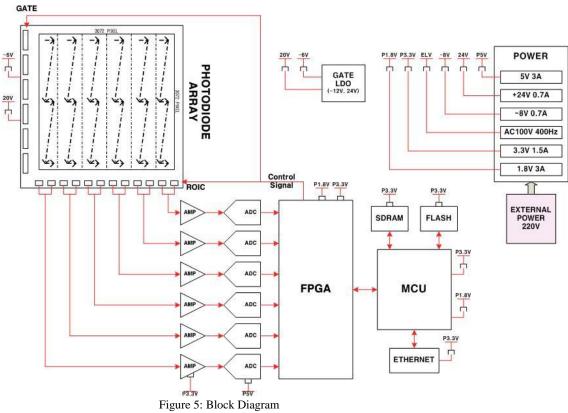
Figure 4:X-ray enable cable

Ethernet Connector

Data transmission using port 5 in figure 2, 10/100Mbps Ethernet (TCP/IP)

Functional Specific Features

Block Diagram



General Rating

Parameter	Unit	Specification
Model	-	LLX240AB01
Sensor type	-	a-Si TFT
X-ray convertor	-	Gd ₂ O ₂ S:Tb
Application	-	General Radiography
Dimension(W x L x T)	mm	500x497x45
Weight	kg	13.4
Pixel size	μm	143
Active area	mm	439.3x439.3
Active array	pixles	3072x3072
Effective area	mm	429x429
Effective array	pixels	3000x3000

Specification

Parameter	Unit	Specification
Model	-	LLX240AB01
A/D	bits	14
Frame rate	fps	240 fph
Dynamic Range	dB	> 73
ADC resolution	bits	14
Spatial Resolution*1	lp/mm	3.5
Sensitivity* ²	LSB/µGy*3	> 80
Energy range	kVp	40 ~ 150

^{*1:} line pair resolution at over 10% MTF

Software Features

Use the 100Mbps Ethernet to enhance compatibility of interface and to transmit the control signal and data

< Functions supported by software >

- LED Check : built-in function checking for the indicator LEDs
- Version check function (Scintillator, panel, board, firmware versions can be checked)
- EL status check and correction
- Readout and gate IC check
- test pattern generation

^{*2:} under RQA5 condition

^{*3: 1}mR=8.69µGy

Environmental requirement

The detector must be operated within the specified temperature and humidity in order to maintain its optimum performance.

Parameter	Specification	
Operation condition	Temperature : $+10 \sim +40$ °C Humidity : $20 \sim 75\%$ (no condensation) Pressure : $70 \sim 106$ kPa	
Storage condition	Temperature : -25 ~ +55 °C Humidity : 10 ~ 95 %(no condensation) Pressure : 70 ~ 106 kPa	

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
- Upper than Intel(R) PRO/100 VE Network card
- OS: Windows XP professional

Installation

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. Therefore it must be grounded by ESD protection equipment before it is installed in operational place. 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.

Caution

Cable Bending Radius is limited by six times of cable's diameter. If you bend a cable over six times of cable's diameter, it is able to make damage to cable.

Connection



Figure 6: Detector



Figure 7: Power supply

Power & Ethernet Connection

- Connect the detector and power supply link cable from the power supply(⑤) to the Detector (⑥, ④)
- Connect the ethernet cable from the detector (1) to the console PC.

Transmission speed may be different with PC performance so it is recommended to use a 100 Mbps switching hub.

X Frame ground needed.

X-ray Enable Connection

 Connect the X-ray enable cable from the detector (②) to the X-ray generator.

Connection description

Signal	Label	Input / Output
READY IN	+12V ~ +24V	Input
	READY IN	Input
READY DONE	READY DONE	Output
	READY DONE COM	Output

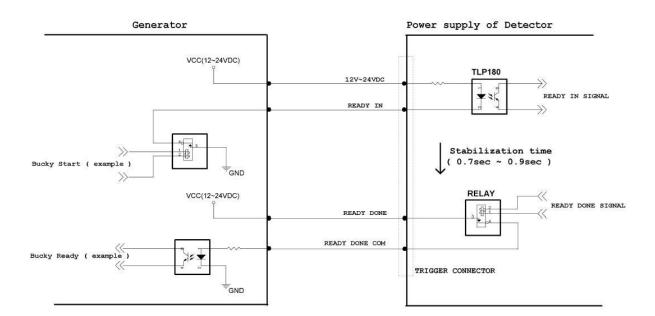


Figure 8: Generator & detector connection

Operating description

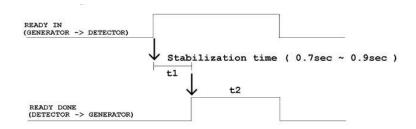


Figure 9: Timing chart

t1 : Offset stabilization time (0.7Sec ~ 0.9sec)

t2: Window time (Editing parameter: Exposure Time)

Operating step

1st step: Generator sends "READY IN" signal to the detector

2nd step: Detector waits for offset stabilization during "t1" second

3rd step: Detector sends "READY DONE" signal to the generator

4th step: Generator makes X-ray exposure in "t2" second (the maximum exposure time is "t2")

Edit parameter in "Functions"

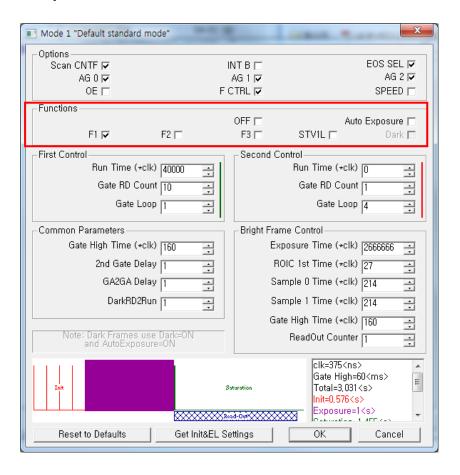


Figure 10: Function edit

IP set up

<Console PC>

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

- → [Properties] → [Internet Protocol (TCP/IP)]
- → [Use the following IP address]

IP address: 192.168.1.20 (Console PC)

X Detector IP address is 192. 168. 1. 80 (default)

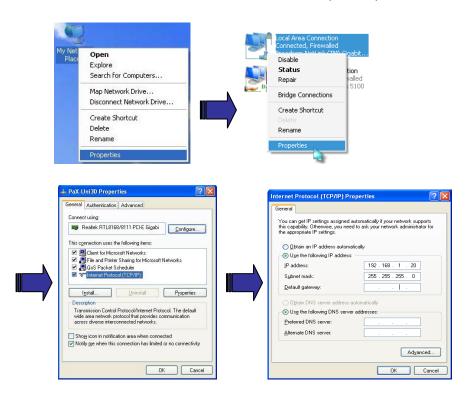


Figure 11: IP set up

X It is possible to change IP address, but it shouldn't be the same as the detector IP address.

Checking Connection

- Check LED on the detector & power supply
- Ping test : [Start] → [Run] → ping –t 192.168.1.80

Power on Sequence

Step	Action
1	Turn on the Console PC and allow it to boot up
2	Turn on the power switch on the power supply The connection must be done before turn on the power supply
3	The LED on the power supply is illuminated when turn on the Power supply
4	The LED's power, Frame, and run are illuminated on the right Side of the detector
5	The LED's power, Frame, and run are illuminated on the right side of the detector
6	Set the host IP address of the PC, 192.168.1.xxx
7	The LLX240AB01 is ready (see below fig.)



Figure 12: Detector cable connection

Description of Detector indicator



Figure 13: LED indicator

LED	Description			
Main Power indicator (a)	Normal: ON Abnormal: OFF			
Not use (b)	Normal: OFF			
Not use (c)	Normal: OFF			
CPU indicator (d)	Normal: Blinking Abnormal: Always on or OFF			

Calibration



X-ray detector should be

used in a stable state within operating temperature range. Acquire X-ray images after powered on and warmed up for 30 minutes to obtain high quality images.

General Principle

Notation

Calibration can be done by image acquisition software. The gainoffset 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 '6200' 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 adjust the gain correction the bright frame and dark frame should be acquired. Only one dark frame is needed. Acquire more than three bright frames at three different levels of median values. The recommended tube energy level is 70kVp with variable tube current and exposure time. Acquire at least 3 frames at same condition is recommended. The median values of bright frames are below.

Point	1	2	3	4	5	6	7	8
Median Value	850~	1850~	2850~	3850~	5850~	7850~	9850 ~	11850~
[LSB]	1150	2150	3150	4150	6150	8150	10150	12150

Table 1: Median value

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).

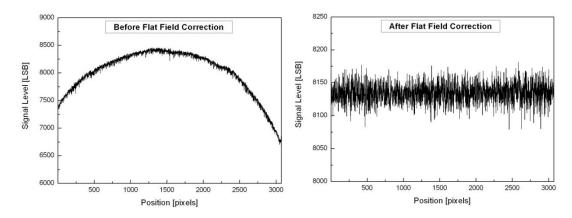


Figure 14: Comparison of flat field correction processing

Calibration

Description of calibration step by step.

1st Step

Click the "Calibration" tab and then click on the "Get Dark" button. The acquired dark frame "dark.raw" will be generated in the "\cal\" folder.

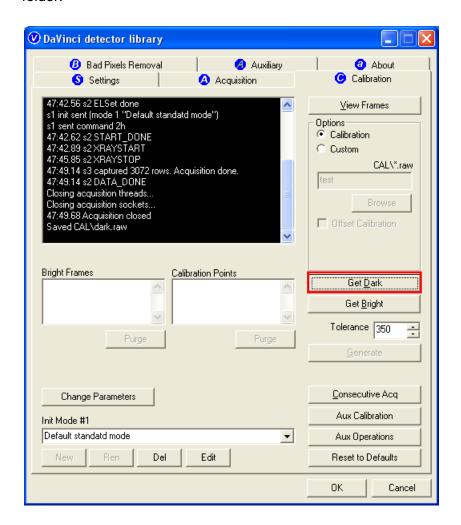
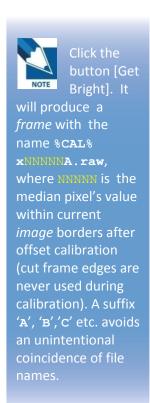


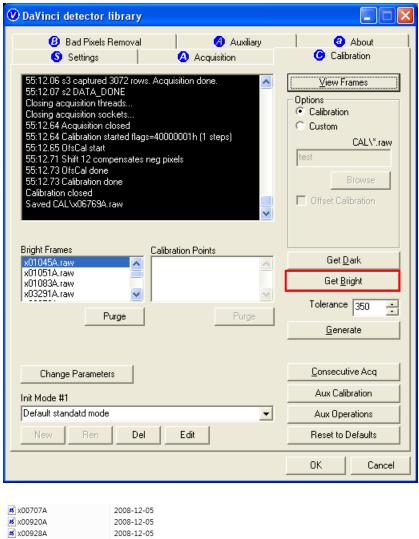
Figure 15: Get dark



2nd Step

Click the "Get Bright" button at six different

levels of X-ray conditions. The X-ray condition should be set or tested beforehand, same as the level of '1.2'. Click the "Get Bright" button at least 3 times for each set of conditions, and then the offset subtracted bright (gain) is generated with a filename of "x 'median value of gain' A".(Refer to NOTE)



 8 x00707A
 2008-12-05

 8 x00920A
 2008-12-05

 8 x00936A
 2008-12-05

 8 x01121A
 2008-12-05

 8 x01198A
 2008-12-05

 8 x01464A
 2008-12-05

 8 x01483A
 2008-12-05

 8 x01505A
 2008-12-05

 8 x02072A
 2008-12-05

Figure 16: Get bright.

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.

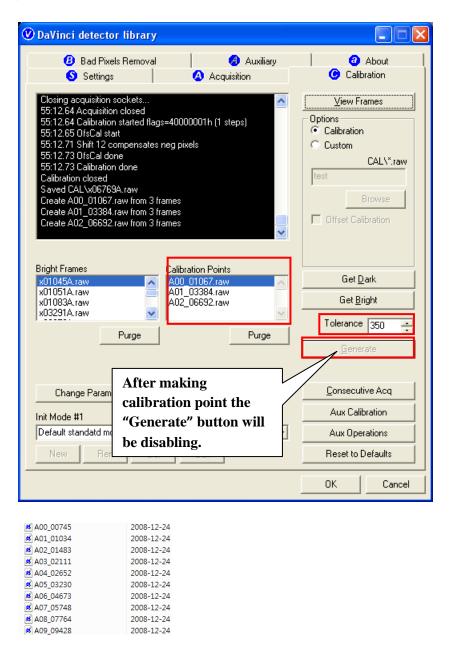


Figure 17: Generate

4th step

After 3rd step, change to the Bad Pixels Removal tab, Click the button "Generate Auto BPM", and then Defect Map will be generated of which the file name is "BPM.raw "in the "\cal\" folder.

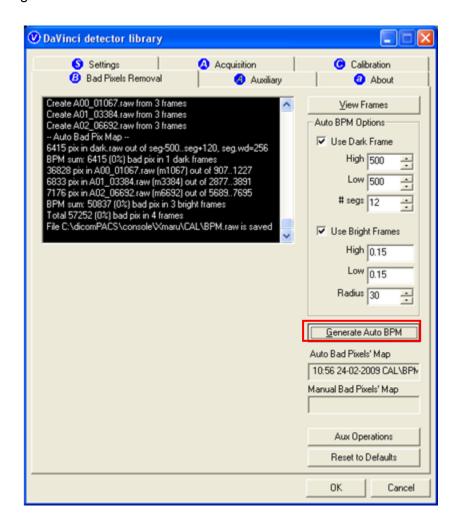


Figure 18: Bad pixels removal

5th step

For additional Defect correction, if "BPMM.raw" exists on the install CD, copy it to the "\cal\" folder.

6th step

On the Acquisition tab, check the box "Offset Calibration", "Gain Calibration", and "Bad Pix Map" to activate each calibration and Bad Pixels Removal, otherwise it will not work when it goes to pre-processing.

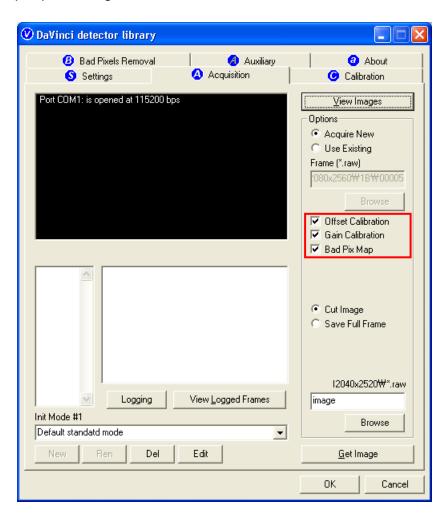


Figure 19: Application of calibration

Image Acquisition Test

Program setup

To acquire images, run Vadav. Exe program.

Please set the following figures

Detector's IP: 192.168.1.80

Detector's number of ADC : 6

Detector's size of image: 3072 X 3072

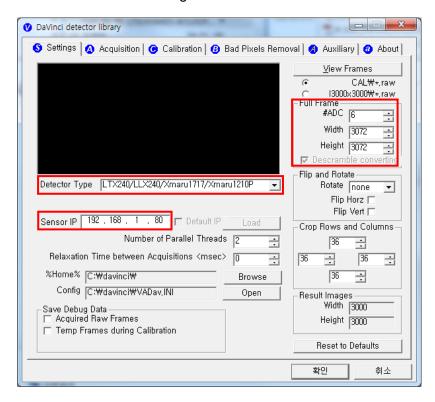


Figure 20: Setup

Get Image

On the Acquisition tab, click the "Get Image" button to get an image. After clicking the button, you will see a pop-up window, which displays in the window the time and process of acquiring the image.

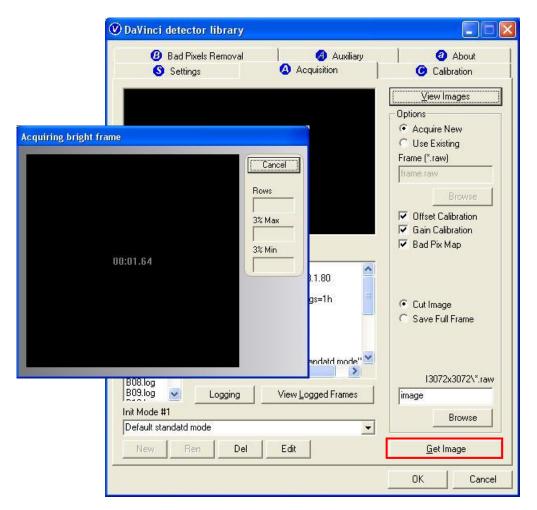


Figure 21: Get image

View Images

Frame and image files have the extension "raw" and contain pixel data in signed 16-bits little-endian format. These files can be viewed in Photoshop or another image editor.



Figure 22: View images

Common controls and displayed statistics

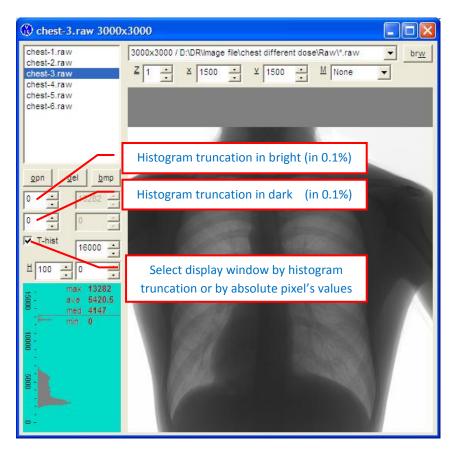


Figure 23: Description of viewer 1

- 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 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.

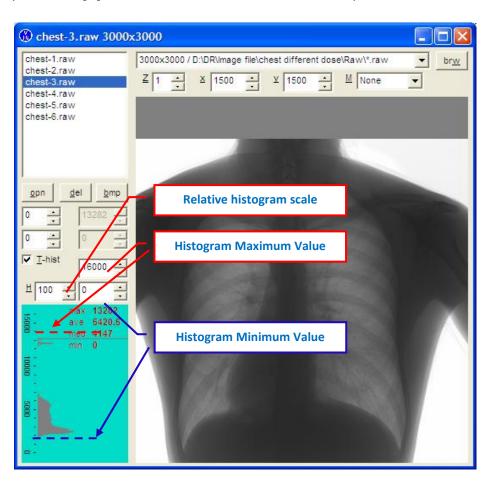


Figure 24: Description of histogram

Marker type "S"

Displays local surround of selected location

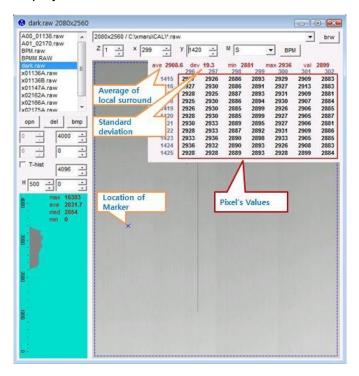


Figure 25: Description of marker type "S"

Marker type "R"

Display profile chart of a row.

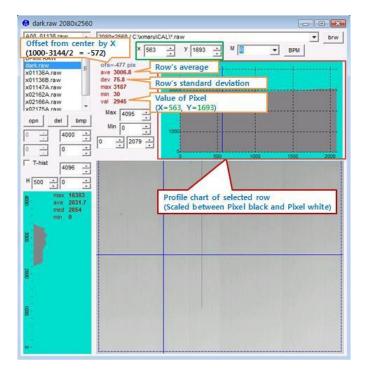


Figure 26: Description of marker type "R"

Marker type "C"

Display profile chart of a column.

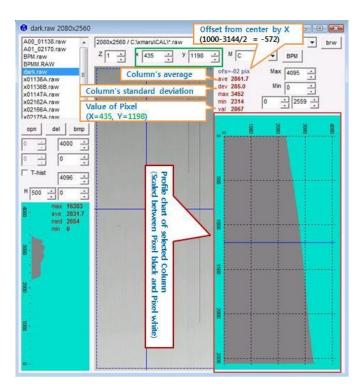


Figure 27: Description of marker type "C"

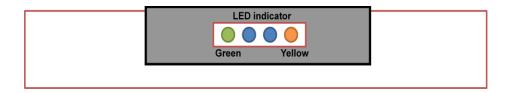
Operation

Recommendation

X-ray detector should be used in a stable state within operating temperature range.

Acquire X-ray images after powered on and warmed up for 30 minutes to obtain high quality images.

Switching power on / off



After turn on the main power switch of the power supply check the four LED indicators. MCU status is OK If the yellow light of the LED is blinking.

- 1) Verify the AC power and set the voltage Select software
- 2) Power switch ON
- 3) If external power supply is OK, then the green light of the LED will be ON
- 4) 3 seconds later, the yellow light of the LED will blink showing that the MCU is working properly.
- If not, power OFF in advance and power ON again after 10 seconds
- 5) If it is linked with the Console PC in order, LED of Ethernet port will light up and twinkle

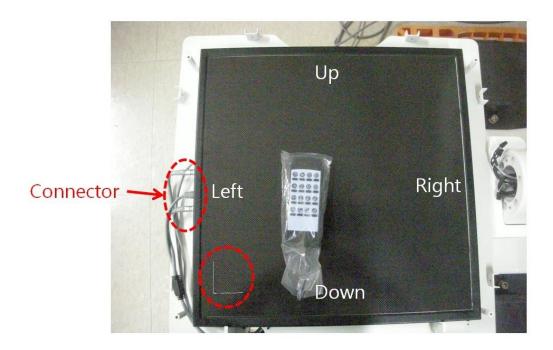
Initialization

Initial data is stored in MCU (Linux) inside of detector and driven by stored parameter data.

The stored initial parameters can be changed in software.

Arrangement

Connectors of detector is left side when acquire image like below.



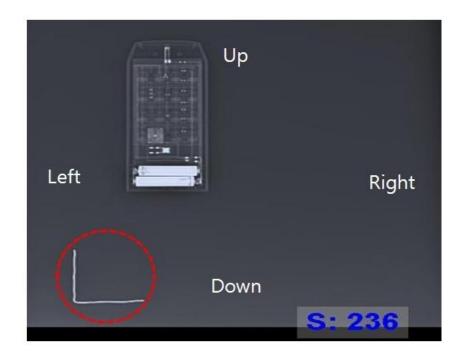


Figure 28: Arrangement

Image acquisition

Refer to the software manual

Safety 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
- Degree of protection against electric shock: Not classified no applied parts
- 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 anesthetics or oxygen.
- Mode of operation: continuous operation
- Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC601-1
- Power supply(SPS01) has tested by IEC 60601-1 standard.

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% UT (>95% dip in Uτ) for 0.5cycle 40% UT (60% dip in Uτ) for 5 cycle 70% Uτ (30% dip in Uτ) for 25 cycle <5% Uτ (<95% dip in Uτ) for 5 s	<5% UT (>95% dip in Uτ) for 0.5cycle 40% UT (60% dip in Uτ) for 5 cycle 70% UT (30% dip in Uτ) for 25 cycle <5% UT (<95% dip in Uτ) 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 UT 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	Compliance	Electromagnetic environment - guidance
inimumity tost	60601-1-2	level	Electromagnetic environment guidance
	test level		
			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	3 Vrms		Recommended separation distance :
IEC 61000-4-6	150 kHz to 80MHz	V ₁ =3Vrms	$d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$
	OOIVII 12		V ₁
Radiated RF	3 V/m		
IEC 61000-4-3	80 MHz to 2.5GHz	E ₁ =3V/m	, , 3,5, / , , , , , , , , , , , , , , , , ,
	2.50112		$d=[rac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
			7 —
			$d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz
			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 deter-
			mined by an electromagnetic site survey,
			should be less than the compliance level in each
			frequency range. Interference may occur in the vicinity of equipment
			marked with the following symbol :
			(1, 1)
			(((<u>*</u>)))
			`

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.

Over the frequency range 150kHz to 80MHz, field strengths should be less than [V,] 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	V ₁ =3Vrms	E ₁ =3V/m	E ₁ =3V/m				
[W]	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

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.

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.

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	Compliance	Electromagnetic environment - guidance
· ·	Test level	level	
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. 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.

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.

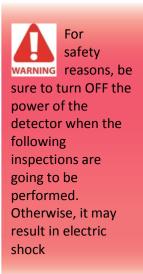
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an

Maintenance

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

Maintenance

- Maintenance of the detector does not directly. Maintenance should be gone 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.



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 the problem still cannot be corrected, please contact VATECH 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.

Daily Inspection

A. Before Turning ON the Power

			Result		
	Inspection	Date /	Date /	Date /	Action
Cable	Check that cables are not damaged or cover of cables is not torn.	Good/ Bad	Good/ Bad	Good/ Bad	Contact VATECH or distributor if there is any problem.
Cable	Check that the plugs and locks of connectors are not loose.	Good/ Bad	Good/ Bad	Good/ Bad	Contact VATECH or distributor if there is any problem.
Detector	Check that the cover or parts are not damaged and not loose.	Good/ Bad	Good/ Bad	Good/ Bad	Contact VATECH or distributor if there is any problem.

B. After Turning ON the Power

Perform the following inspection with the detector power supply.

		Result			
	Inspection	Date /	Date /	Date /	Action
General	Check the LED indicator	Good/ Bad	Good/ Bad	Good/ Bad	Connect the power cable

Monthly Inspection

Perform the following inspection periodically at least once a month. Contact VATECH representative or distributor if there is any problem or if you cannot do it.

		Result			
	Inspection	Date /	Date /	Date /	Action
General	Check the performance of the instrument by performing exposures using a phantom or a resolution chart	Good/ Bad	Good/ Bad	Good/ Bad	Contact VATECH or distributor if there is any problem.

Yearly Inspection

Perform the following inspection periodically at least once a year. Contact VATECH representative or distributor if there is any problem or if you cannot do it.

		Result			
	Inspection	Date	Date	Date	Action
		1	1	1	
General	Check the performance of the instrument by performing exposures using a phantom or a resolution chart	Good/ Bad	Good/ Bad	Good/ Bad	Contact VATECH or distributor if there is any problem.

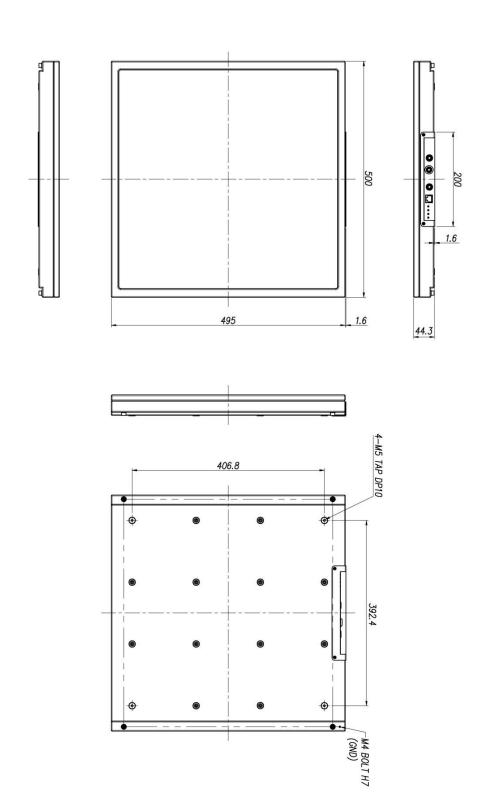
Warranty Seal

Do not remove warranty seal, or the warranty will expire.



Appendix

Dimension (Detector)



Dimension (Power Supply)

