Digital Radiography System

MAXXray User Manual

(for veterinary use)

Rev 0.0

Vieworks Co., Ltd.
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Revision History

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Accident Reporting

The CE Council Directive 93/42/EEC concerning Medial Devices require that "the manufacturer of medical devices submit a report to Local competent authorities whenever he becomes aware of information that reasonably suggests that one of his installed devices:

- may have caused or contributed to a death or serious injury, or
- has malfunctioned and, if the malfunction recurs, is likely to cause or contribute to a death or serious injury.

In order for Vieworks to comply with these requirements, all users of this equipment, operators and service technicians, are required to provide the Quality Assurance Manager at Vieworks with the following information regarding all reportable events as soon as possible:

1) Identification of the model and serial number.
2) Description of the event. Including whether any serious injury or death has been occurred.
3) Identification of the person who is submitting the information including phone number and fax number if available.

Reference to standards

EN60601-1	Medical electrical equipment **Part 1: general requirements for safety**
EN60601-1-1	Medical electrical equipment **Part 1: General requirement for the safety Collateral standard : Safety requirement for medical electrical systems**
EN60601-1-2	Medical electrical equipment **Part 2: electromagnetic compatibility–requirements and tests**

Authorized representatives

If you have any accident, please contact the authorized representatives

Table of Contents

1. Safety

1.1 Safety Guidelines

⚠ Caution

Always be alert when operating this equipment. If a malfunction occurs, do not use this equipment until qualified personnel correct the problem.

This Product was designed and manufactured to ensure maximum safety of operation and to meet all the safety requirements applicable to electronic medical equipment. However, anyone attempting to operate the system must be fully aware of potential safety hazards. It should be operated and maintained in strict compliance with the following safety precautions and operating instruments contained herein:

1) The product should be installed, maintained and serviced according to Vieworks maintenance procedures and by Vieworks personnel or other qualified maintenance personnel approved in writing by Vieworks. Operation and maintenance should be done in strict compliance with the operation instructions contained in the manuals.

2) The system, in whole or in part, cannot be modified in any way without written approval from Vieworks.

3) Before authorizing any person to operate the system, verify that the person has read and fully understand the Service Manual. The owner should make certain that only properly trained and fully qualified personnel are authorized to operate the equipment. An authorized operators list should be maintained.

4) Prevent unauthorized personnel from access to the system.

5) It is important that this Service Manual be kept at hand, studied carefully and reviewed periodically by the authorized operators.

6) The owner should ensure continuous power supply to the system, with voltage and current according to the product specifications. If power failures are not infrequent, a UPS(Uninterrupted Power Supply) should be installed to avoid loss of data.

7) If the product does not operate properly or if it fails to respond to the controls described in this manual, the operator should immediately contact Vieworks field service representative, report the incident and await further instructions.

8) The images and calculations provided by this system are intended to be used as tools for the competent user. They are explicitly not to be regarded as a sole incontrovertible basis for clinical diagnosis. Users are encouraged to study the literature and reach their own professional conclusions regarding the clinical utility of the system.

9). The user should be aware of the product specifications and of the system's accuracy and stability limitations. These limitations must be considered before making any decision based on quantitative values, in case of doubt, please consult a Vieworks representative.

1.2 General Hazards

1.2.1 Radiation hazards

This system can be interfaced to x-ray generating equipment. Be certain to follow the safety instructions and specifications for wearing proper lead shielding when in the presence of x-ray generating equipment.

All personnel must wear dosimeters during all phases of installation, operation and maintenance of the system and the equipment to which it is interfaced.

1.2.2 Electric shock hazard

A three conductor AC power is supplied with this system to provide the proper electrical grounding. To minimize the shock hazard, the power cable must be plugged into a UL-approved three-contact electrical outlet.

Do not remove or open system covers or plugs. The internal circuits of the system use high voltages that can cause serious injury or death from electrical shock. The operator should never be allowed to open the panels of the system.

1.2.3 Explosion Hazard

Do not operate the equipment in the presence of flammable or explosive liquids, vapors or gases. Do not plug in or turn on the system in hazardous substances are detected in the environment.

If flammable substances are detected after the system as been turned on, do not attempt to turn off the system or unplug it. Evacuate and ventilate the area before turning the system off.

1.2.4 Implosion Hazard

Do not subject the system to serious mechanical shocks, as the cathode ray tube(CRT) can explode if struck or jarred. This may result in flying pieces of glass and coating that can cause serious injury.

1.3 Owner's Responsibility

Caution

Do not use the system if unsafe conditions are known to exist. In case of a hardware failure that could cause hazardous conditions(smoke, fire and etc), turn the power OFF and unplug the power cords of all subsystems.

The owner is responsible for ensuring that any one using the system reads and understand the Service Manual and other relevant literature, and fully understands them. Vieworks makes no representation, however, that the act of reading this manual renders the reader qualified to operate, test and calibrate the system.

1.4 System Diagnostic

The *MAXXrayCalibration* software runs a system diagnostic. Run *MAXXrayCalibration* software when install system or every 1 year after installation.

If an error is detected, report detailed error to Vieworks field service representative.

Caution

The owner is responsible for ensuring that diagnostic of system is performed every year. Do not try to use the system if system diagnostic is fail.

1.5 Calibration

To ensure the optimal performances of the system it is important to verify that system is calibrated.

Caution

The owner is responsible for ensuring that the system calibration is performed at installation time or if the system is repaired. Do not try to use the system if system calibration is not performed.

1.6 Distances measurements

Distances measurements in millimeters are possible only after distance calibration has been performed using a reference object

Caution

The operator is responsible for performing distance calibration with a reference object and verifying the results of the distance calibration before taking any distance measurements on an image.

1.7 Left/Right Marker

The operator is responsible for the correct and clear marking on the left or right side of the image to eliminate possible errors.
The software includes an option to mark the image with L (left) or R (right) indicator from acquisition phase through printing and archiving. If the operator chose, for any reason, not to use L/R markers, he must use an alternative way to eliminate any possible mistake.

1.8 Images Back-up

To avoid the possibility of loosing images, which might result in patient being exposed to additional doses of radiation, it is important to back-up the images by filming or by using the CD or DVD option. This should be done as a routine operation for every patient.
If the hard disk of workstation is about to full, the operator should back-up images and delete the images to make room on hard disk for new patient.

Caution

The operator is responsible for backing-up images of each patient. Do not accumulate images in the system without having a back-up.

1.9 User Limitations

The MAXXvue software has the technician mode, this mode could only be operated with the inputting PASSWORD. The technician mode should be operated by the personnel who is qualified by Vieworks.

1.10 Cleaning the system

Use only isopropyl alcohol to clean surfaces of the system. Do not use detergents or organic solvents to clean the system. Strong detergent, and organic cleaners may damage the finish and cause structural weakening. Do not clean the system with turning the power on.

1.11 Overheating

Do not block the ventilation ports of the detector to prevent overheating of the detector. Overheating can cause system malfunction and damages.

1.12 Electrical fire

- This equipment is not suitable for use in the presence of a flammable an aesthetic mixture with air or with oxygen or nitrous oxide.
- Conductive fluids that drain into the active circuit components of the system may cause short circuits that can result in electrical fire. Therefore, do not place fluids or food on any part of the system.
- To avoid electric shocks and burns caused by use of the wrong type of fire extinguisher, make sure that the fire extinguisher at the site has been approved for use on electrical fires.

1.13 EMI/EMC Precaution

During installation of the system, care must be taken to prevent the potential risk of electromagnetic interference between this equipment and other devices. The device has been tested for EMI/EMC compliance, but interference can still occur in an electromagnetically noisy environment.
Attempt to maintain a suitable distance between electrical devices to prevent cross-interference.

1.14 EMC Information

1.14.1 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 B	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	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

1.14.2 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 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 0.5cycle 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 0.5cycle 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.			

1.14.3 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 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms 150 kHz to 80MHz	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. Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 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,[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 : 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz	3 V/m 80MHz to 2.5GHz	

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.

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

The 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.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150kHz to 80MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80MHz to 800MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800MHz to 2.5GHz $d = [\frac{7}{E_1}]\sqrt{P}$
	V_1=3Vrms	E_1=3V/m	E_1=3V/m
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 metres (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.

1.14.5 Immunity and Compliance Level

Immunity test	IEC 60601 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

1.14.6 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 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms 150 kHz to 80MHz	The EUT must be used only in a shielded location with a minimum RF shielding effectiveness and, 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	3 V/m 80 MHz to 2.5GHz	3 V/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.

1.15 Maintenance precautions

Do not open enclosures, disconnect or connect any cables or accessories. Only qualified personnel by Vieworks can do the maintenance.

1.16 Disposal

This product contains harmful materials such as lead. Improper disposal of this product may result in environmental contamination.

When disposing of this equipment, contact Vieworks representative. Do not dispose of any part of this equipment without consulting a Vieworks representative first.

Vieworks does not assume any responsibility for damage resulting from disposal of this equipment without consulting Vieworks.

1.17 Changing Fuse

⚠ **Caution** For Continued Protection Against Risk of Fire, Replace Only with Same Type and rating of Fuse. Disconnect Power Before Changing Fuse.

Use only fuse to meet the specification of the system when you replace fuse with another one.

1.18 Others

> **Caution**
> No User- Serviceable Parts Inside.

1.19 Appropriation

> **Caution**
> Don't make operation except for the intended purpose

The system, in whole or in part, cannot be modified in any way without written approval from Vieworks.

1.20 Using together with other equipment

Warning: When the unit is used together with other equipment in the patient area, the equipment shall be connected according to Standard UL 60601-1 and IEC 60601-1.

1.21 Classification

1) CLASS I EQUIPMENT
2) BF Type
3) NO protection against ingress of water
4) NOT suitable for use in the presence of a flammable an aesthetic mixture with air or with Qxide
5) Continuous operation

1.22 Installation and Maintenance

> **Caution**
> Only qualified service personnel, who have received training from Vieworks should perform this installation and troubling shooting.

Only qualified service personnel, who have received training from Vieworks should perform this installation and trouble shooting. Calibration procedures should be performed at the system installation time or if the x-ray generator is changed otherwise the system quality is decreased.

2. System Description

2.1 Intended use

MAXXray system is indicated for digital imaging solution designed for general radiographic system for human use. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures.

It controls x-ray exposure and x-ray dosage by means of interfacing with x-ray generator.

Various features of this system enable the operator to diagnose easier and faster than conventional non-digital techniques.

Computerized window, image inversion, image processing, zooming, panning, window level adjustment, contrast adjustment, and various features enable the operator to view diagnostic details difficult to see using conventional non-digital techniques.

2.2 System components

MAXXray system consists of detector, image transfer device, power supply unit, software and its accessories.

And there are two kind of detectors

MAXXray system components

Detector	RXDN-6000D,RXDN-6500D
Power Supply Unit	RXDN-6000P-15
Software	
Viewer	*MAXXvue*
Configuration	*MAXXvue*Configure
Calibration and Diagnostic	*MAXXray*Calibration
Accessories	
	Camera Interface Cable (P/N : 1110-3517-01A)
	DC Power Cable (1200-43407-01A)
	Generator Interface Cable (P/N : 1170-3417-01A)
	RS232 Cable (P/N : 1170-3414-01A)
	AC Power Cable (P/N : 1190-6203-01A)

Image Grabber : Recommended, not part of MAXXRAY

Matrox Meter II dig

RXDN-USB2N

RXDN-USB2M

Workstation : Recommended, not part of MAXXray

OS	Windows XP professional
CPU	Minimum Pentinum 4, 3.0 GHz
Memory	Minimum 2G Byte
Hard Disk	Minimum 80G Byte
Ethernet	Minimum 100 Mbit/s
Monitor	1600x1200, Color
CD Rom	CD or DVD R/W

2.3 Component description

1) Detector

Create X-ray image by using CCD camera and output the result in RS-644 format.

2) Power supply unit

Supply DC-power to detector.

3) MAXXvue

Software to view X-ray image. Get image from detector, process it to ease the diagnostic, save it in database and manage it.

4) MAXXrayCalibration

Diagnose detector and report the result. Calibrate the system.

5) MAXXvueConfigure

Configure parameters for MAXXray Digital Imaging System

3. System Specification

3.1 CCD

CCD	FFT(Full Frame Transfer) CCD
Effective Pixel Number	2040 × 2478 (RXDN-6000D)
	2040 X 2780 (RXDN-6500D)
Cell pitch	9 ㎛ ×9 ㎛
Fill factor	100%

3.2 Area of Image

14" X 17" (RXDN-6000D)

12″ X 16″ (RXDN-6500D)

3.3 Scintillator

Gadolium or CsI

3.4 Time of Image Capture and Transmission

Shorter than 3.5 second

3.5 Time of Image Capture and Image Processing

Shorter than 10 second

3.5 CCD Cooling System

CCD cooling system cools CCD to reduce thermal noise of the image.

1) Cooling Element

Thermoelectric Cooler(TEC)

2) Operation Temperature(CCD)

Maintain -5±1℃ at 25℃ of surrounding temperature.

3) Cooling Speed(CCD)

To be kept -5±1℃within 15 minutes after power on at 25℃ of surrounding temperature.

3.6 Image Specification

1) Image Format

2040 X 2478 (RXDN-6000D)

2040 X 2780 (RXDN-6500D)

2) Field of View

Captured image should reflect 100±2% of scintillator size

Scintillator size : 14" X 17" (RXDN-6000D),
12" X 16" (RXDN-6500D),

3.7 Black Level

1) Definition

It is the average pixel value of the pixels located within diameter of 20 pixels from the center of the dark image. Dark image should be captured using MAXXrayCalibration software after cooling CCD enough.

2) Specification

It should be 2500 +/- 1500

3.8 Resolution

It should be more than 2.8 lp/mm(RXDN-6000D), 3.3 lp/mm(RXDN-6500D) at the center of the detector screen.

The measure resolution, follow the below procedure.

- Locate resolution chart (Nuclear Associates Model :07-523 or the equivalent) at the center of the detector screen with the diagonal position.
- Line pairs that could be separated by adjusting window level is the resolution.

3.9 Measurement

Distance : +/- 1%

Angle : +/- 1%

3.10 Operation Environmental Condition

Temperature : 10℃ - 30℃

Humidity : 10 – 70%

Atmospheric Pressure : 500 – 1060 hpa

3.11 Transport and Storage Environmental Condition

Temperature : -30℃ - 70℃

Humidity : 10 – 90%

Atmospheric Pressure : 500 – 1060 hpa

3.12 Electrical Specification

3.12.1 AC Power Input(PSU)

100 - 240VAC +/- 10%, 50/60Hz

3.12.2 Power Consumption

Less than 95W (Detector itself)

3.13 Interface

1) Image data	RS-644
2) System Control	RS-232C
3) RS-232	Baud rate : 19,200 bps
	Parity bit : Even
	Data bit : 8 bit
	Stop bit : 1 bit

4. System Installation

MAXXray system use Matrox Meter II Digital frame grabber, RXDN-USB2N, RXDN-USB2M as an image grabber

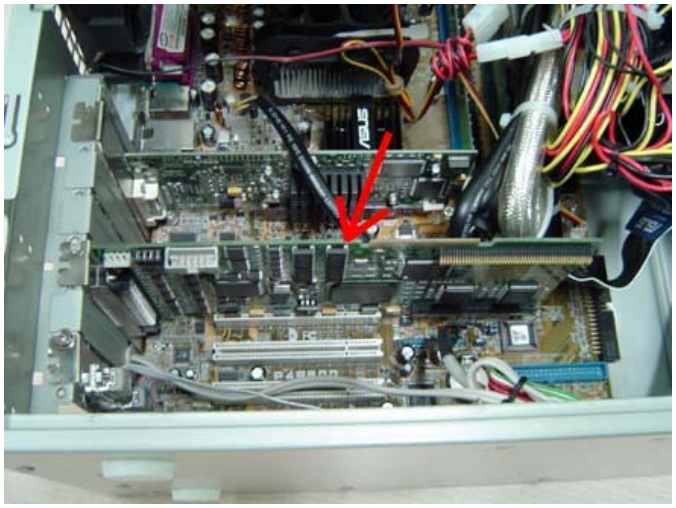
- Refer to 4.1 for Matrox Meter II Digital Image grabber Installation
- Refer to 4.2 for RXDN-USB2N
- Refer to 4.3 for RXDN-USB2M

> **Caution**
>
> The product should be installed by qualified maintenance personnel approved by Vieworks.

4.1 Matrox Meter II Digital Image Grabber Installation

4.1.1 Install Matrox Meter II Digital

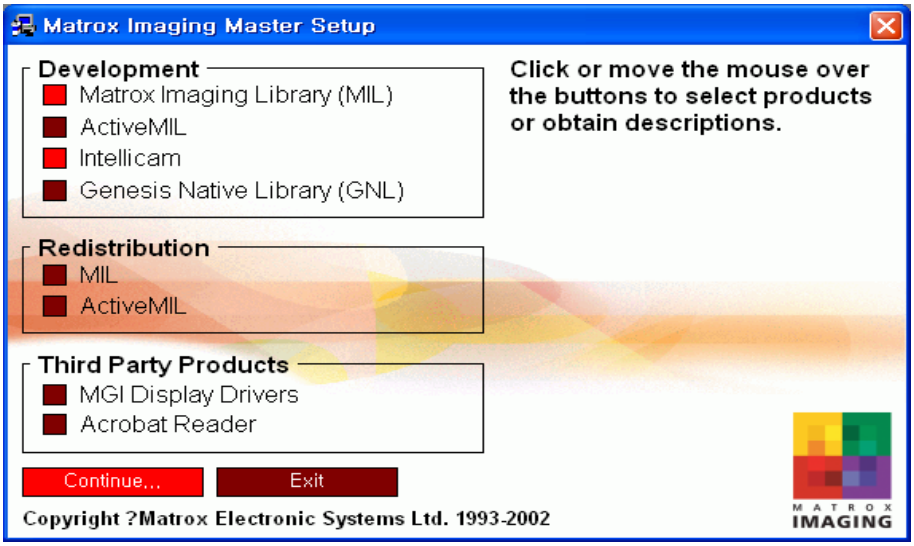
1) Install 'Image grabber board(Meteor II Digital-4L)' into one of the PCI slots



4.1.2 Install Matrox Meter II Digital Driver

1) Insert the MilLite 7.5 CD into the CD-ROM drive

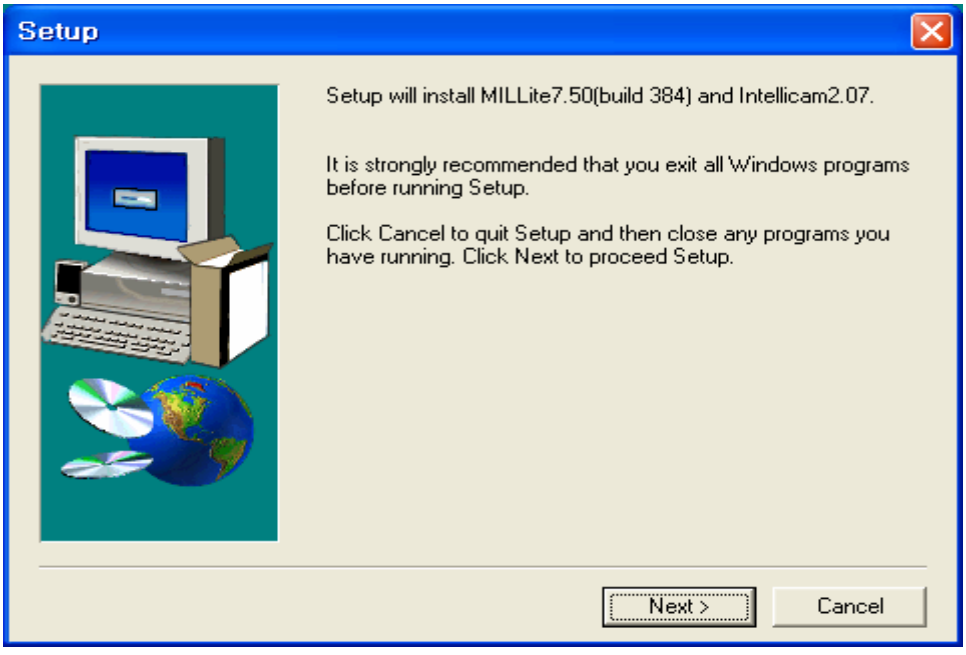
2) Select 'Matrox Imaging Library' and 'Intellicam'. Then Click Continue



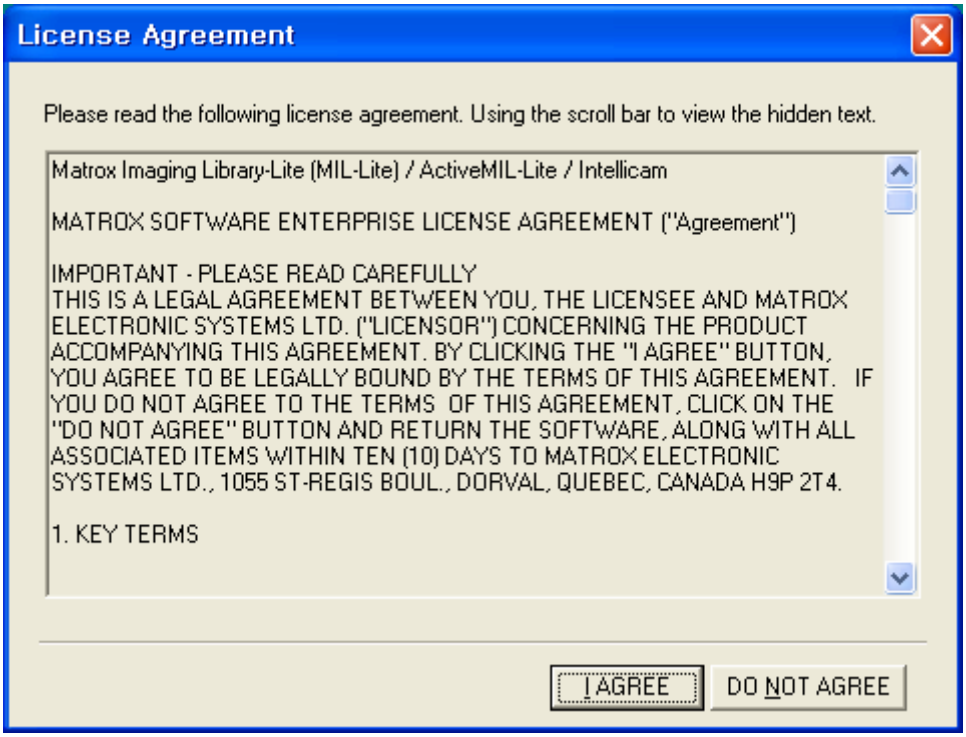
Caution

If autorun is not enabled in your computer, browse the contents of the MilLite 7.5 and double click the Setup.exe file to run the CD

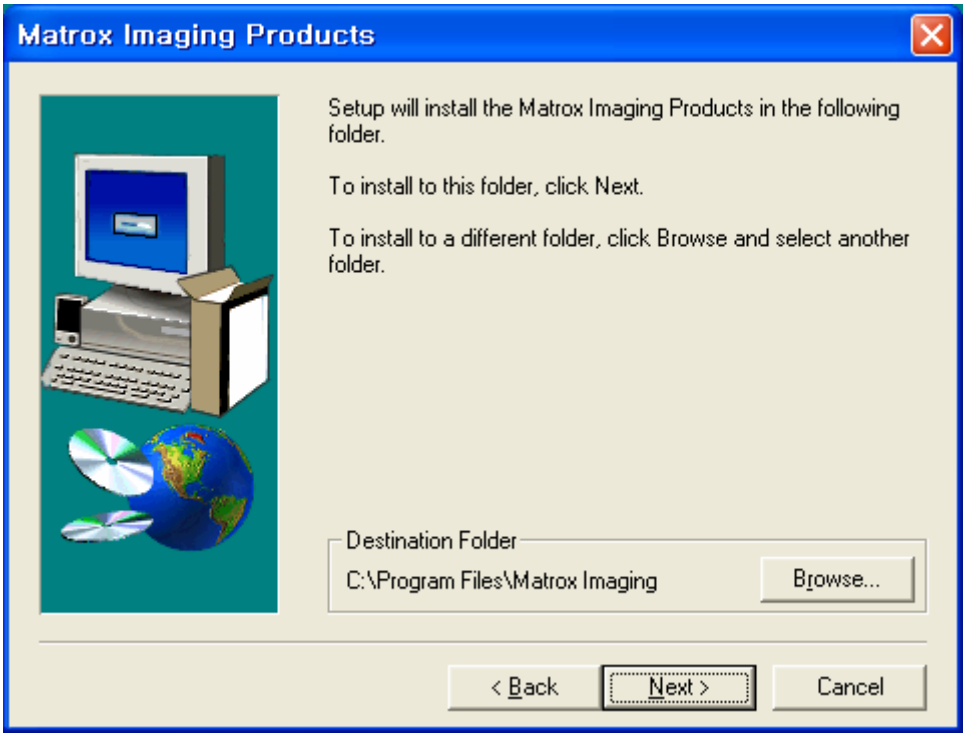
3) Click "Next" button



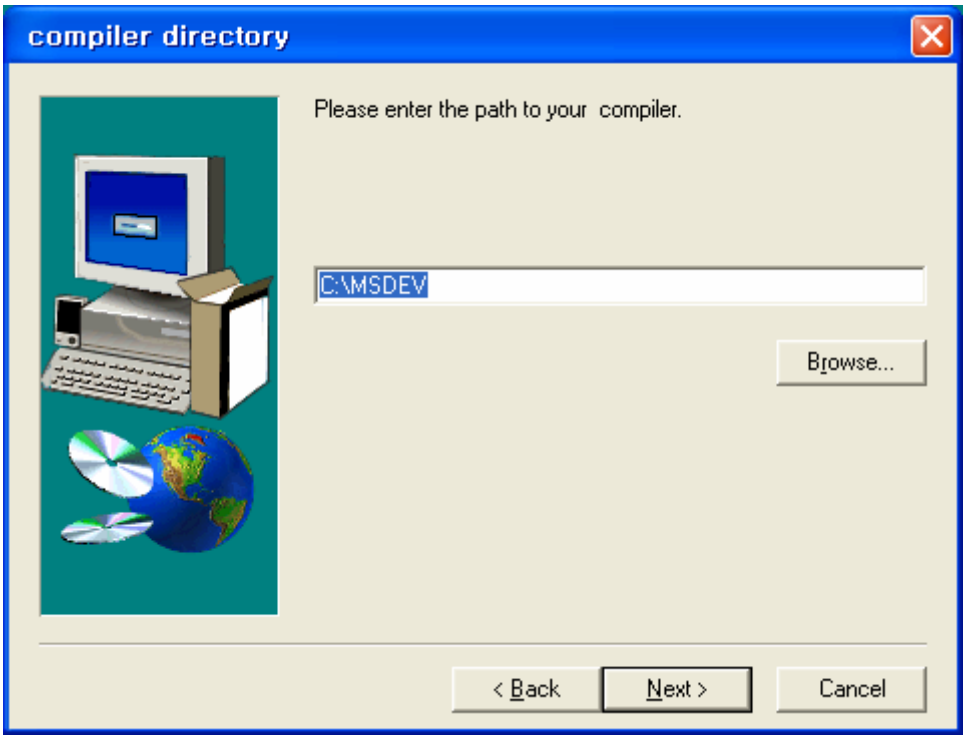
4) Click "I Agree" button



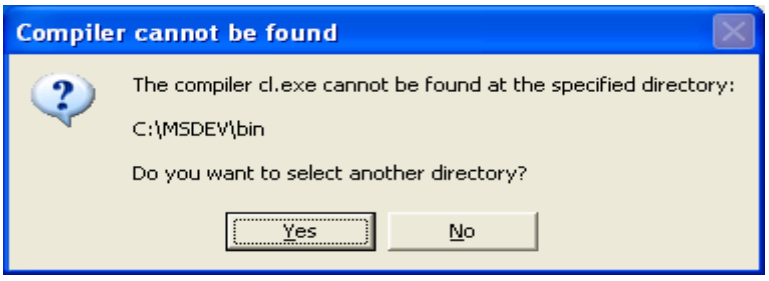
5) Click "Next" button



6) Click "Next" button



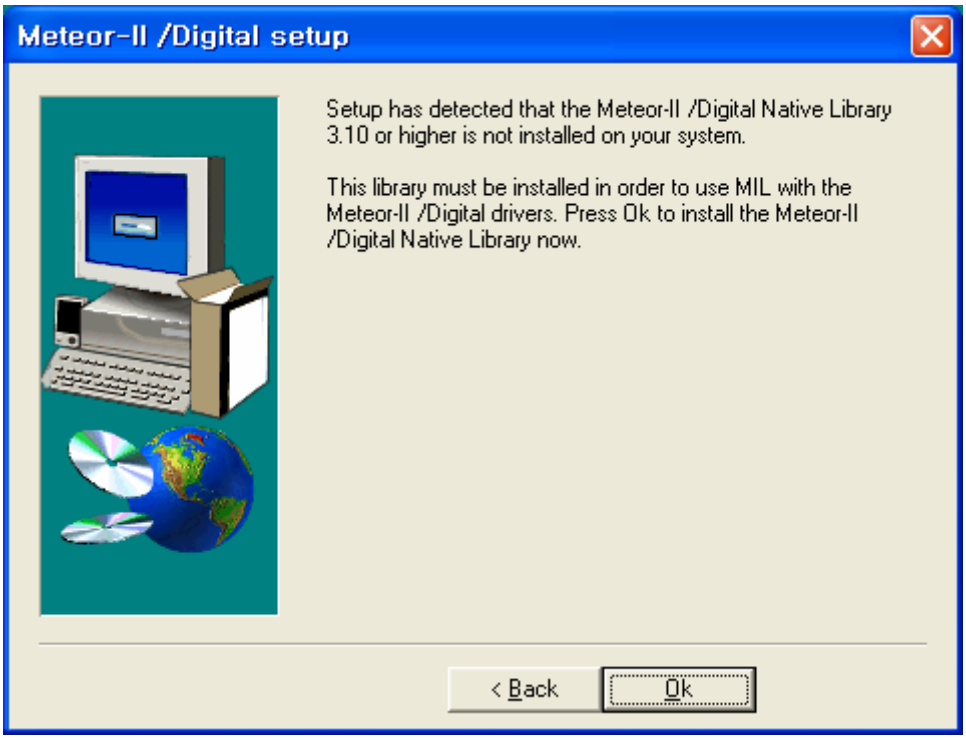
7) Click "No" button to continue



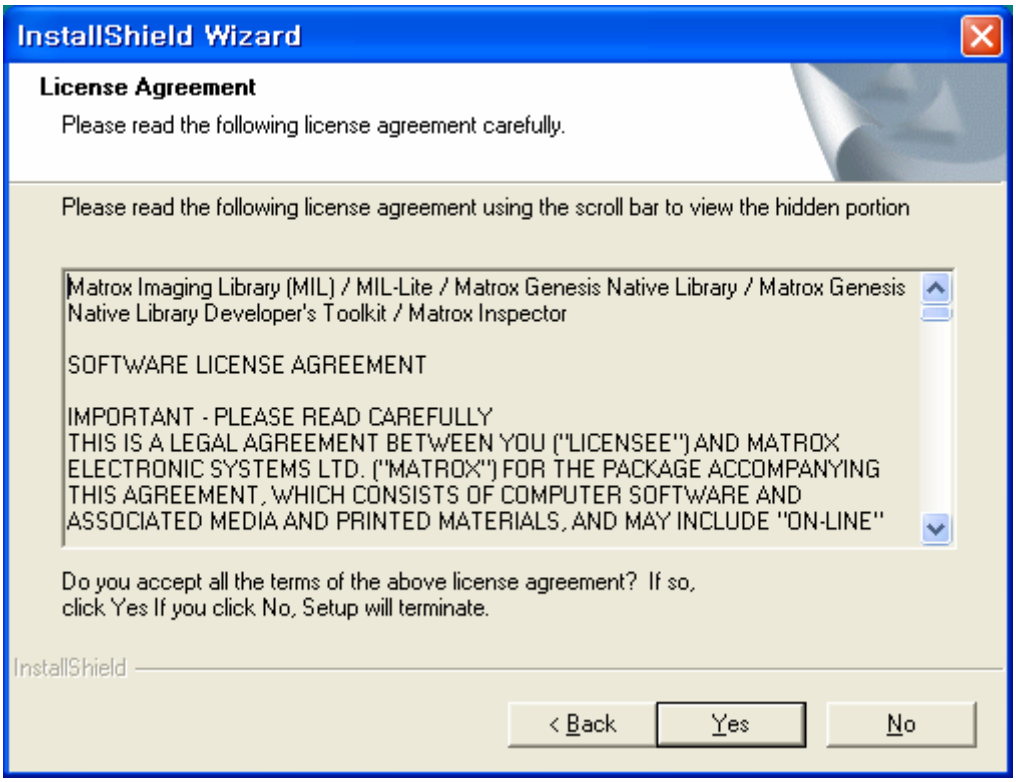
8) Check "Meteor-II/Digital" and "VGA", then click "Next" button

9) Click "No" button

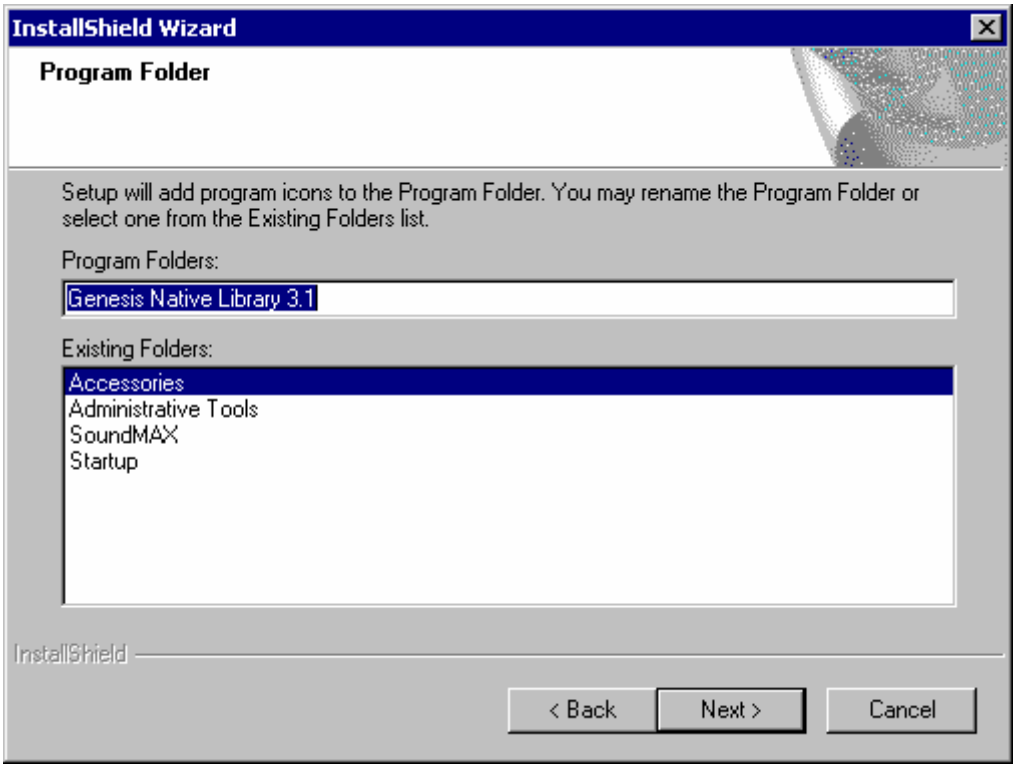
10) Click "OK" button



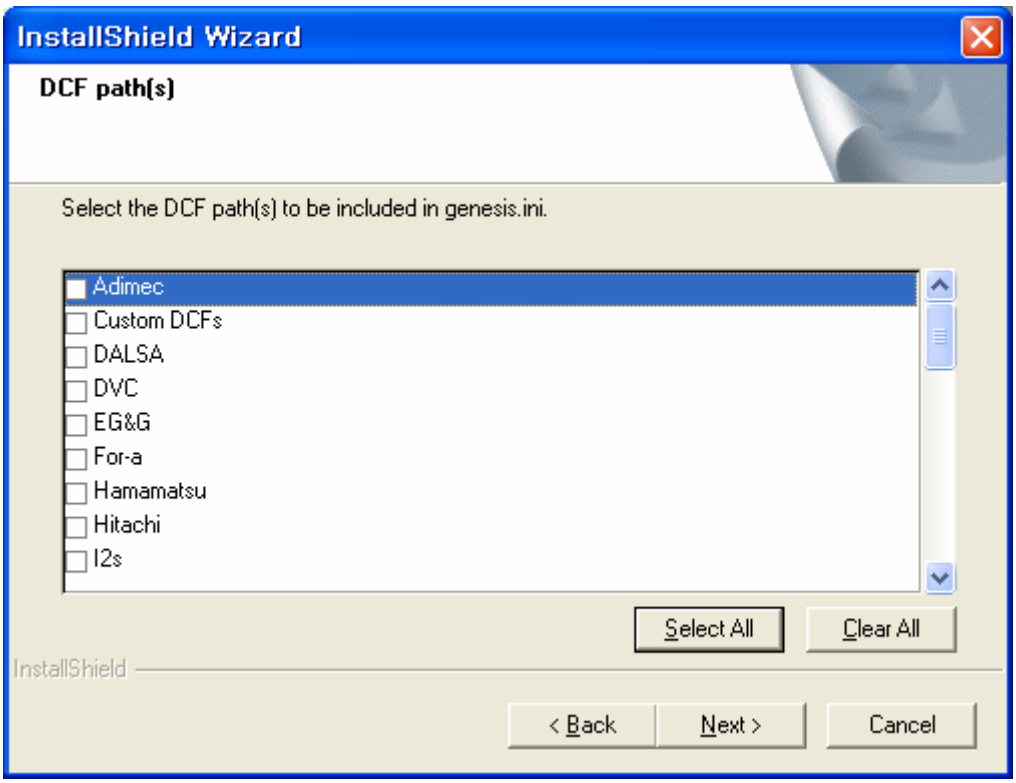
11) Click "Yes" button



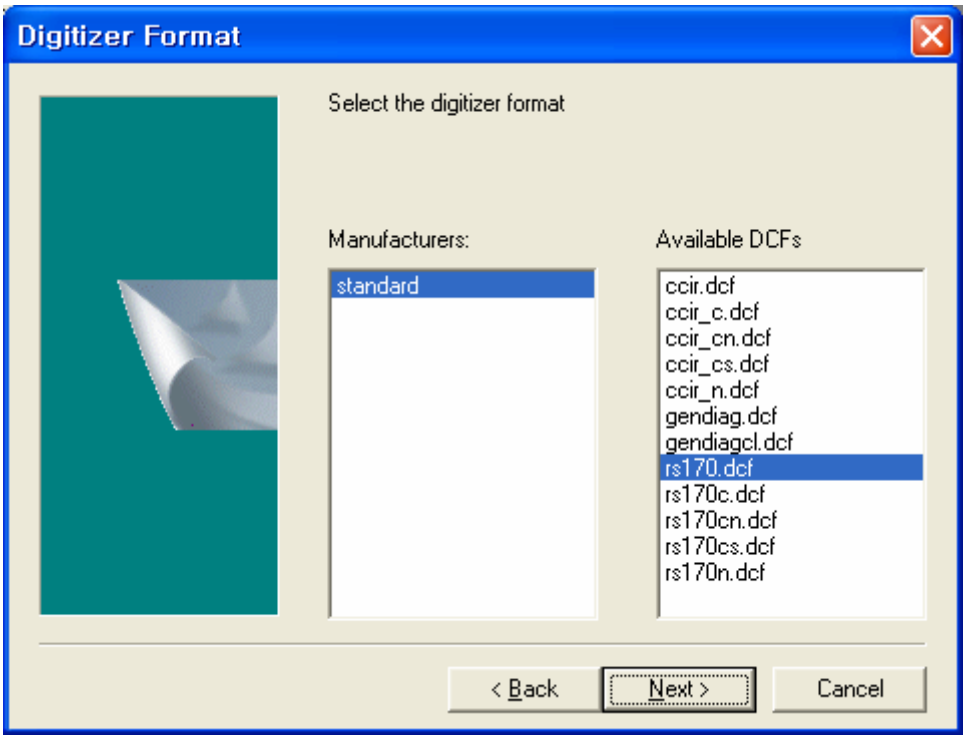
12) Click "Next" button



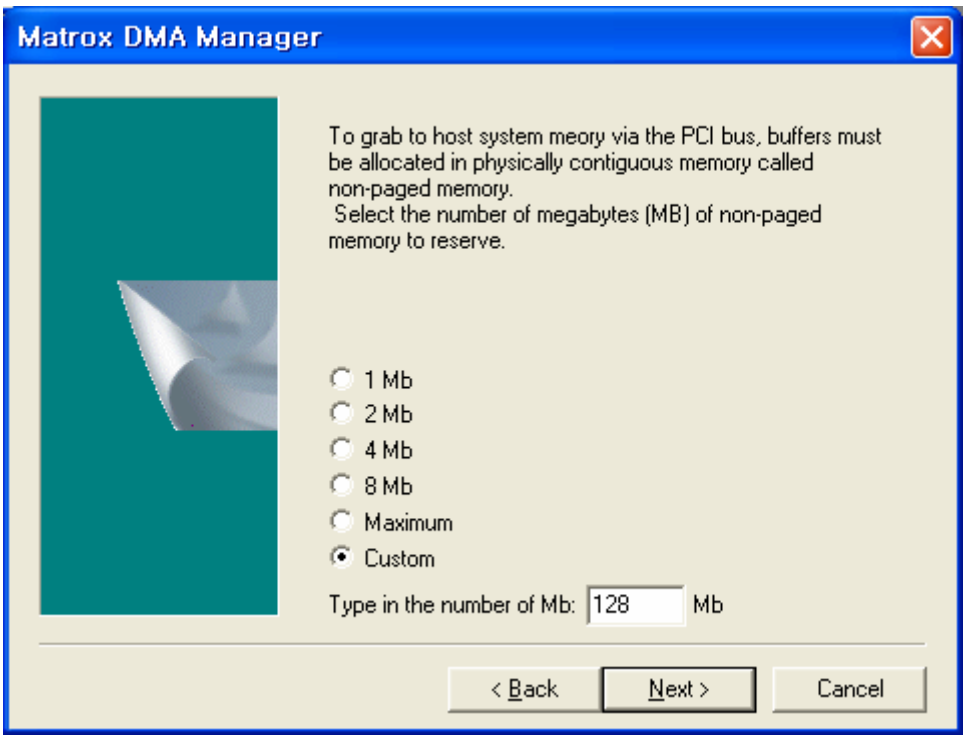
13) Click "Next" button



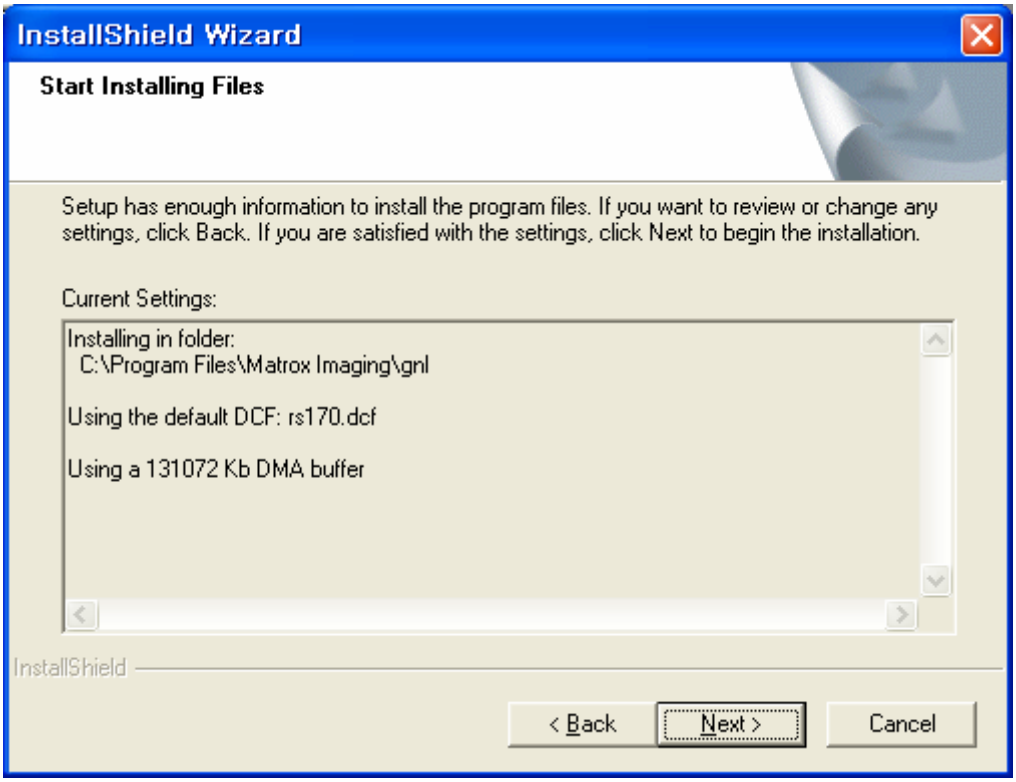
14) Click "Next" button



15) Select "Custom"' and input "128" into the edit box and Click "Next" button

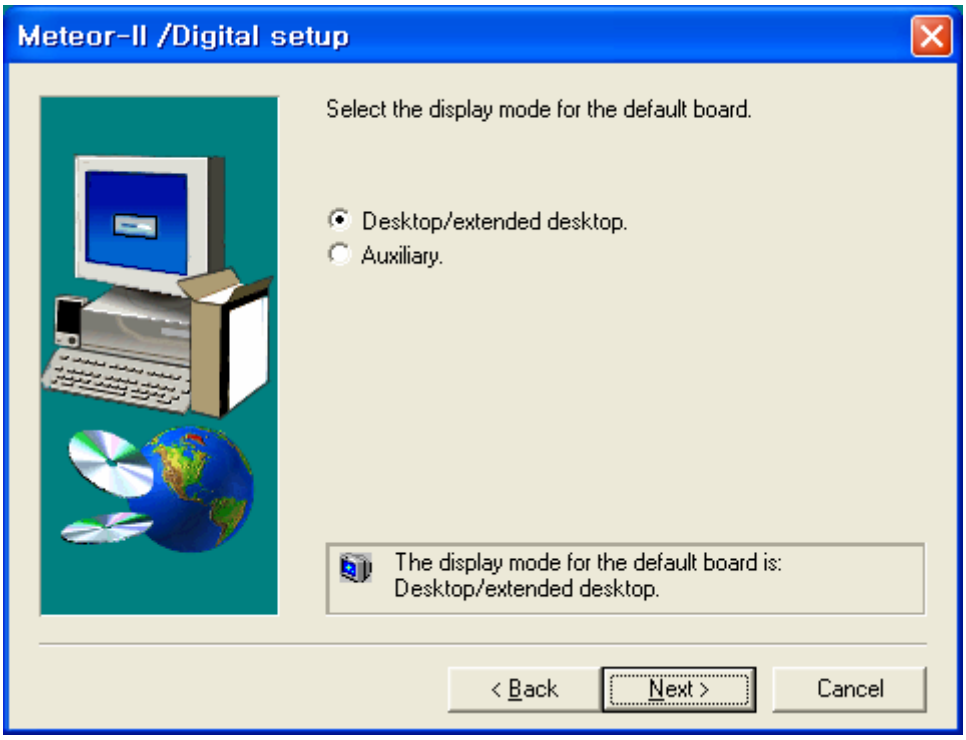


16) Click "Next" button

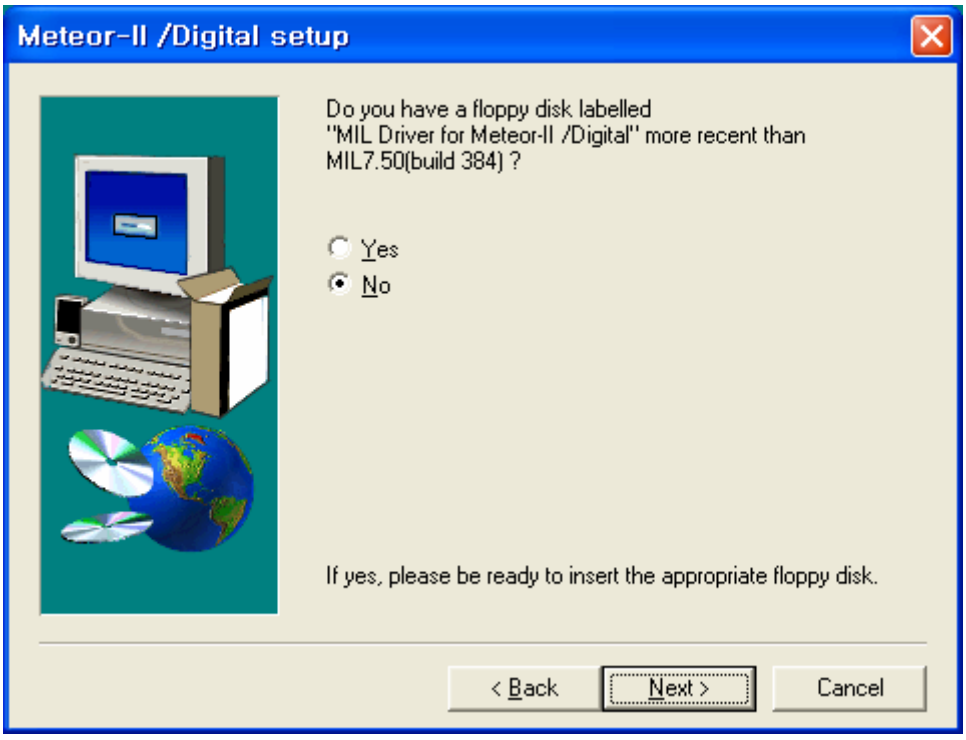


17) Click "Finish" button

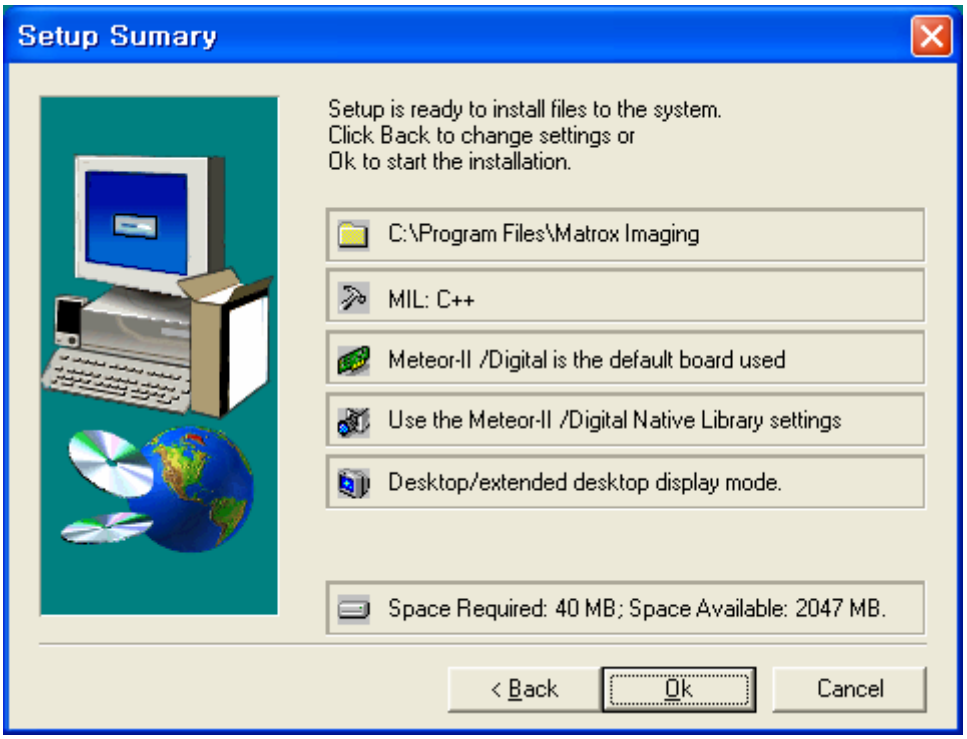
18) Click "Next" button



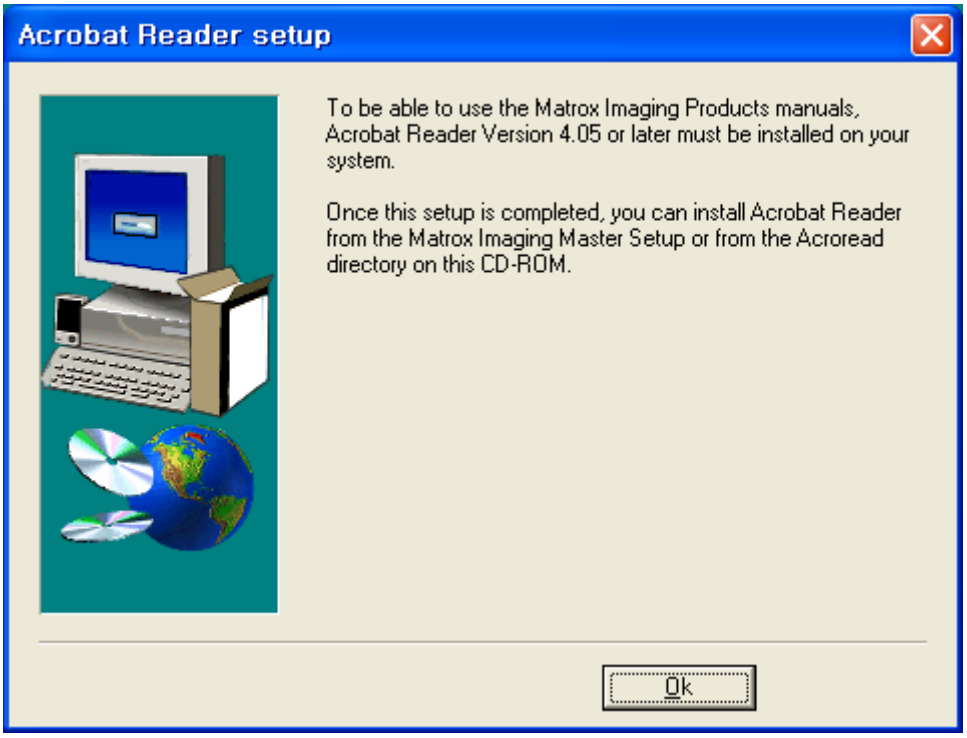
19) Click "Next" button



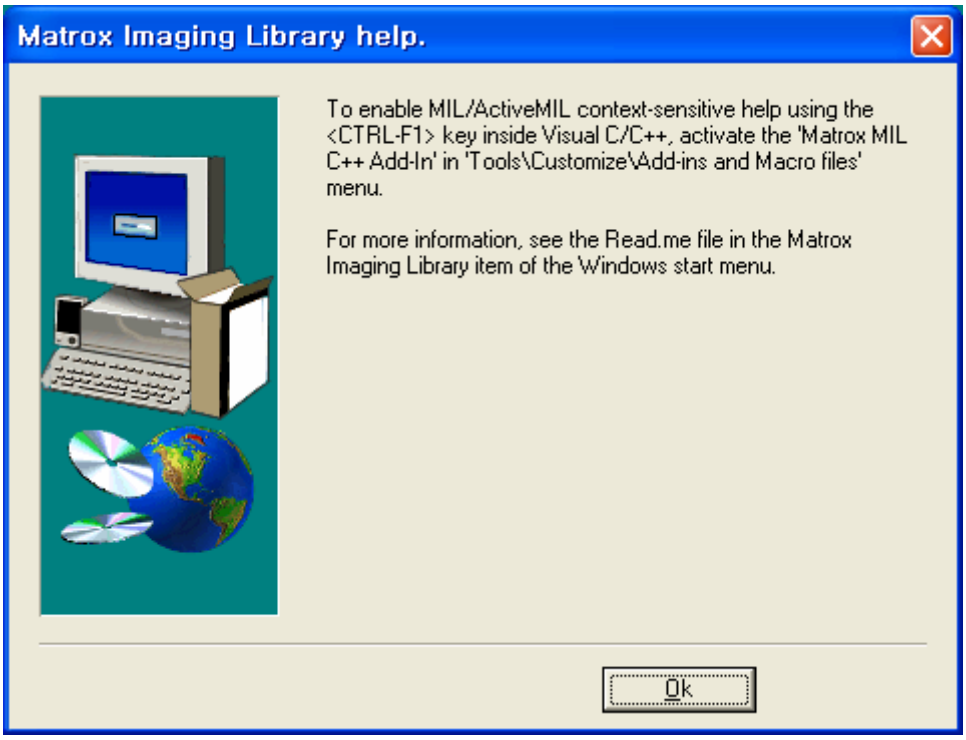
20) Click "Ok" button



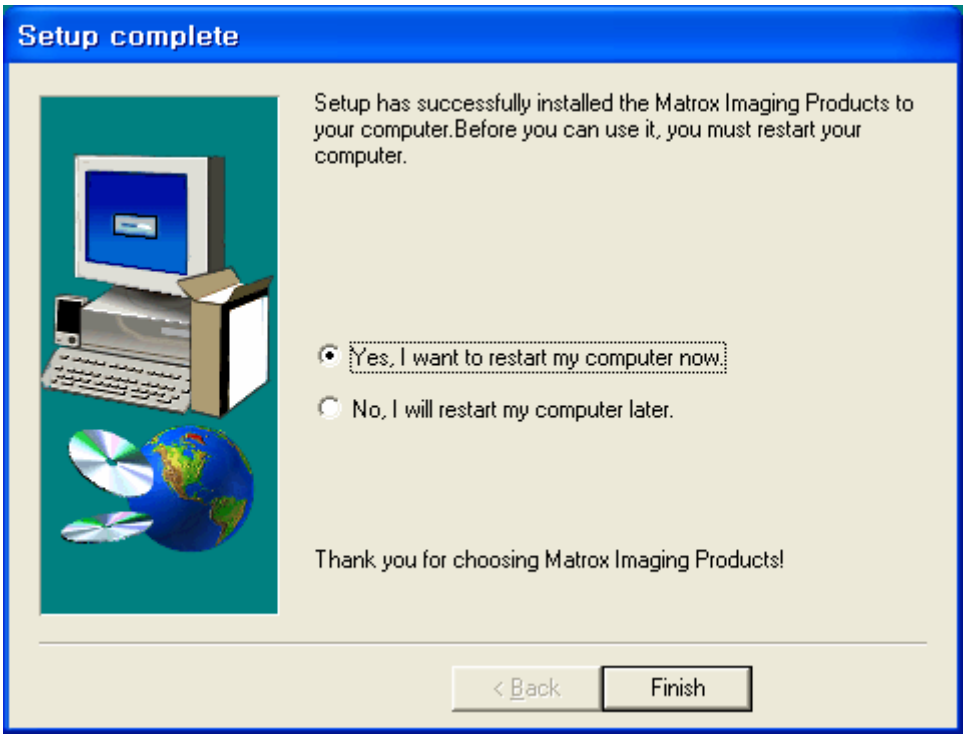
21) Click "Ok" button



22) Click "Ok" button

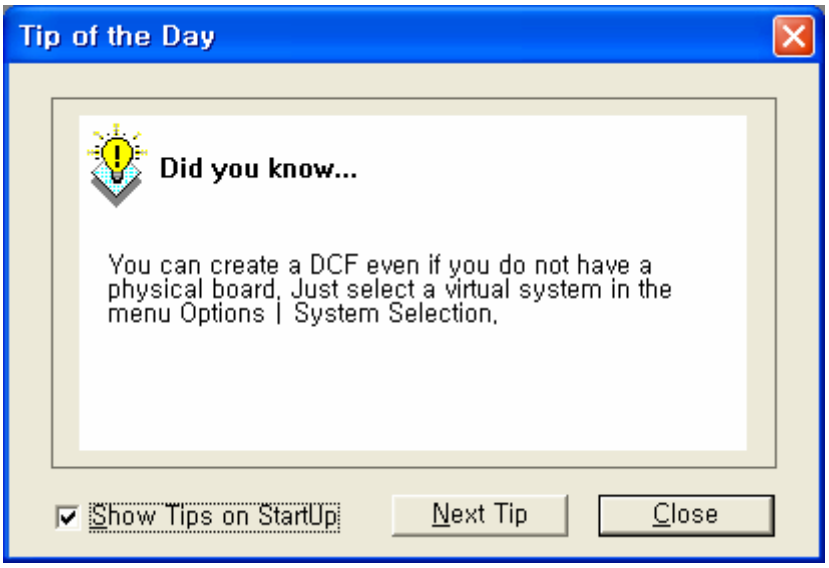


23) Check " Yes, I want restart my computer now" and click "Finish" button

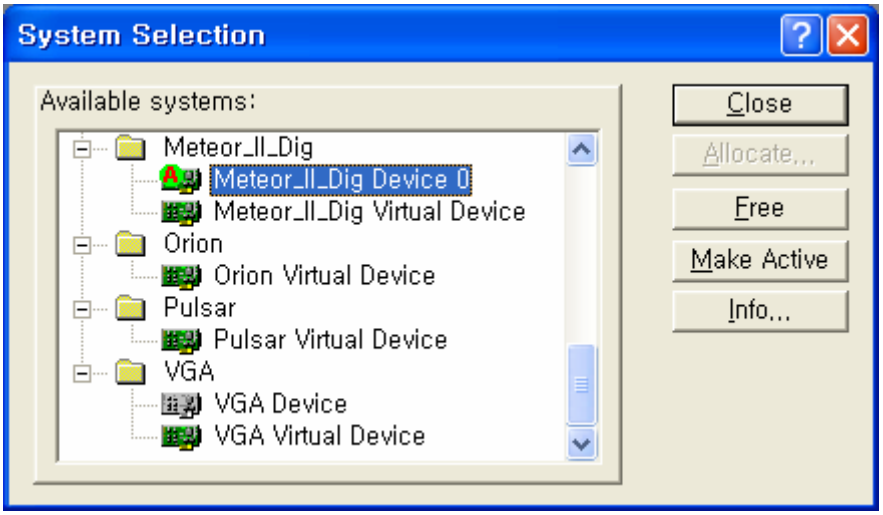


Then the computer will restart automatically.

24) Run the 'Start->Program->Matrox Imaging Products->Intellicam->Intellicam'. When the following window display, click the 'Close' Button



25) When the following window display, confirm that 'Meteor_II_Dig Device 0' is activated (It means that Meteor II Digital has been successfully installed)



Note) If you can not see the window, you can open it running 'Options->System Selection'

Click "Close" button

Now the installation of the frame grabber driver is finished

4.2 RXDN-USB2N Installation

※ If you have RXDN-USB2N, skip this section

4.2.1 Hardware Installation

1) Connect the power-cable and USB-cable to RXDN-USB2N Grabber

2) Turn the RXDN-USB2N power on

3) Connect the USB-cable to the PC

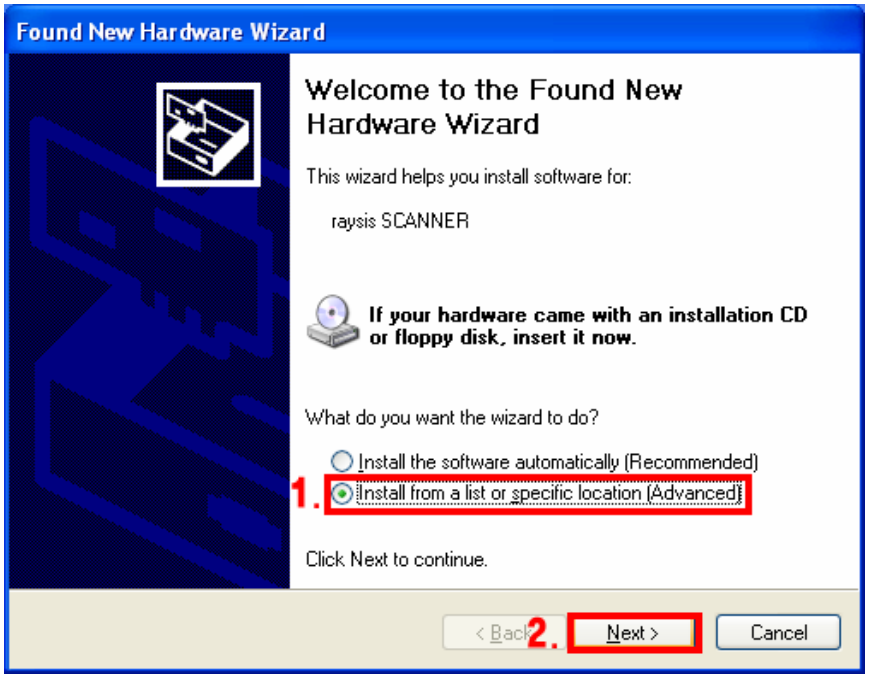
4.2.2 Software Installation

If USB cable is connected with the RXDN-USB2N powered on, the following installation wizard will be

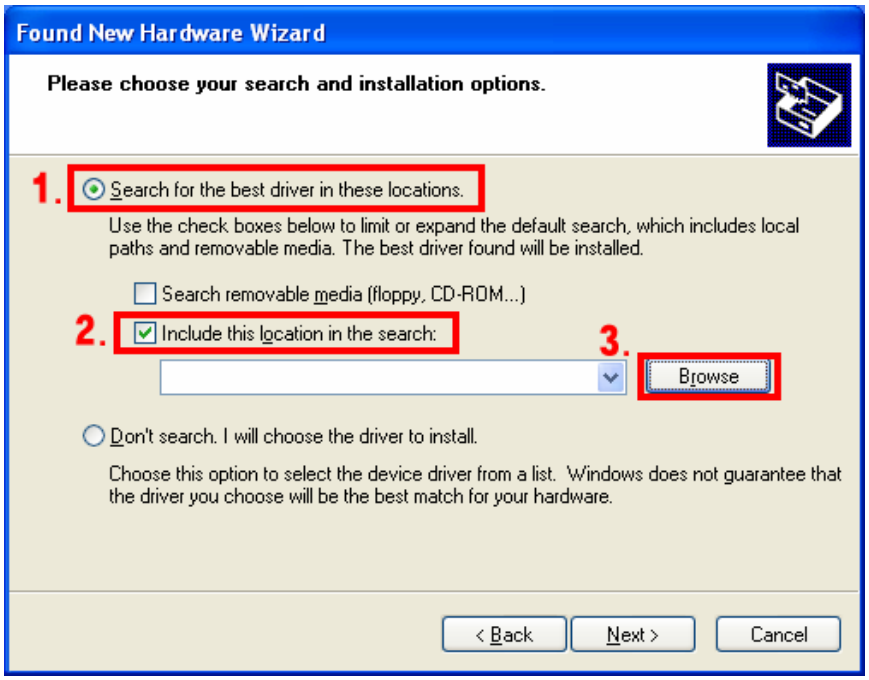
executed automatically.

The Driver of the USB Image Driver is provided in the S/W Package CD by vieworks co, Ltd

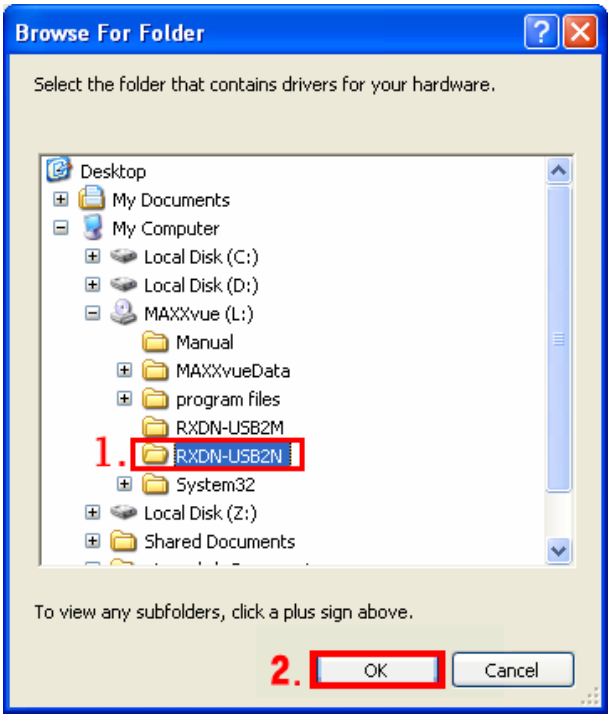
1) Select "Install from a list or specific location (Advanced)" then click "Next" button



2) Select "Search for the best driver in these location" and check "Include this location in the search" and click "Browse" button.



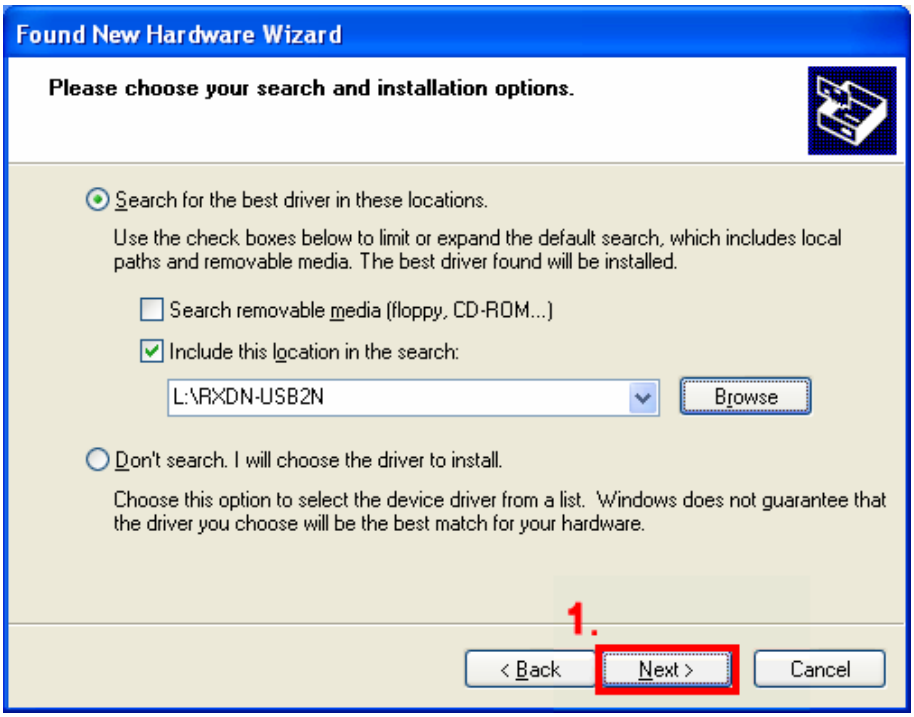
3) Select folder in which driver file USB2.0 Grabber is located, then click "OK" button.



Note : The drive name can be different from above, it is shown for example

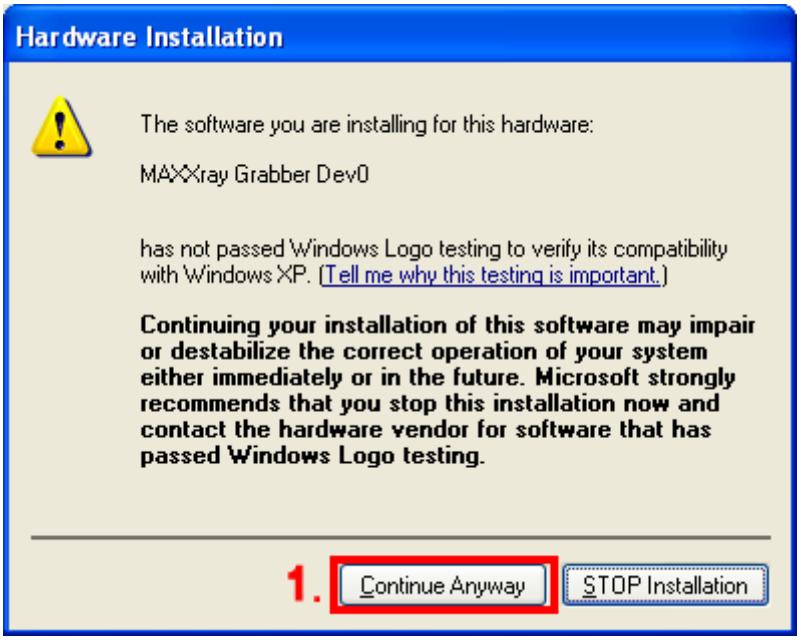
Then following window will be displayed.

Click "Next" Button.

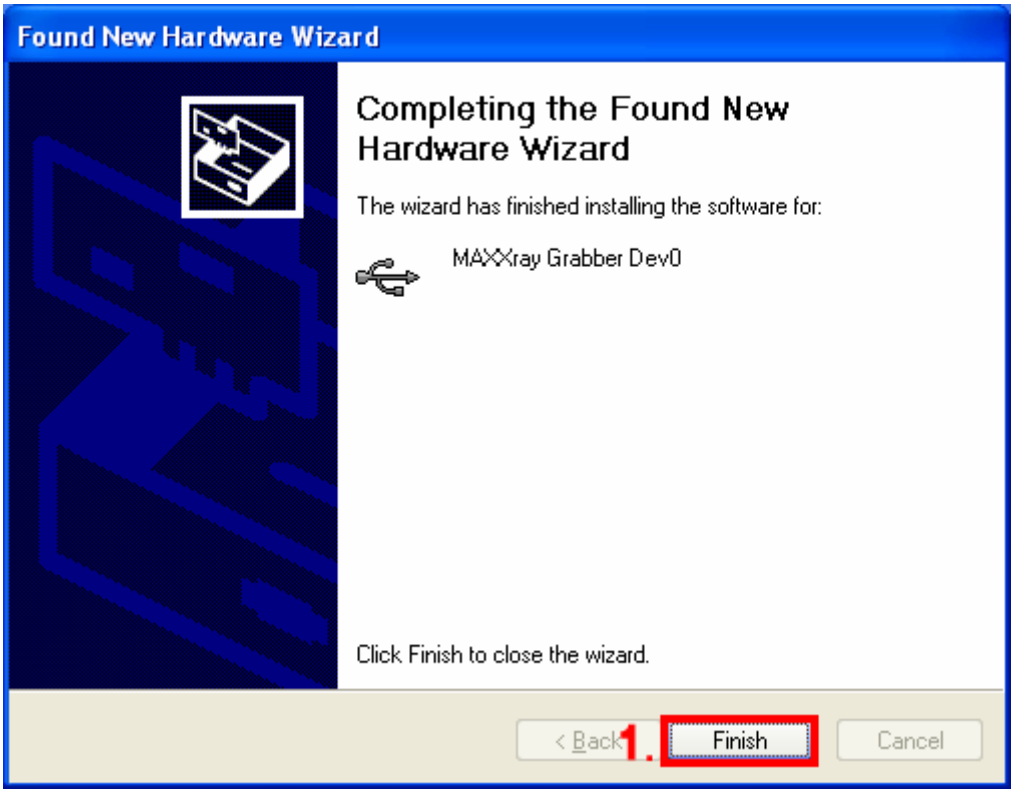


Note : The drive name can be different from above, it is shown for example

4) Click "Continue Anyway" button



4) Click "Finish" button

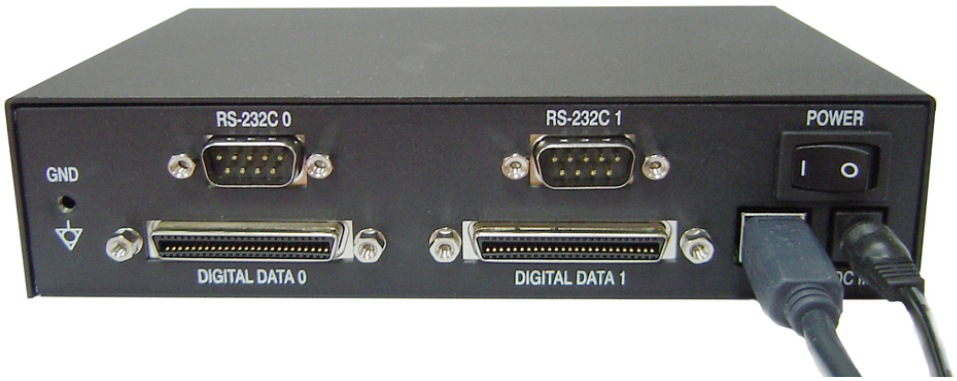


4.3 RXDN-USB2M Installation

※ If you have RXDN-USB2N, skip this section

4.3.1 Hardware Installation

1) Connect the power-cable and USB-cable to RXDN-USB2M



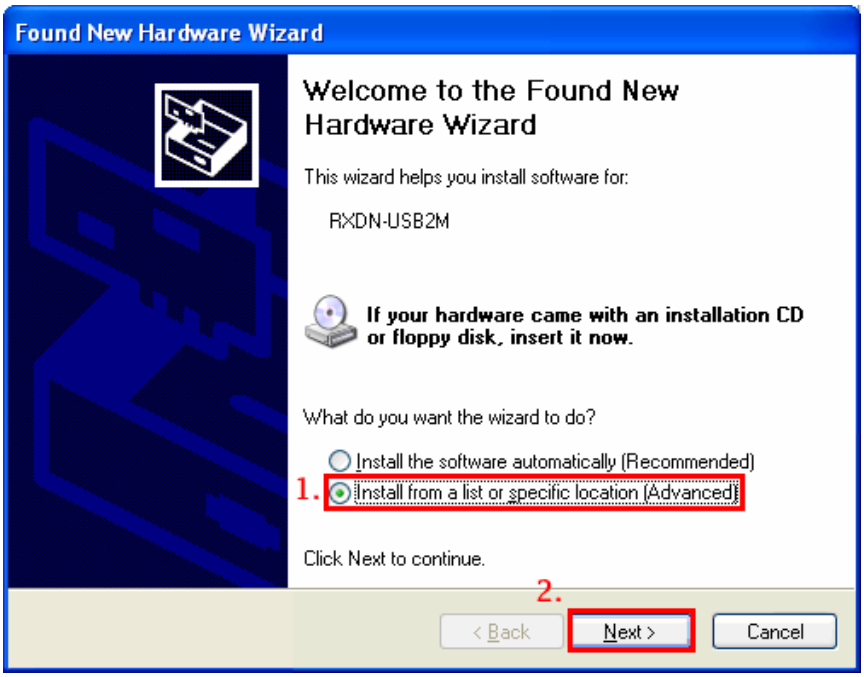
2) Turn on the power switch of RXDN-USB2M

3) Connect the other end of the USB-cable to the PC

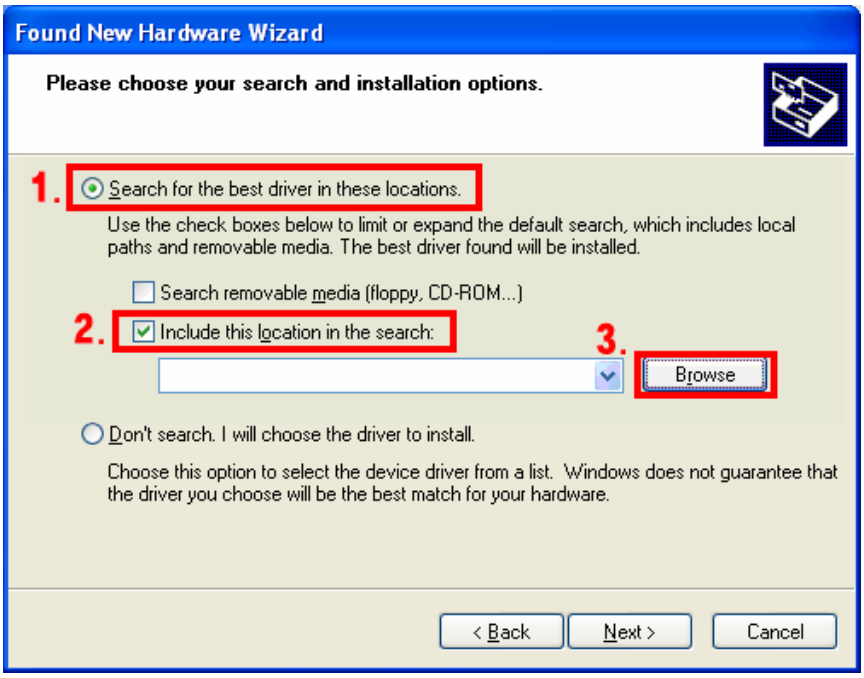
4.3.2 Software Installation

If you connect the USB cable with RXDN-USB2M powered on, the following installation wizard will be executed automatically.

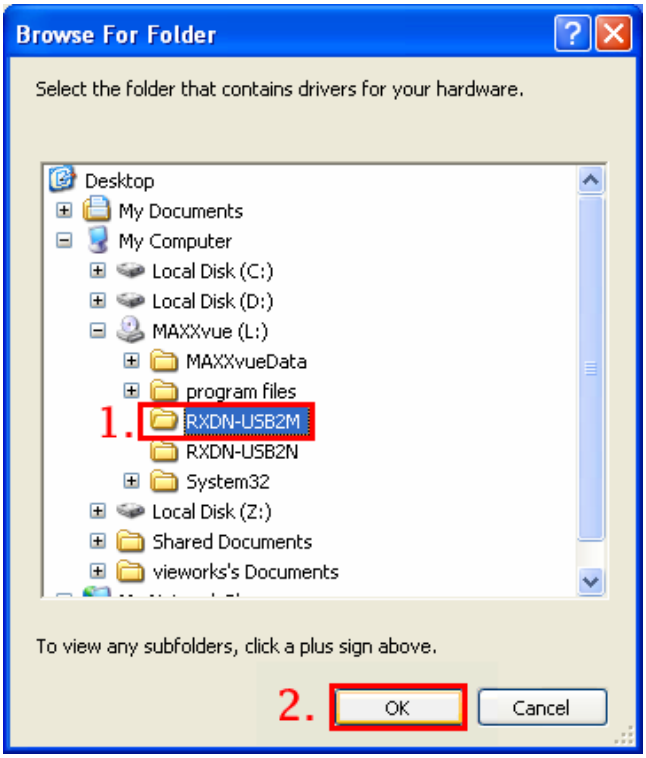
1) Select "Install from a list or specific location (Advanced)" then click "Next" button.



2) Select "Search for the best driver in these location" and check "Include this location in the search" and click "Browse" button.

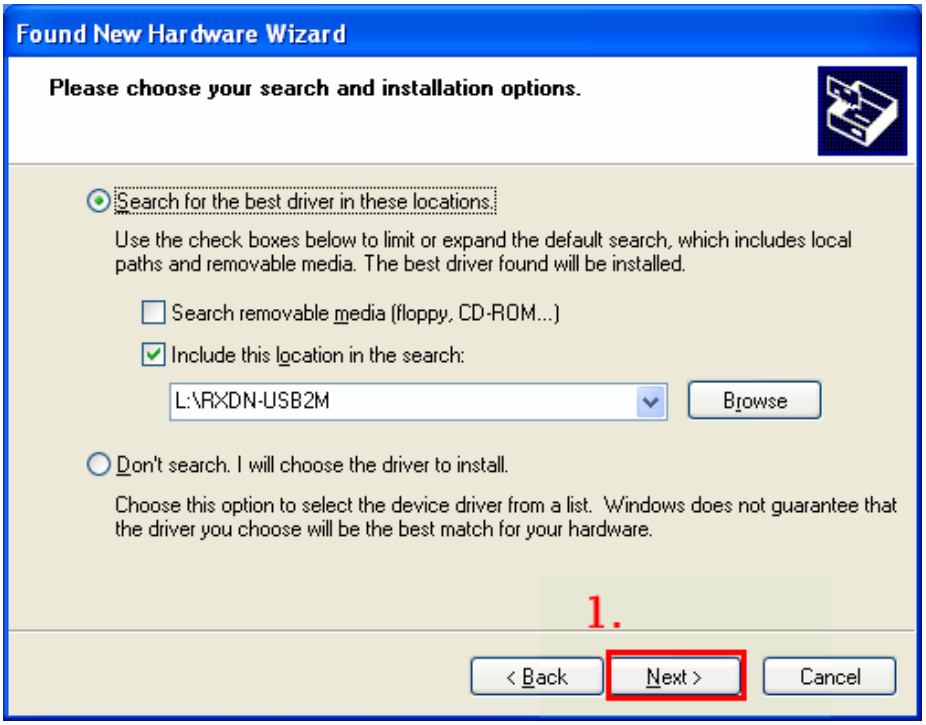


3) Select folder in which driver file of RXDN-USB2M is located, then click "OK" button.



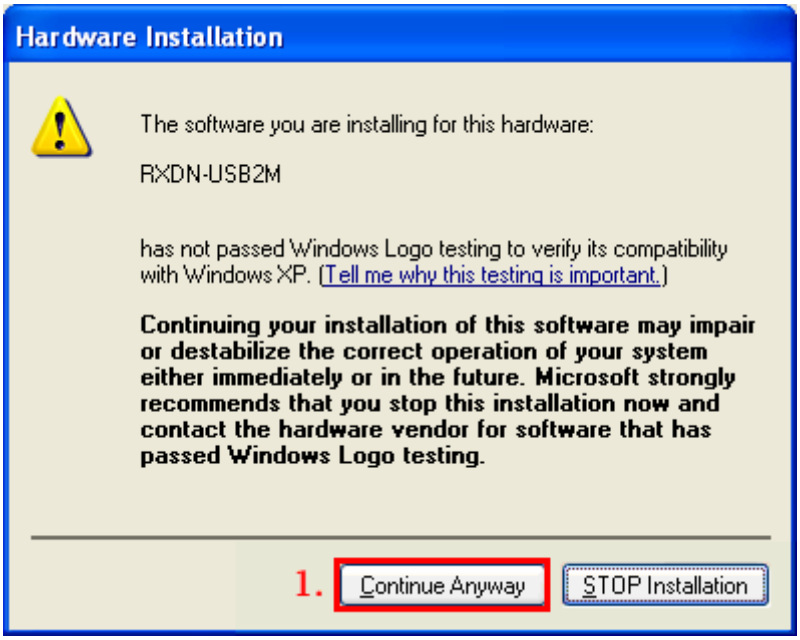
Note : The drive name can be different from above, it is shown for example

If the following window will be displayed, click "Next" Button.

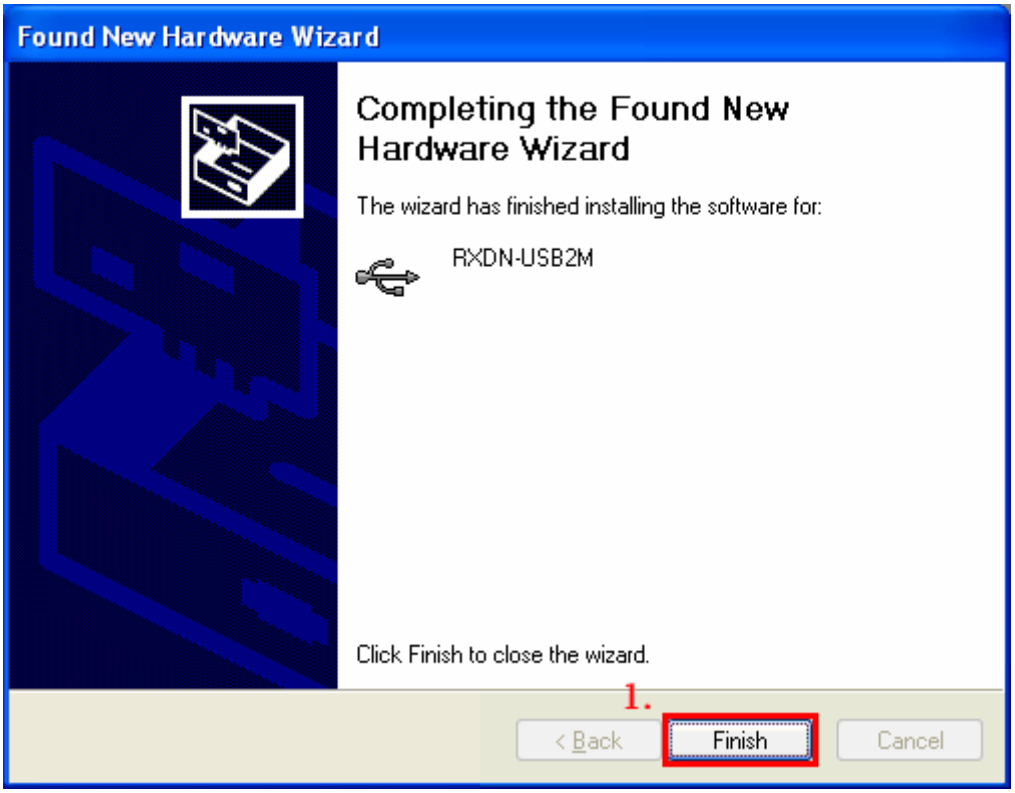


Note : The drive name can be different from above, it is shown for example

4) Click "Continue Anyway" button



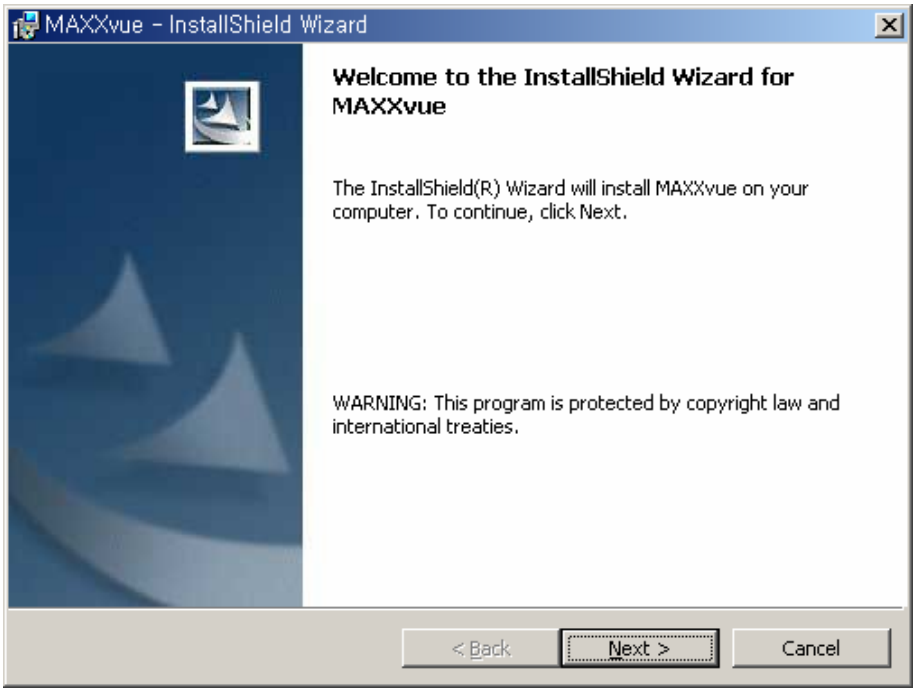
4) Click "Finish" button



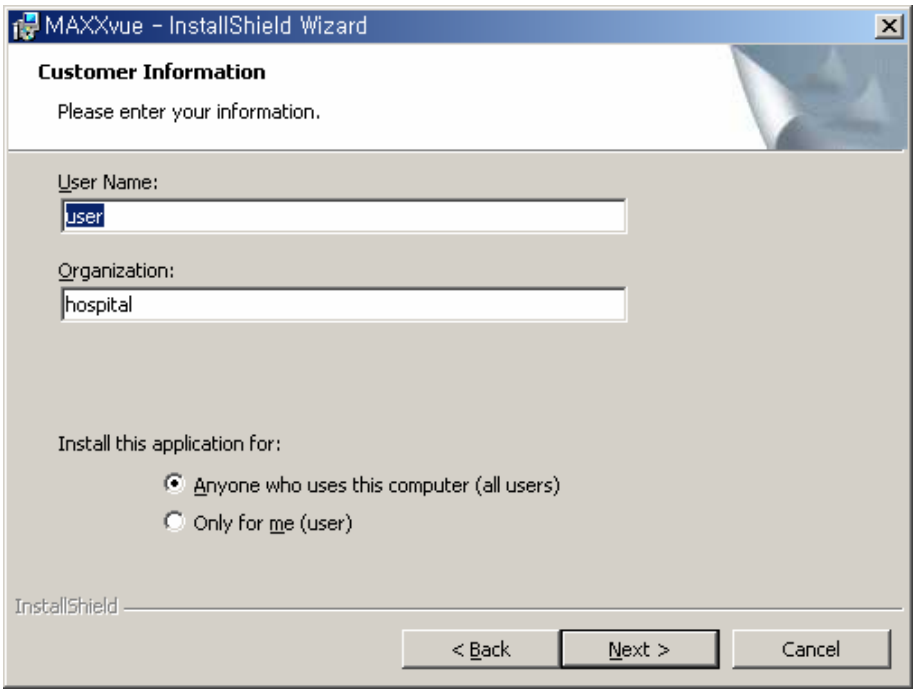
5 MAXXvue Installation

1) Insert MAXXvue CD in CD Drive

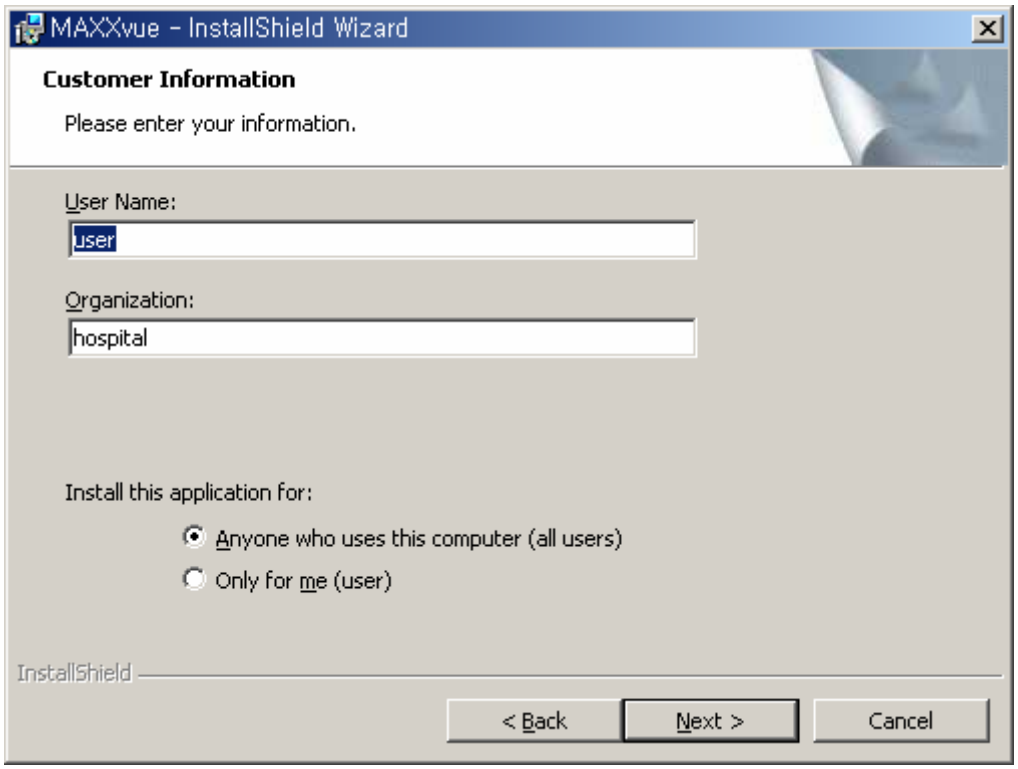
2) Run "Setup.exe" program then InstallShield Wizard will be displayed, click "Next" button



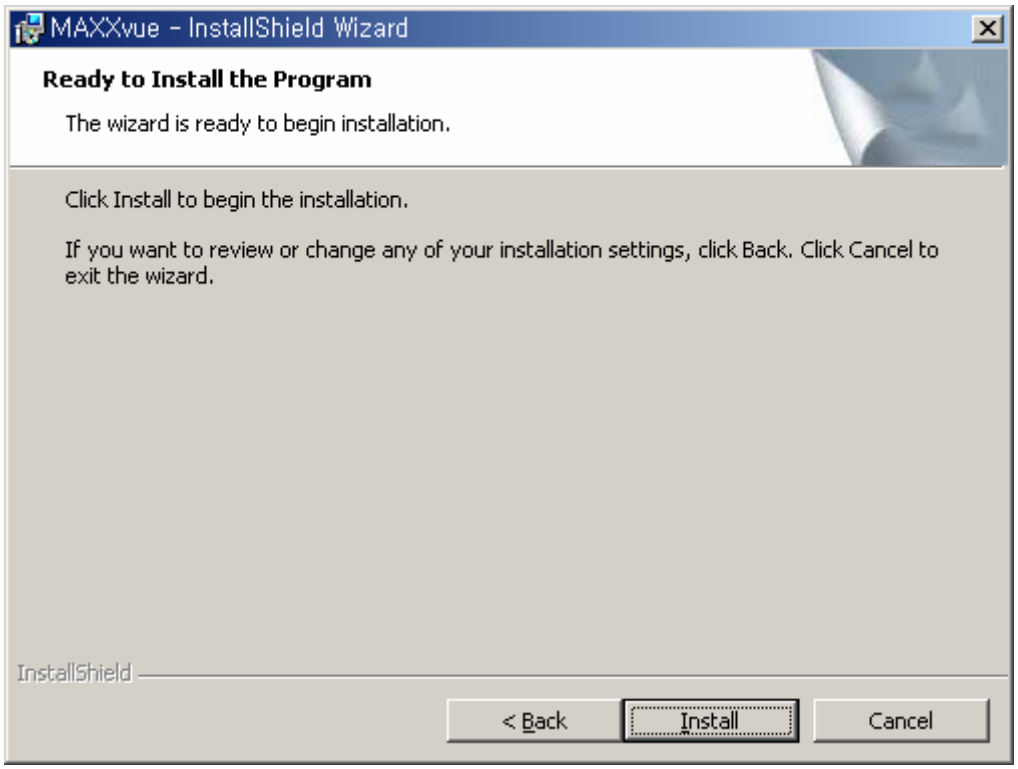
3) Input User Name and Organization , and select user, then click "Next" button



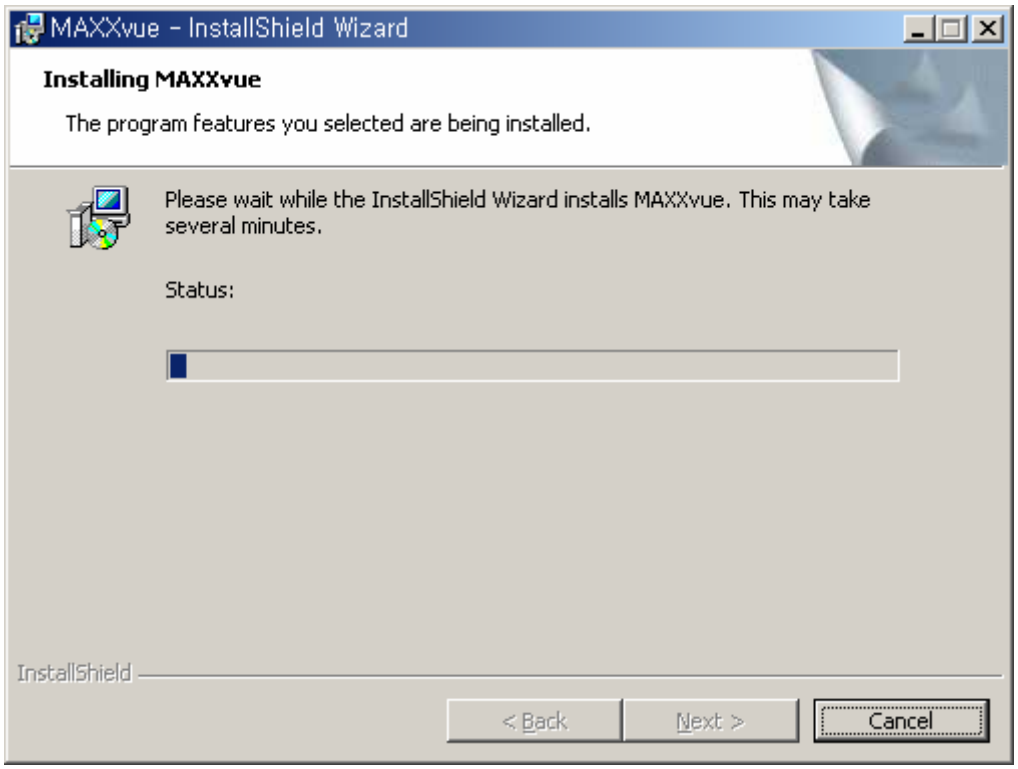
4) Select setup type as Complete then click "Next" button



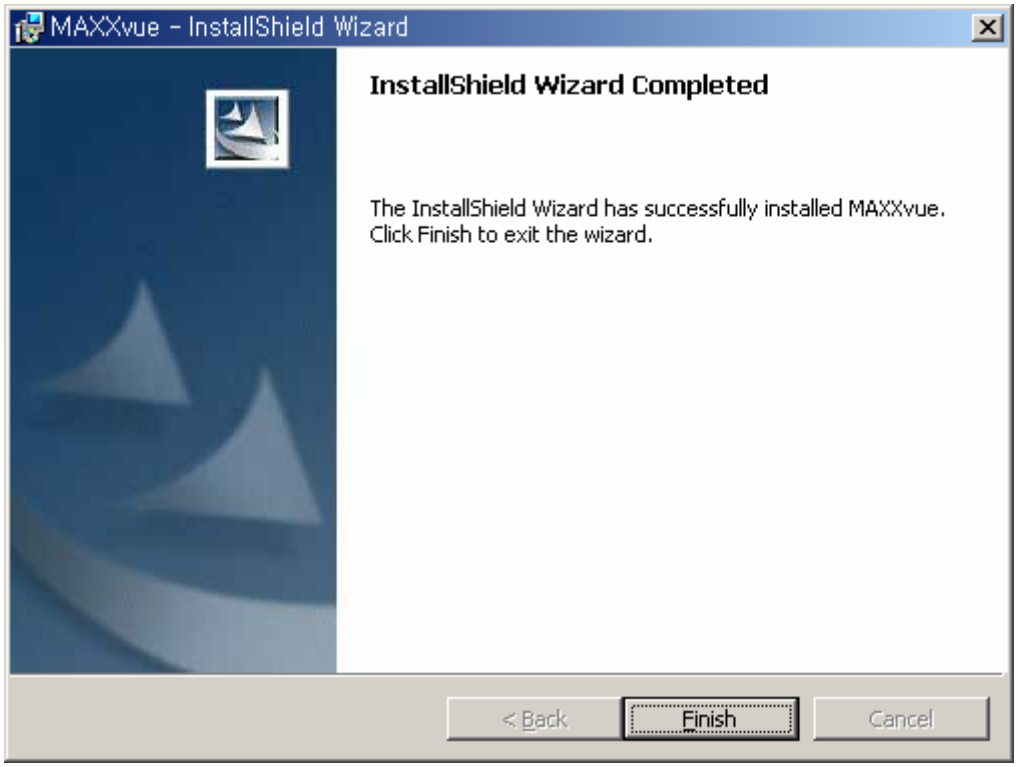
5) "Ready to Install the Program" window will be displayed, press "Install" Button



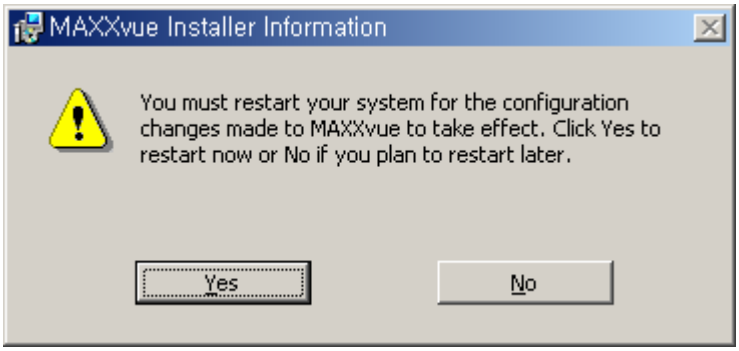
6) "Installing MAXXvue" will be displayed, Now the InstallShield is installing MAXXvue.



7) After finishing installation of MAXXvue, "InstallShield Wizard Completed" window will be displayed, Then press "Finish" button.



8) The following message box will be displayed, press "Yes" button to restart computer.



Now the *MAXXvue* software is successfully installed to the following directory.

Software	c:₩program files₩*MAXXvue*
Data	d:₩*MAXXvue*Data

Executable File List

MAXXvue.exe	Viewer program
*MAXXray*Calibration.exe	Diagnosis and Calibration program
MAXXvueConfigure	Configure program

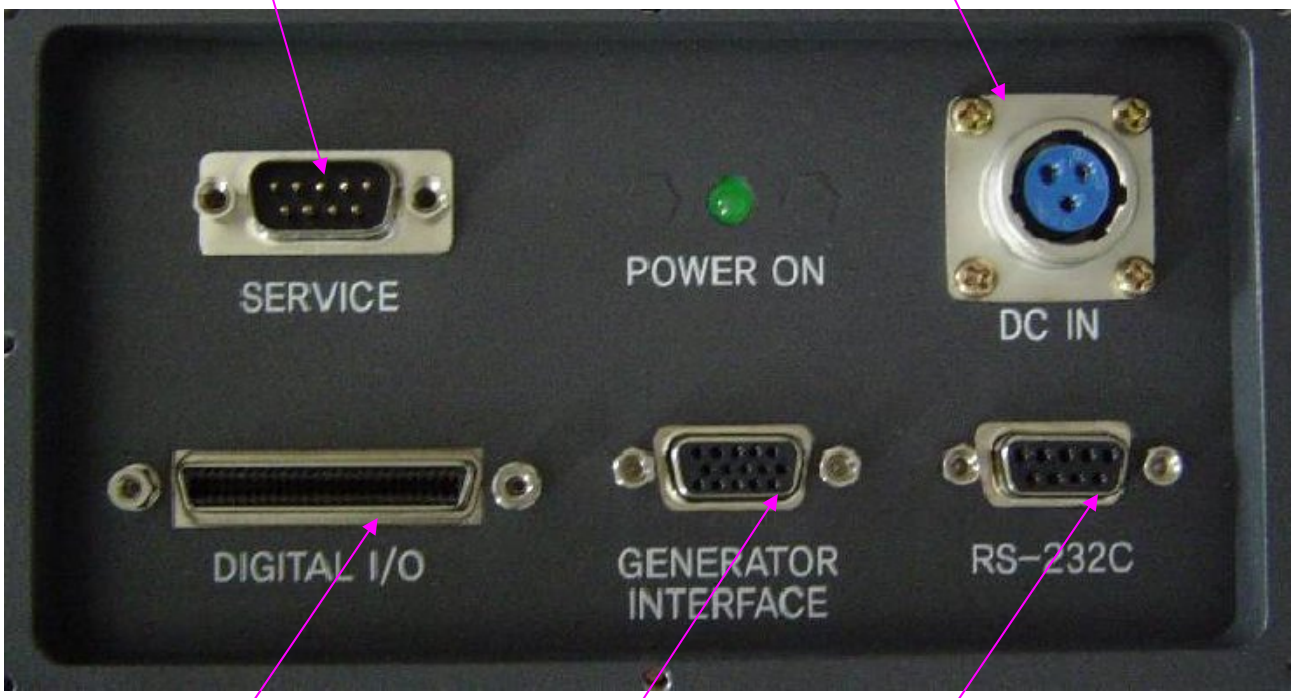
6. Hardware Installation

Keep the following step to connect cables between Detector and PC, If the system is used with High Frequency x-ray generator, the interface between x-ray generator and Detector is not needed, but this system is used with single phase x-ray generator x-ray generator should be interfaced with the detector.

If this system is used with single phase x-ray generator, after finishing procedure mentioned in chapter 4, do the additional installation procedure following Appendix C

F/W Upgrade Connector

DC Power Connector



Data Connector

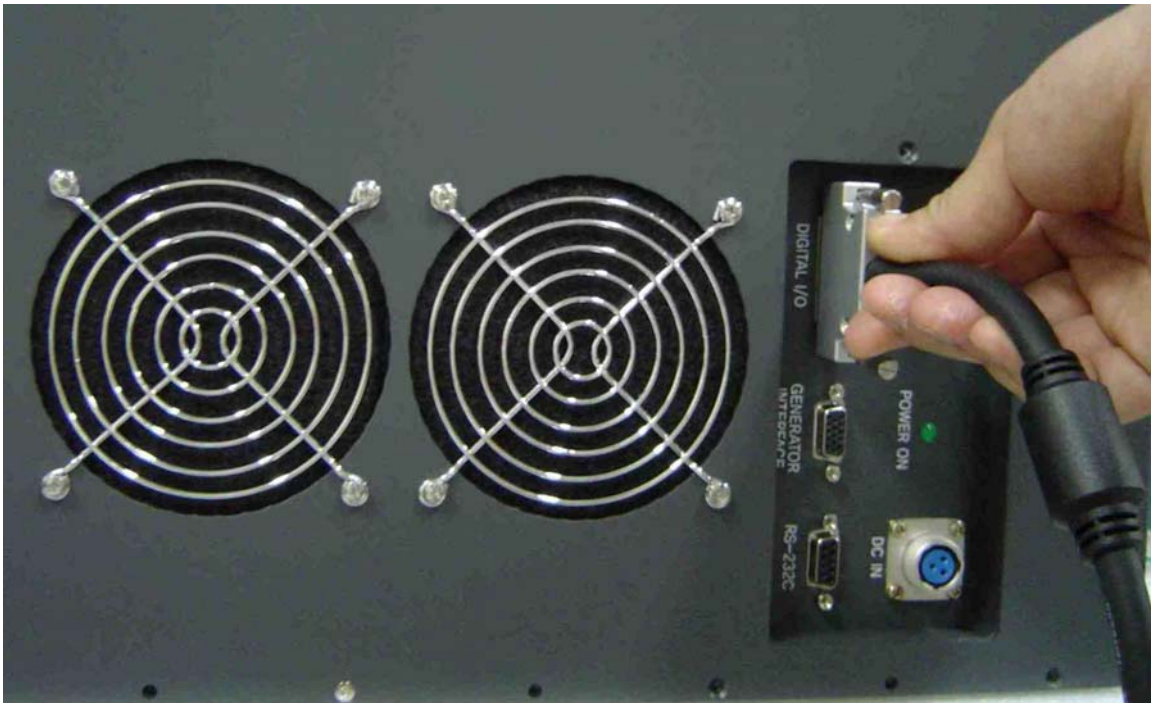
Control Connector

RS232 Connector

<Connector Layout>

6.1 Connect DC Power cable to Detector

6.2 Connect Data cable to Detector



6.3 Connect RS232C cable to Detector

6.4 Connect DC Power cable to Power Supply Unit

6.5 Connect Data cable to capture board in workstation

※ If you are provided with RXDN-USB2N or RXDN-USB2M, skip this section

6.6 Connect Data cable to RXDN-USB2N

※ If you are provided with Matrox Meteor II dig Grabber or RXDN-USB2M, skip this section

6.7 Connect Data cable to RXDN-USB2M

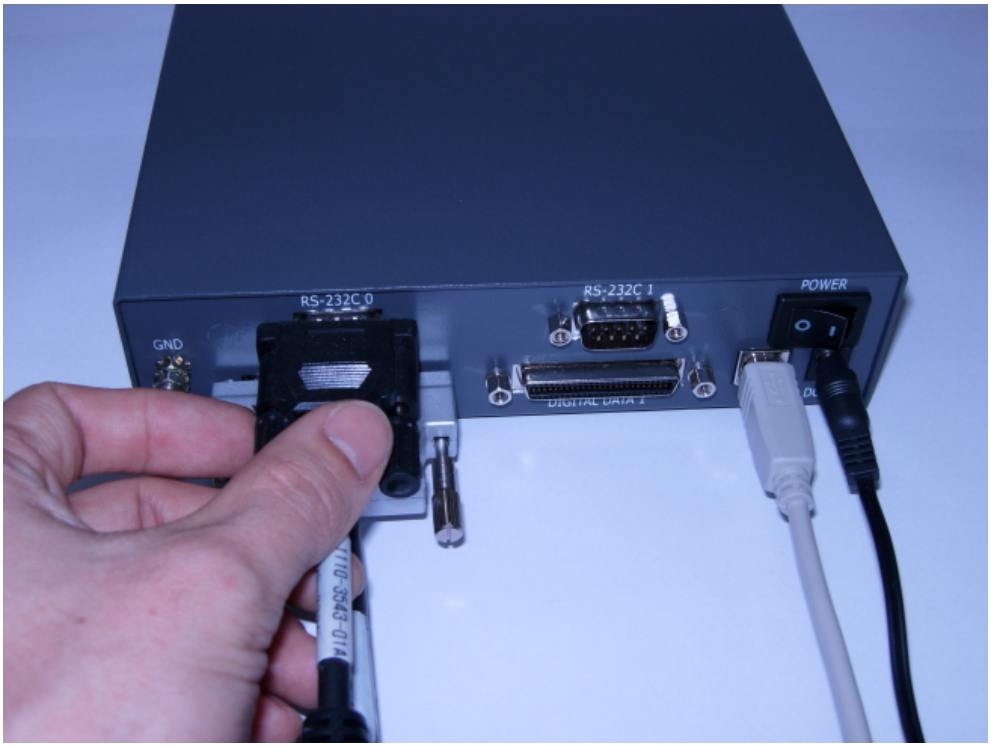
※ If you are provided with Matrox Meteor II dig Grabber or RXDN-USB2N, skip this section

6.8 Connect RS232C cable to COM port of the workstation

※ If you are provided with RXDN-USB2M, skip this section

6.9 Connect RS232C cable to COM port of the RXDN-USB2M.

※ If you are provided with Matrox Meteor II dig Grabber or RXDN-USB2N, skip this section



6.10 Plug in AC Power cable to power supply unit

7. Preparation for operating MAXXray system

To operate MAXXRAY system, following step should be executed

1) Select USB Image Grabber and detector

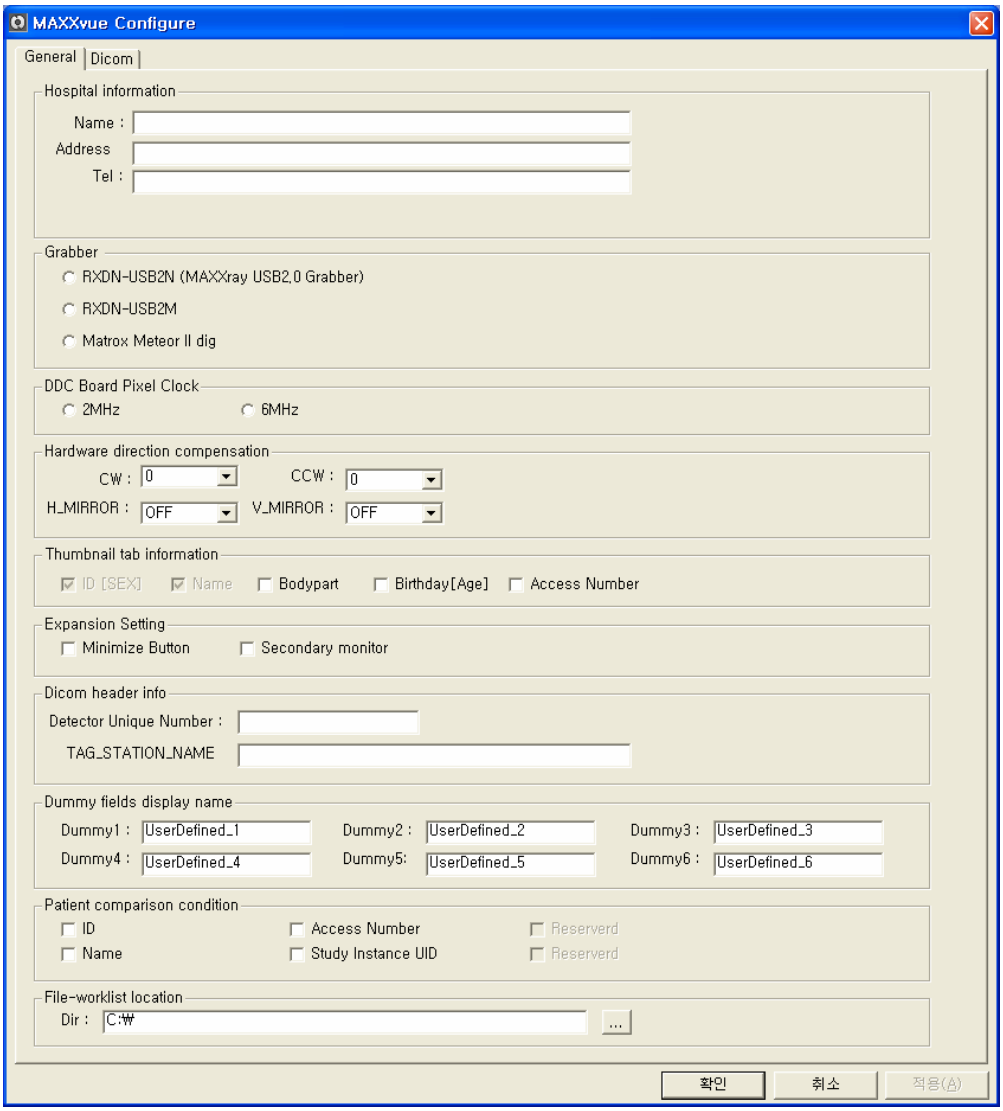
2) Diagnostics and calibration

3) Configuration of MAXXvue

7.1 Select USB Image Grabber and Detector

1) Run MAXXvueConfigure in "C:₩program files₩MAXXvue" folder

2) Select Image Grabber



7.2 Calibration

Refer to clause 9

7.3 Configuration of MAXXvue

Refer to clause 10

8. Diagnosis

After the installation of the Detector, check if the detector is operating normally.

This diagnostic procedure will check operating state of detector and will generate diagnostic file for reporting about installed detector.

Diagnostic will be performed in following sequence with the diagnostic software.

8.1 Procedures of Diagnosis

1) Serial Communication Test

2) Set Parameter of Detector

3) CCD Cooling Test

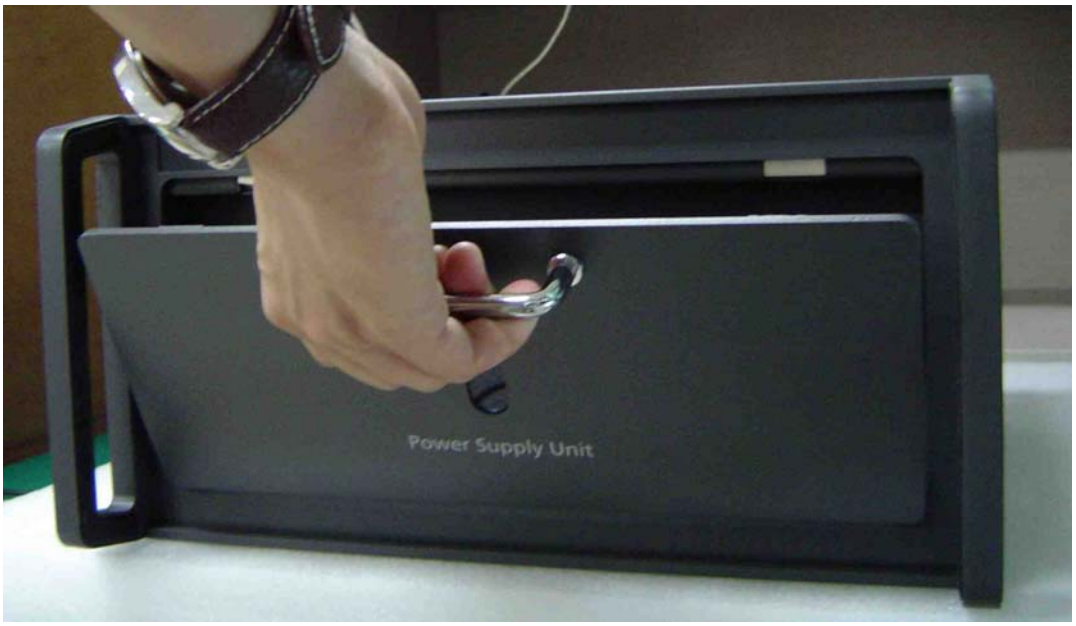
4) Black Level Test

5) Flat Field Test

6) Resolution Test

8.2 Preparation for Diagnosis

1) Pull out protect cover of Power Supply Unit



2) Turn on the power of power supply unit

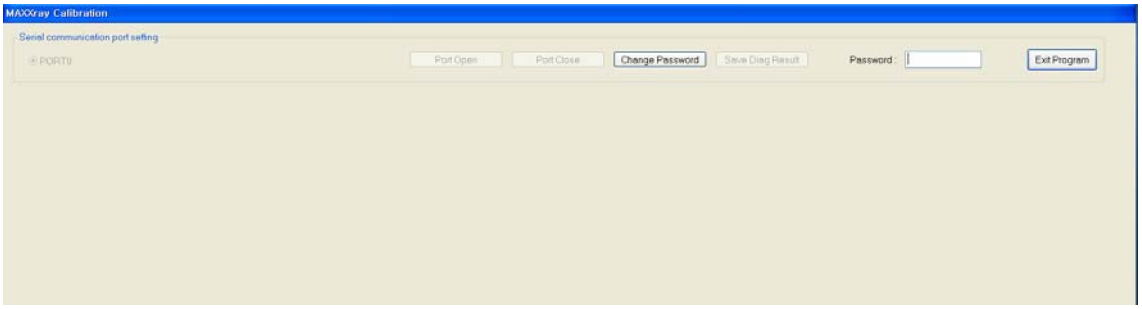
3) Close protect cover of Power Supply Unit

4) Run MAXXrayCalibration Software

8.3 Password Input

Input Password, only after inputting password this software will operate.

The default password is "vieworks".



Caution

The password of the following program is same and if you change the password in the one of those program, the password of those program will be changed simultaneously

MAXXvue.exe

*MAXXray*Calibration.exe

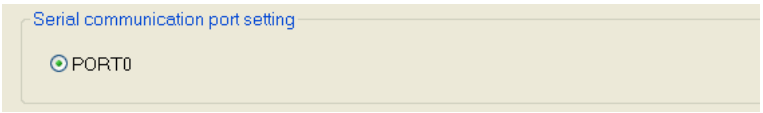
MAXXvueConfigure..exe

8.4 Serial Communication Test

Select a communication port and click "Port Open" button to establish RS232C connection.

The selection of a communication port varies depending on the selection of Image Grabber.

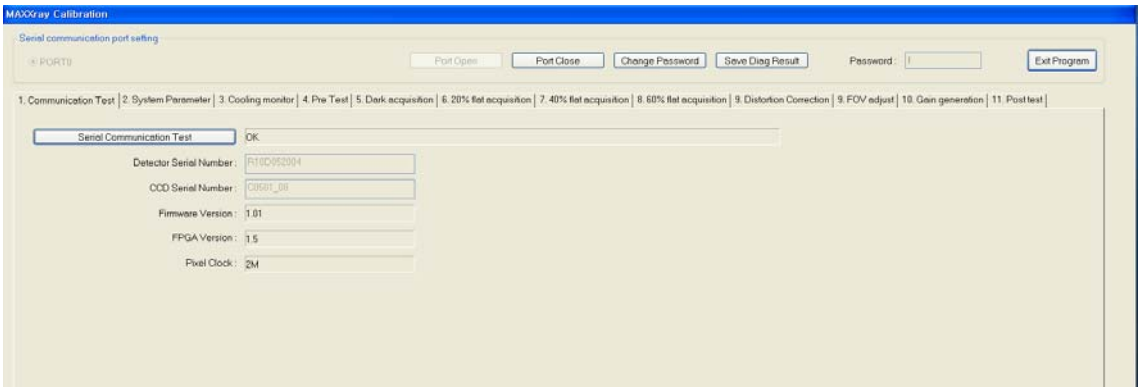
1) If you chose "RXDN-USB2M"



2) If you choose "RXDN-USB2N"

Select an appropriate port and device and click "Serial Communication Test" button.

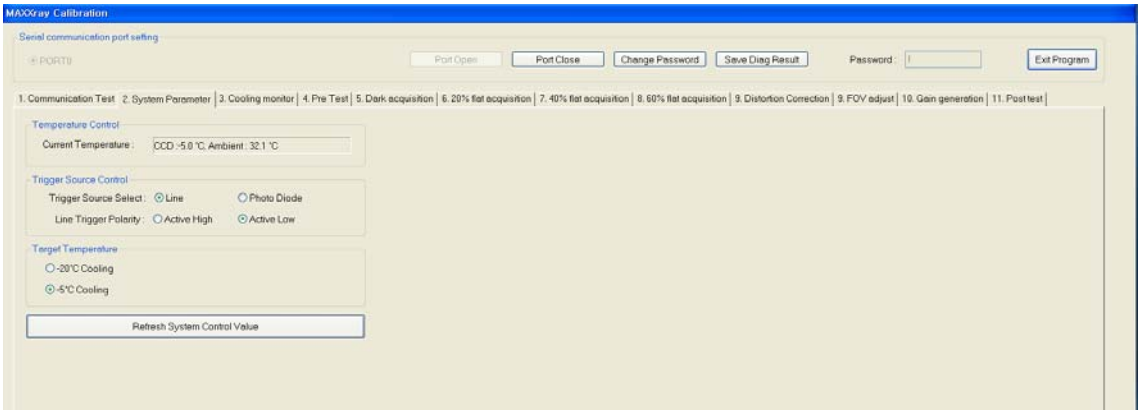
Then the test result will be displayed on the text box



8.5 Set parameter of Detector

Select "System Parameter" tab.

Click "Refresh System Control Value" button to get parameter of detector, then the parameters of detector will be displayed on the parameter field



Select "Line Trigger Polarity" and "Target Temperature" for proper one.

Current temperature field display temperature of CCD and the ambient temperature

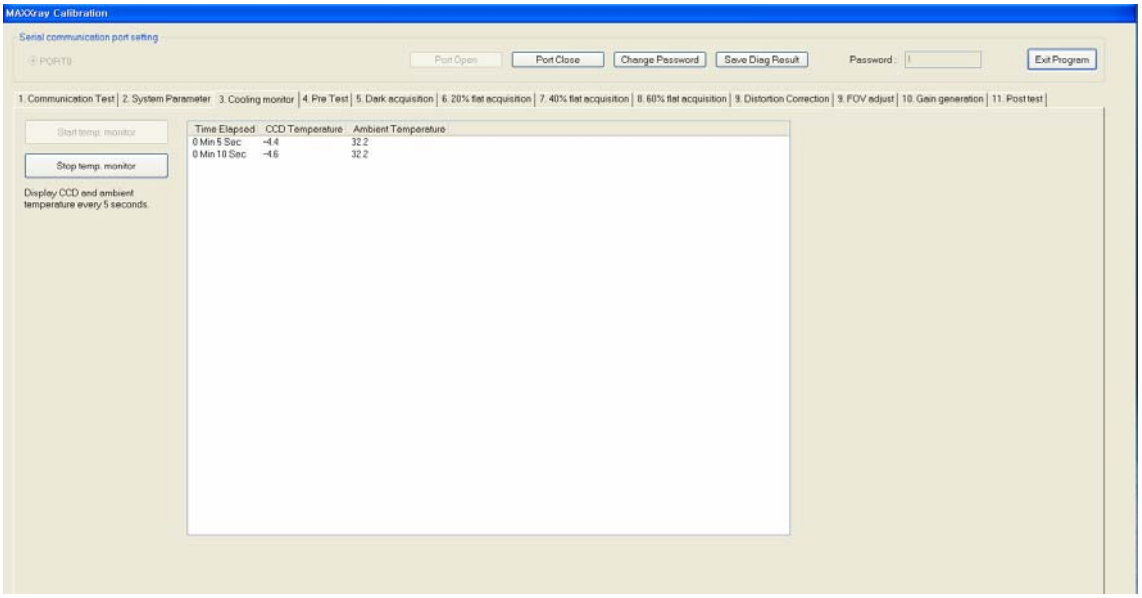
8.6 CCD Cooling Test

Wait for 15 minutes after turning on power because CCD cooling requires some time to reach the set temperature.

Select "Cooling monitor" tab.

Click "Start Temp Monitor" button then the temperature of CCD and ambient temperature will be displayed every 5 second.

Click "Stop Temp Monitor", if the CCD temperature is under –4 degree



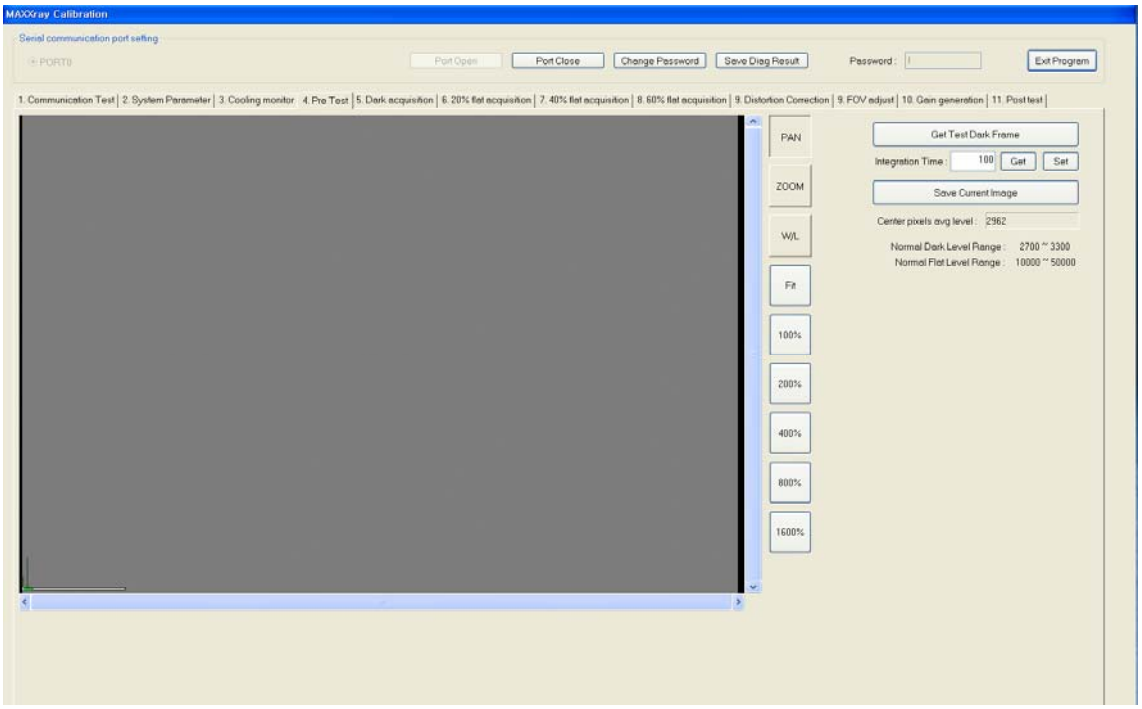
If the elapsed time is over 15 minutes and CCD temperature is over –4 degree, then the CCD cooling is abnormal.

8.7 Black Level Test

Select "Pre-resolution Test" tab.

Click "Get Test Dark Frame" button then dark frame image and the center dark level will be displayed.

If center dark level is not within 0 to 1000, then the detector is abnormal



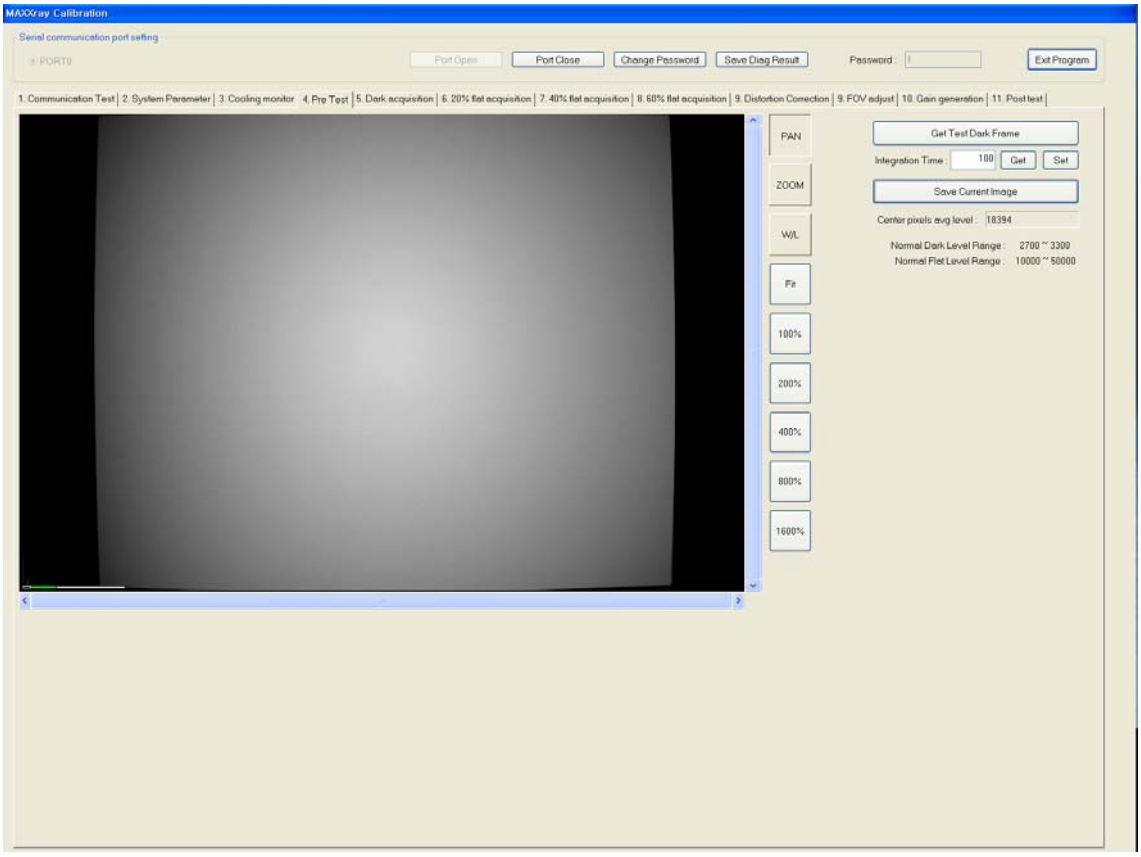
By clicking the "Save Current Image" button, save current image as "Dark.raw".

8.8 Flat Field Test

Set SID is 1m, then set x-ray generator to 60KV 5mas

Make an x-ray expose without any target, then the flat field frame image and the center flat level will be displayed.

If the center flat level is not within 500 - 16000, then the detector is abnormal.



By clicking the "Save Current Image" button, save current image as "Flat.raw".

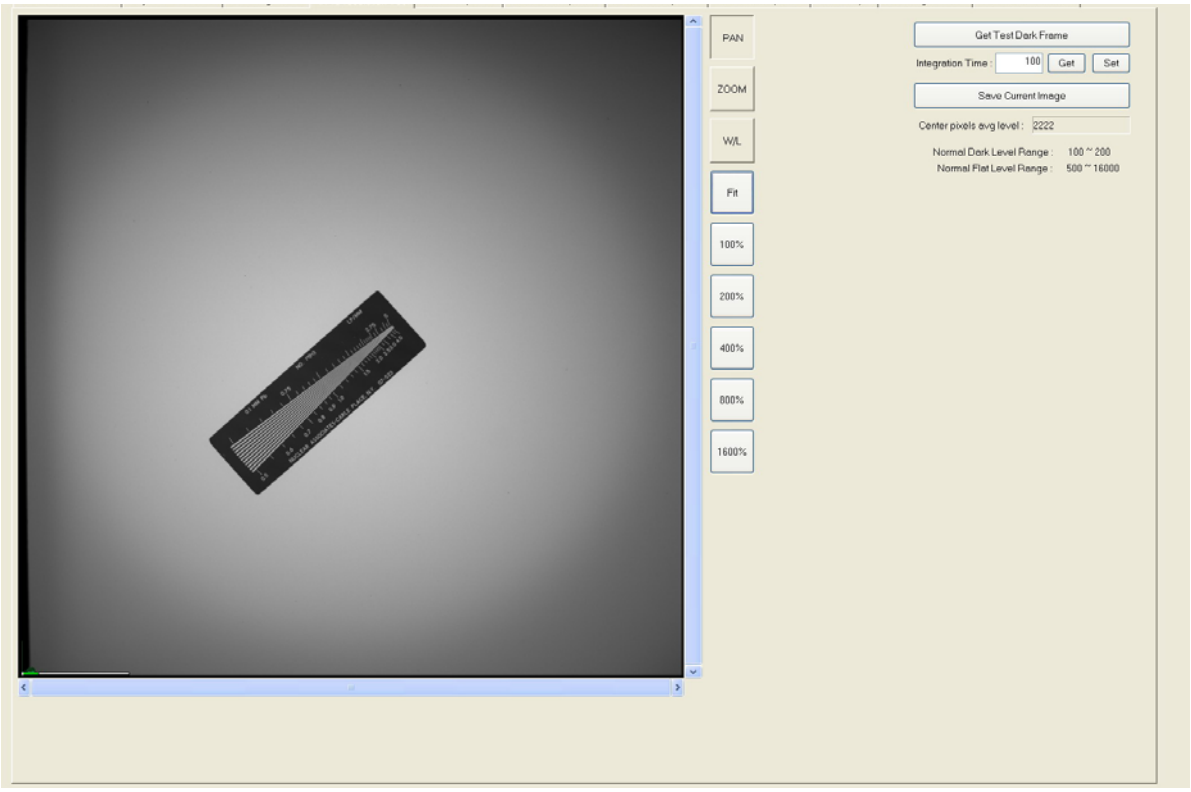
6.9 Resolution Test

Attach resolution chart (Maker : Nuclear Associate, model 07-523-2) on the center of detector in diagonal direction

Set x-ray generator to 60KV 10mas and SID to 1m

Make an x-ray expose, then the resolution chart image will be displayed on the image window

Check the best resolution with adjusting "Zoom", "W/L" and "PAN".



By clicking the "Save Current Image" button, save current image as "Pre_resolution.raw".

8.10 Save Result of Diagnosis

By clicking the "Save Diag Result" button, save diagnostic result as "Diag_result.txt".

9. Calibration

Calibration procedure compensates defect pixels and calibrates pixel gain using the installed x-ray generator and x-ray tube.

The calibration should be performed on the following case

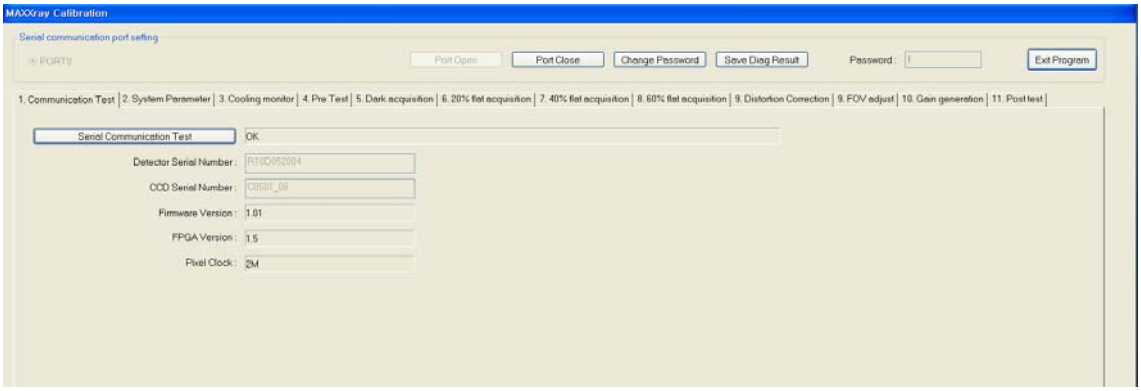
Detector installation
X-ray generator replacement
X-ray tube replacement

Procedure of Calibration

1) Acquire Black image
2) Acquire 20% flat filed image
3) Acquire 40% flat filed image
4) Acquire 60% flat filed image
5) Distortion correction
6) Adjust FOV
7) Generate calibration data
8) Test calibration data

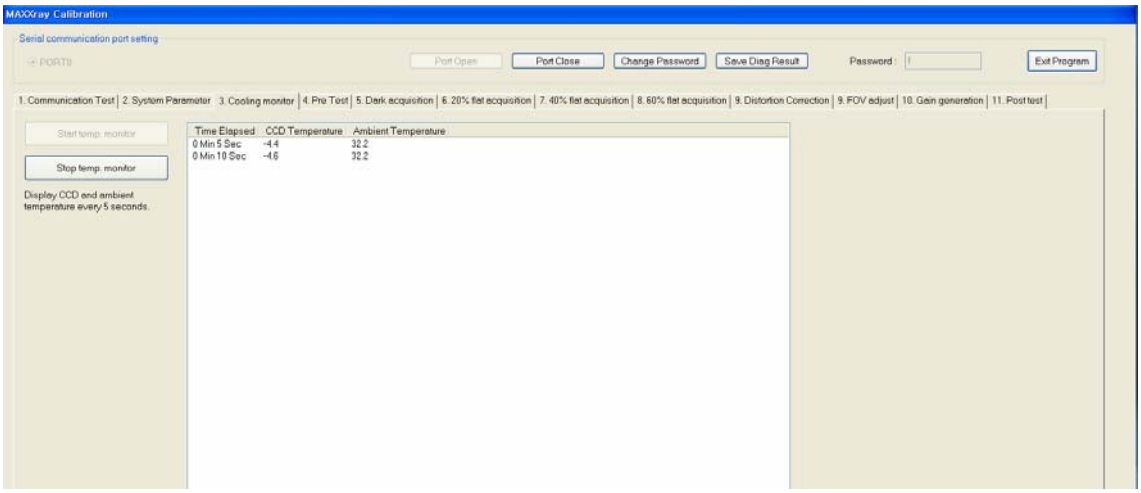
9.1 Preparation for Calibration

- Run Calibration software
- Input password
- Establish RS232 connection by clicking "Open Port" button
- Click the "Serial Communication Test" button



- Select "Cooling monitor" tab

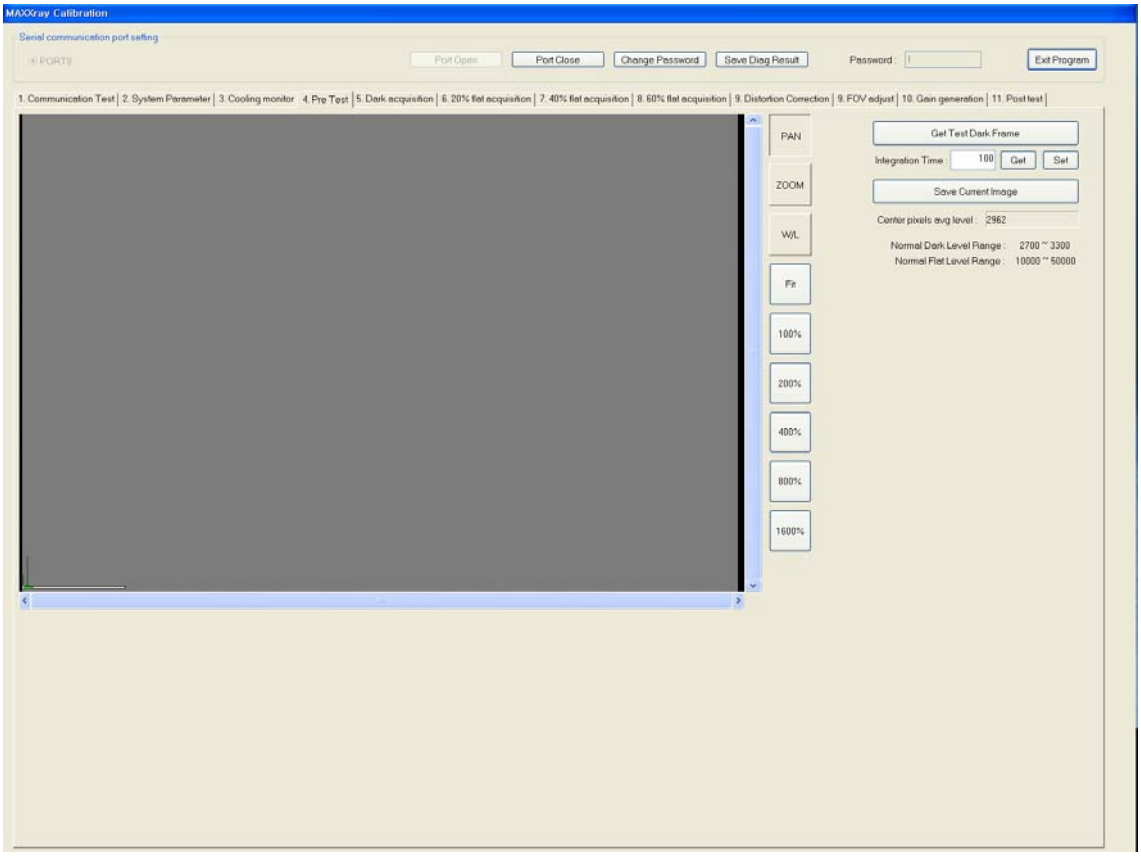
- Read CCD temperature by clicking "Start Temp. Monitor" button and wait until CCD temperature is under –4 degree, then click "Stop temp. Monitor" button.



- Set SID to 1.8m or 1m.

9.2 Acquire Black image

Select "Dark Frame Acquisition" tab.



Click "Test Shot" button in Dark Data Acquisition area to get black image and make sure black center value is 500 +/- 500

Input Dark Accumulation Time data, the data means the number of dark frames used in calibration. The recommended data is 20.

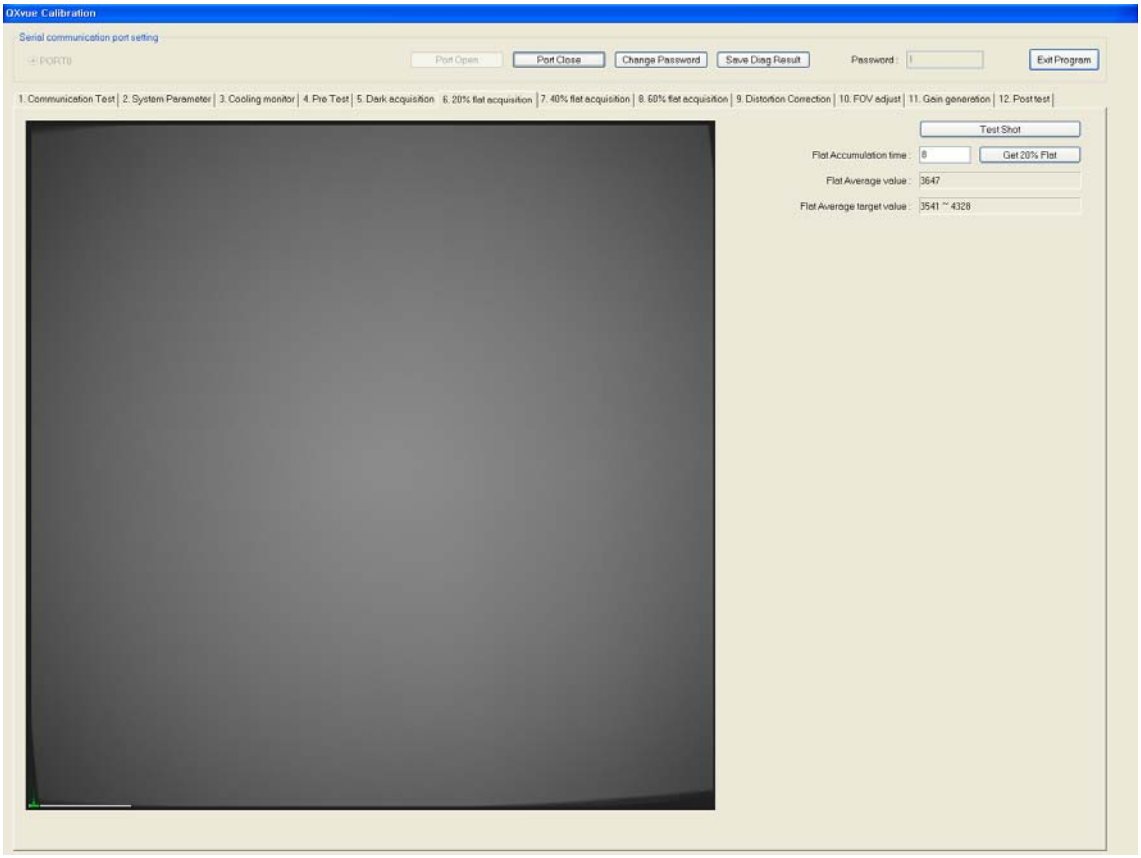
Click "Get Dark" button to get dark frame data automatically, then the calibration software will get dark frame data automatically.

During the test of the Calibration, you can control the Window/Level by dragging the mouse. And you can change the level rapidly by dragging and pressing the SHIFT key at the same time.

9.3 Acquire 20% flat field image

Set x-ray generator to 60KV, 5mas

Select "20% Saturation Flat Image Acquisition" tab.



Click "Test Shot" button and make an x-ray exposure to get a flat field image and then, you can see center value in the "flat Average value" text box

Make sure the value in "flat Average value" text box should exist within the difference of 10% of the value in "Flat Average Target value" text box, if not, adjust the x-ray dose and repeat getting a flat field image until you get the flat level of the flat field image within the recommended level.

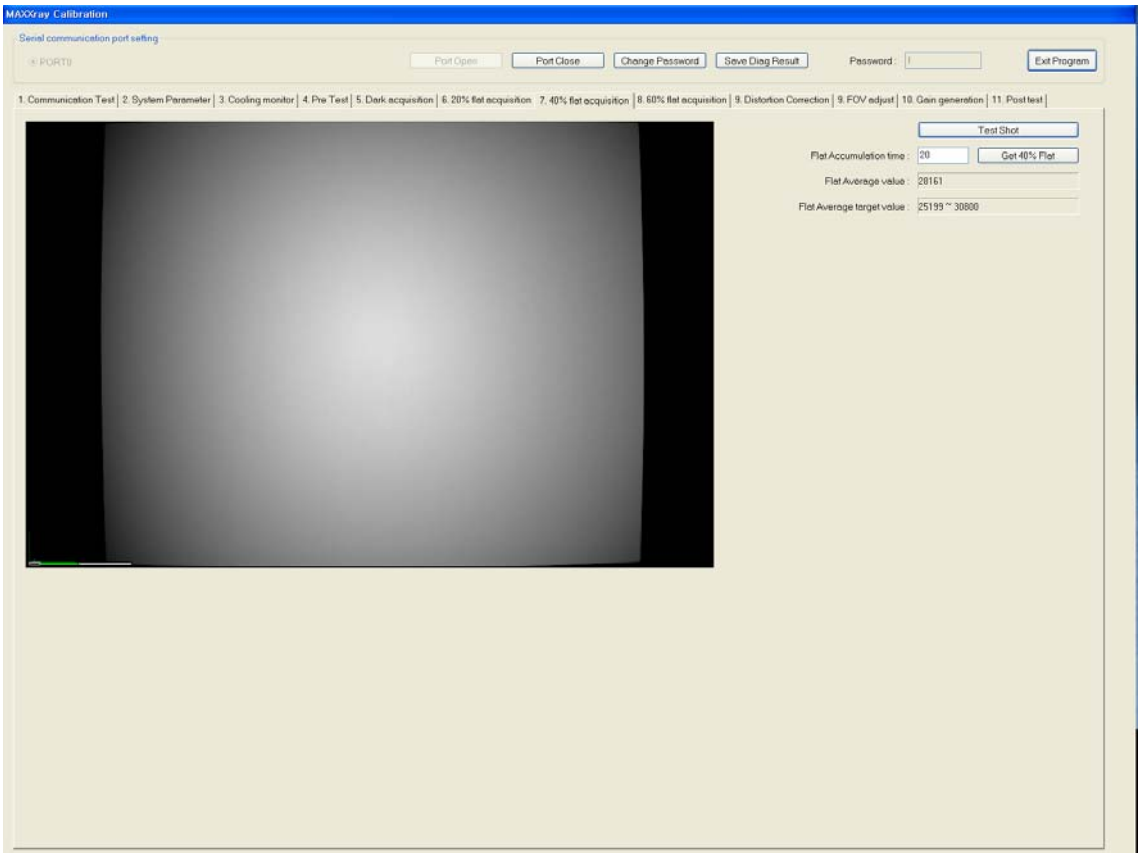
Input Flat Accumulation Time data, the data means the number of flat field images used in calibration. The recommended data is 20.

Wait until Ready of Nth expose message box appear, then make an x-ray exposure to get another flat field image.

Repeat getting the number of flat field image you selected

9.4 Acquire 40% flat field image

Select "40% Saturation Flat Image Acquisition" tab.



Adjust x-ray generator dose

Click "Test Shot" button and make an x-ray exposure to get a flat field image and then, you can see center value in the "flat Average value" text box

Make sure the value in "flat Average value" text box should exist within the difference of 10% of the value in "Flat Average Target value" text box, if not, adjust the x-ray dose and repeat getting a flat field image until you get the flat level of the flat field image within the recommended level.

Input Flat Accumulation Time data, the data means the number of flat field images used in calibration. The recommended data is 20.

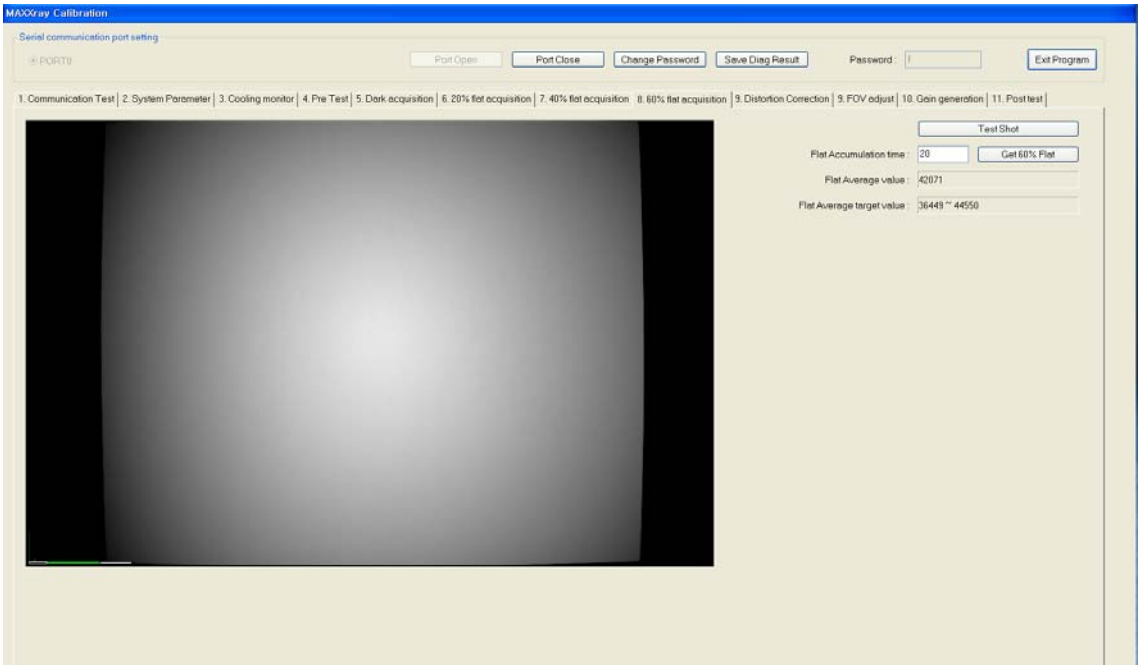
Click "Get 40% Flat" button to get flat field images then Ready of Nth expose message box will appear and then make an x-ray exposure, then calibration software will get a flat field image and will display Nth expose made.

Wait until Ready of Nth expose message box appear, then make an x-ray exposure to get another flat field image.

Repeat getting the number of flat field image you selected

9.5 Acquire 60% flat field image

Select "60% Saturation Flat Image Acquisition" menu.



Adjust x-ray generator dose

Click "Test Shot" button and make an x-ray exposure to get a flat field image and then, you can see center value in the "flat Average value" text box

Make sure the value in "flat Average value" text box should exist within the difference of 10% of the value in "Flat Average Target value" text box, if not, adjust the x-ray dose and repeat getting the flat field image until you get the flat level of the flat field image within the recommended level.

Input Flat Accumulation Time data, the data means the number of flat field images used in calibration. The recommended data is 20.

Click "Get 40% Flat" button to get flat field images then Ready of Nth expose message box will appear and then make an x-ray exposure, then calibration software will get a flat field image and will display Nth expose made.

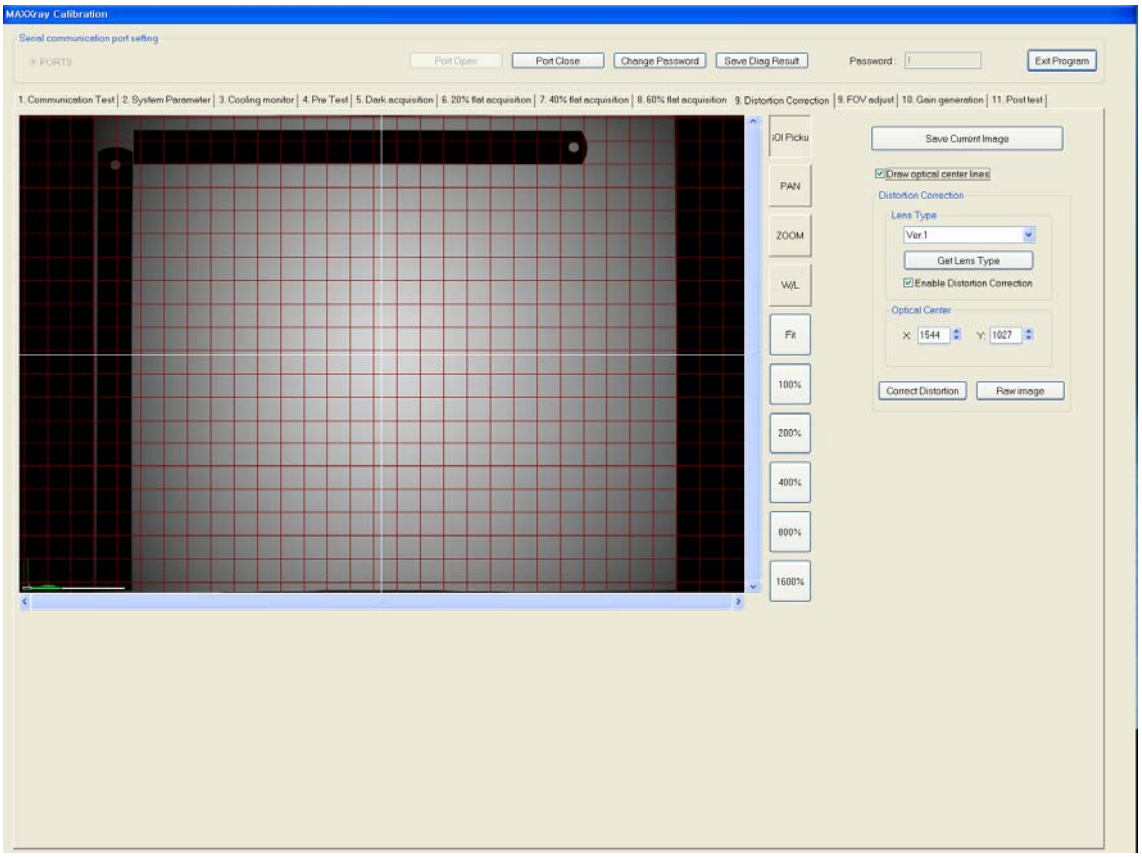
Wait until Ready of Nth expose message box appear, then make an x-ray exposure to get another flat field image.

Repeat getting the number of flat field image you selected

9.6 Distortion Correction

Select "Distotion correction" tab

Put object that is straight on the sides, and expose x-ray



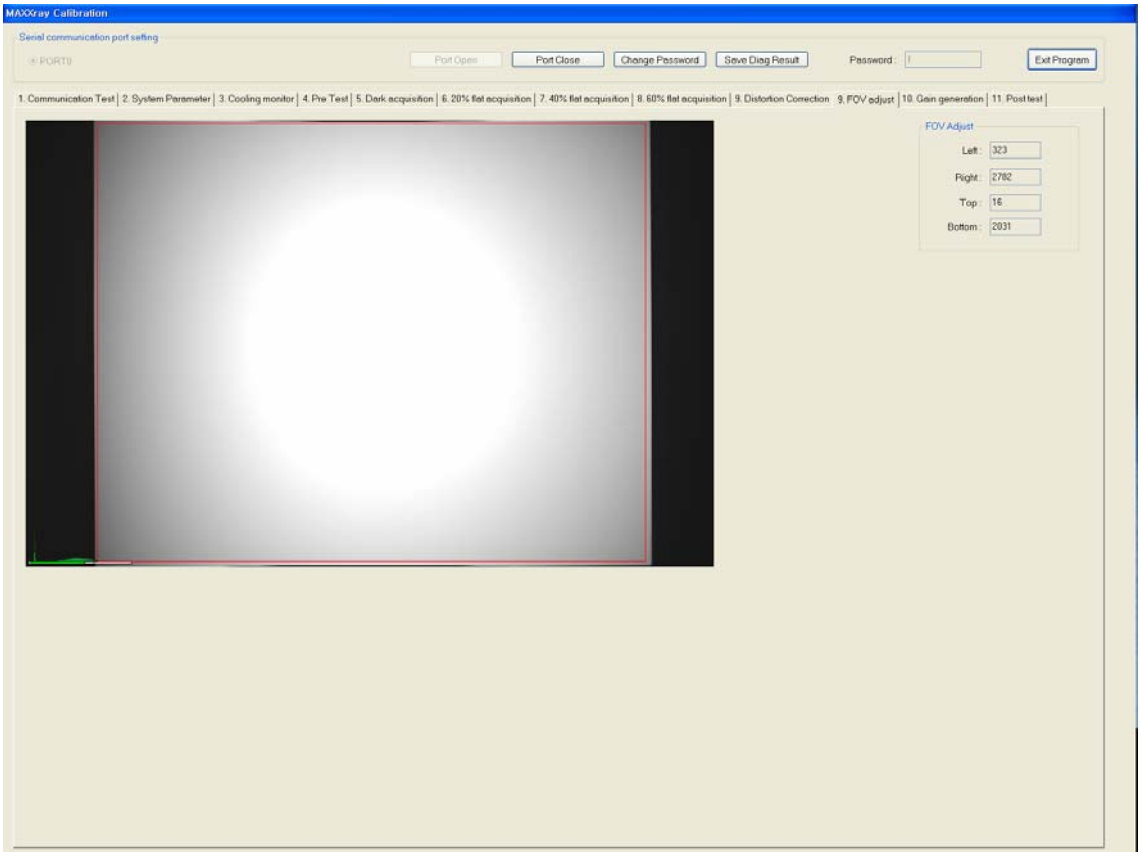
Distortion corrected image will be displayed

If the distortion is not corrected then change "Lens Type" and click "Correct Distortion" button, then distortion corrected image will be displayed.

If disable "Enable Distortion Correction", then distortion will not be corrected.

9.7 Adjust FOV(Field of view)

Select "FOV Adjust" tab



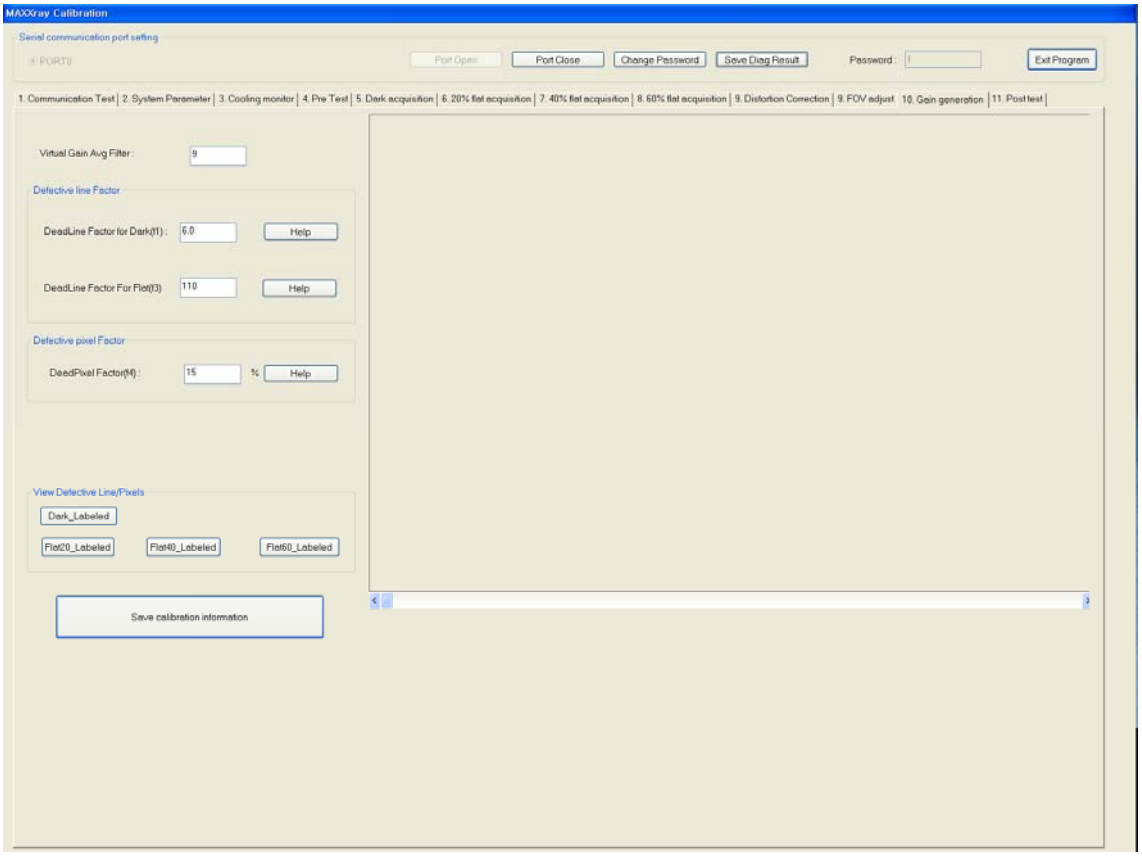
Adjust Window/Level to see image clearly.

Adjust right or left line of the red square to locate vertical red line just inside of the white part of the image by dragging the mouse.

Adjust top or bottom line of the red square to locate horizontal red line just inside of the white part of the image by dragging the mouse.

9.8 Generate Calibration Data

Select "Gain generation" tab



Click "Save calibration information" button, then calibration software will generate calibration data file, and then will display the following message box

Click "OK" button to finish calibration.

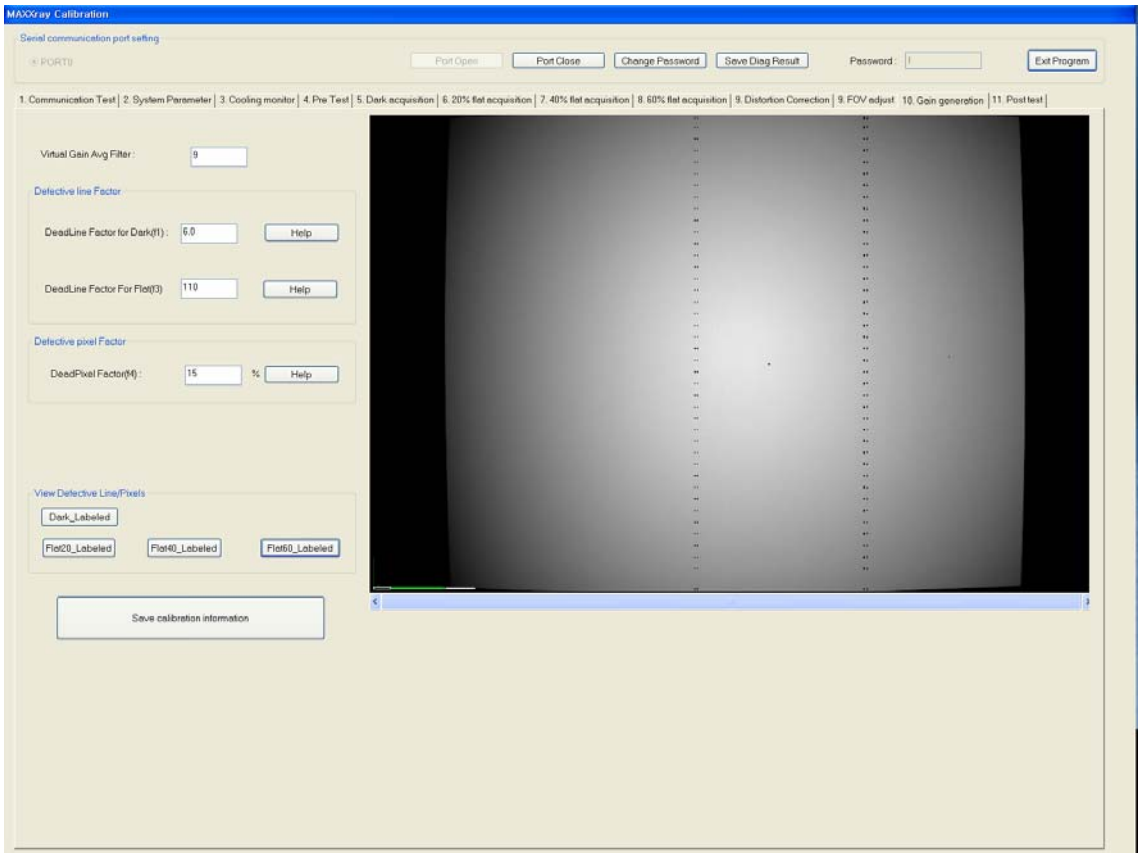
If click "Dark_Labeled", then detected defect pixel and defect line will be indicated with ▶◀ marker in dark image.

If click "flat20_Labeled", then detected defect pixel and defect line will be indicated with ▶◀ marker in

Flat20% image

If click "flat40_Labeled", then detected defect pixel and defect line will be indicated with ▶◀ marker in Flat40% image

If click "flat60_Labeled", then detected defect pixel and defect line will be indicated with ▶◀ marker in Flat60% image

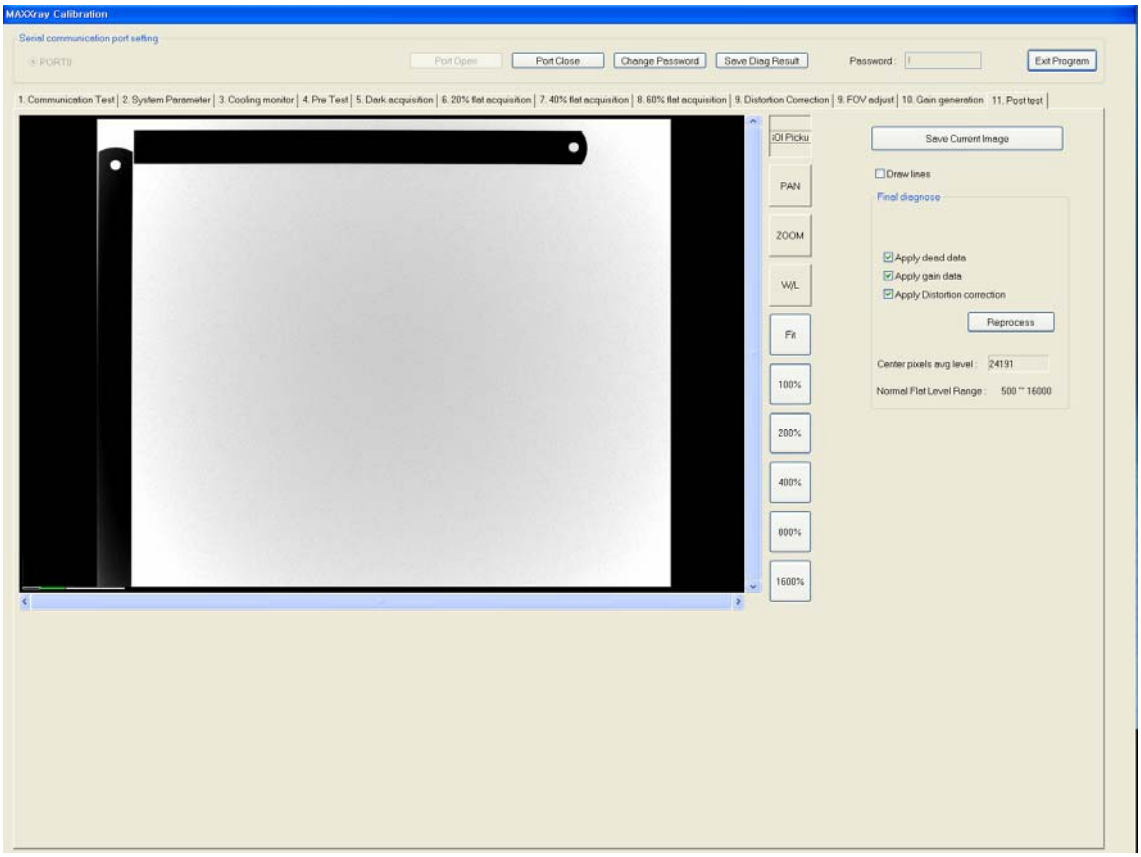


9.9 Test Calibration Data

Select "Post-resolution test" tab.

Check "Apply dead data" and "Apply gain data".

If you make an x-ray exposure, image will be displayed after being applied calibration data.



"Apply dead data" is an option applying dead pixel compensation.

"Apply gain data" is an option applying CCD pixel gain compensation.

"Apply Distortion correction" is an option applying distortion correction.

After changing options, click "Reprocess" button then you will get image processed with selected options.

By clicking the "Save Current Image" button, you can save current image.

10. MAXXvue Configuration

10.1 What is Configuration

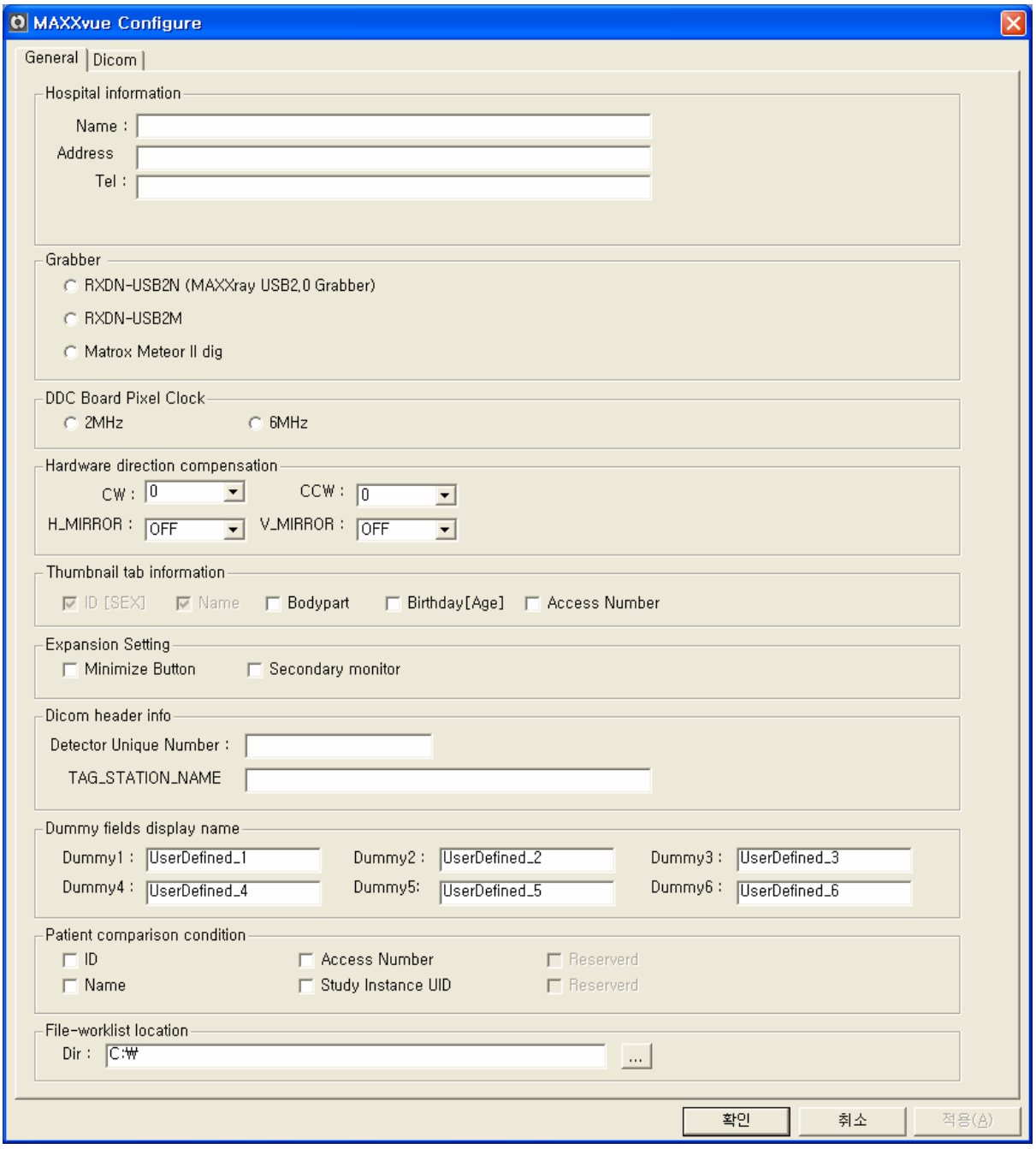
Using configuration software we can set the various parameters that is used in the MAXXvue, so the proper setting of parameter is important.

Configuration of MAXXvue is needed when the MAXXray is installed, and this job should be performed before using MAXXvue.

Configuration of MAXXvue is consist of two parts
General parameter setting : Basic information used by MAXXvue
Dicom parameter setting : Worklist related DICOM header setting
Mobile parameter setting : specific parameters for mobile application

The configuration software is located at "C:₩program files₩MAXXvue" folder

10.2 General parameter setting



10.2.1 Hospital information

- They are the name, address and telephone number of the hospital in which the MAXXray system is installed.
- The values of the name field and address field is put into the 'institution name' tag and 'institution address' tag respectively when creating DCM files.

10.2.2 Image Grabber Selection

. Matrox Meter II dig : If you installed Matrox Meter II dig for the image grabber device, choose this one.

. RXDN-USB2N : If you installed RXDN-USB2N for the image grabber device, choose this one.

. RXDN-USB2M : If you installed RXDN-USB2M for the image grabber device, choose this one.

10.2.3 Hardware direction compensation

- This is used to set the image direction
- The image direction can be checked using "MAXXrayCalibration" program
- CW means rotate 90 degree clockwise
- CCW means rotate 90 degree counter clockwise
- H_MIRROR means horizontal mirroring
- V_MIRROR means vertical mirroring

10.2.4 Thumbnail tab information

- Select the item(s) to be displayed in the thumbnail tab.
- Patient ID and Patient name is default and the additional information can be displayed in the thumbnail tab according to the setting

10.2.5 Expansion setting

If the "Minimize Button" check box is set, you will have the Minimize button above the 'Exit' button.

If the "Secondary Monitor" check box is set, the processed image will be displayed to secondary monitor.

10.2.6 Dicom header info

1) Detector Unique Number

- The 12-digit number unique for each detector which constitutes 'Study Instance UID', 'Series Instance UID' and 'SOP Instance UID'
- If you run MAXXrayCalibration, the field is automatically filled in.

2) TAG_STATION_NAME

- A string for 'station name' tag
- This is used to distinguish the detectors if two or more detectors are installed in the same hospital

10.2.7 Device Name

- If "Two detector" were selected, you can enter the names for each detector that will be displayed in detector select buttons in MAXXvue.

10.2.8 Dummy fields display name

- Dummy field is used for the connection with the worklist server
- If the worklist server send some information that is not mentioned in the DICOM standard, then MAXXvue can receive that information using dummy fields
- Dummy field will be displayed as set name in the order list

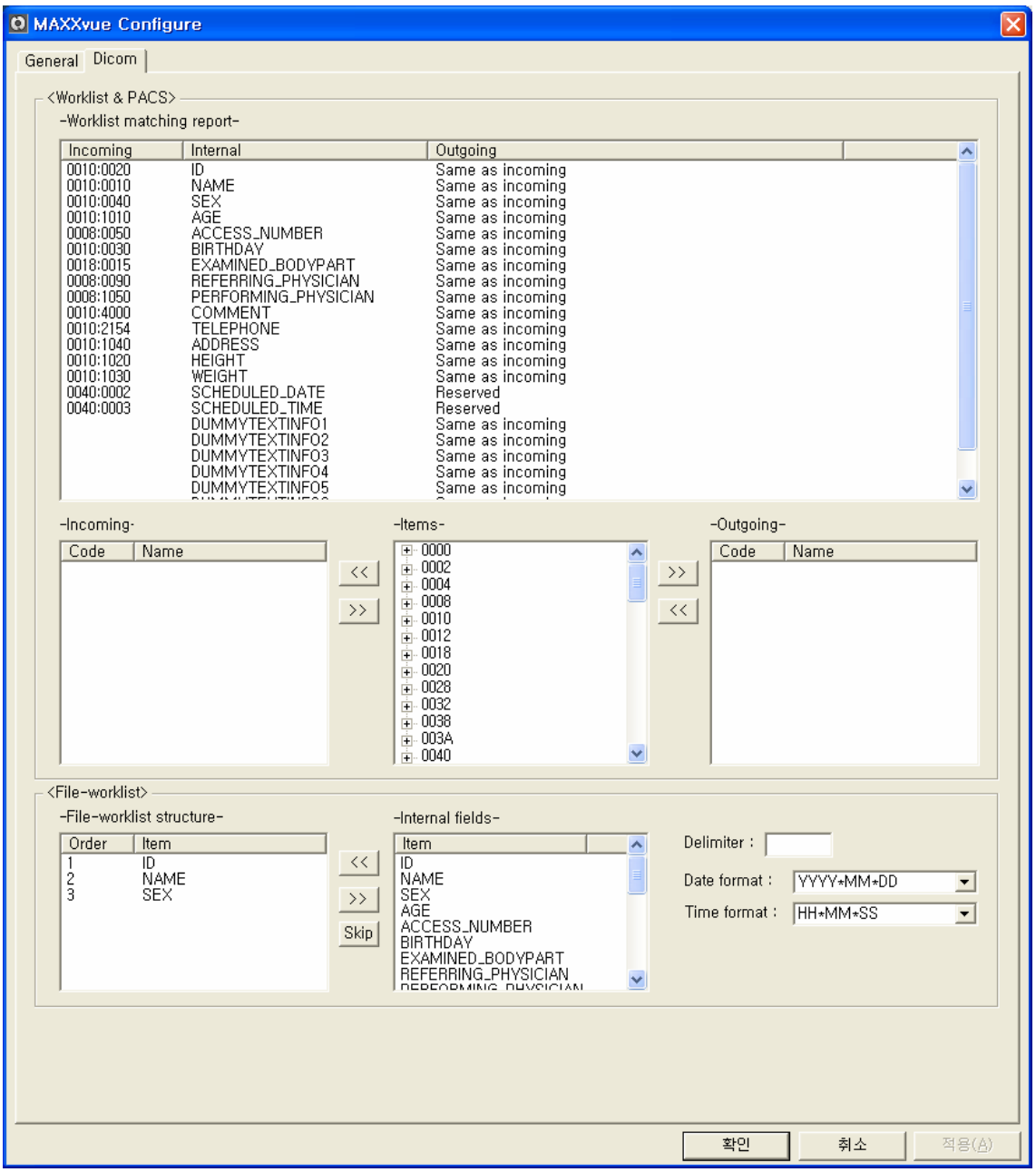
10.2.9 Patient comparison condition

- MAXXvue distinguishes among patients by comparing the selected fields of patients when inserting the patients from the worklist server into the local patient list database
- When we query study order from the worklist server, if all selected patient comparison field data is equal to already registered order, MAXXvue ignore that study order
- If none of comparison field is select, then Patient ID will be used as comparison field
- If any comparison field is selected than only the selected field will be used as comparison field

10.2.10 File-worklist location

- If worklist server is not available and the study ordering system is providing study order using text file MAXXvue can receive patients list from that file
- MAXXvue check assigned folder and if there is new order file MAXXvue will load study order from that file and after loading, MAXXvue will delete that file

10.3 DICOM parameter setting



MAXXvue use internally defined tag name related patient information for DICOM, these information will be filled when we register patient or receive study order from the worklist server.

After x-ray exposure these information will be stored to the internal database and will be put to the DICOM file as DICOM tag when we make DICOM file.

When MAXXvue receive order from the worklist server that might not be the standard DICOM tag, so MAXXvue has DICOM tag converting function to make standard DICOM file.

10.3.1 Worklist

1) Definition

- Incoming : Receiving tag from the worklist server
- Internal : Internally defined field name of the patient information and study order in MAXXvue
- Outgoing : DICOM tag that will be stored to DICOM file

2) Worklist Matching

- Select internal field name then currently matched tag will be displayed in the items table.
- Select incoming tag from the list and register it by clicking "<<" button
- Select outgoing tag from the list and register it by clicking ">>" button

10.3.2 File-worklist

- The format of file worklist should be text file and the field should be separated by delimiter
- The delimiter is user-defined and should be registered in the "delimiter" table
- Internally defined fields for patient information and study order is listed in the "internal field" table
- Set the matching internal field name according to the text order in the worklist file
- Internal field will be translated to the DICOM tag set at 3.1.2
- The delimiter could be one or more characters.
- The date and time format used in worklist file can be selected, and all characters located in the place of where star-closure(*) exists is ignored.

  <Date format>

  YYYY : Year represented by full four digits

  MM : Month as digits with leading zero for single-digit months

  DD : Day of month as digits with leading zero for single-digit days

  <Time Format>

  HH : Hours with leading zero for single-digit hours; 24-hour clock

  MM : Minutes with leading zero for single-digit minutes

  SS : Seconds with leading zero for single-digit seconds

11. Trouble Shooting

Note :

Trouble shooting must be performed by technician who is trained by the Vieworks Co., Ltd or an organization certified by Vieworks Co., Ltd..

If an unqualified person performs troubleshooting on the system resulting in damaging the detector, software or hardware, then the Vieworks Co. or its representative is not responsible for the detector repair even if the warranty is not expired.

* Please refer to the warranty section 10 of this manual for more details.

11.1 Failure Mode

Failure Mode	Repairing Procedure
Power LED is not lit	Refer to 9.2
Serial Communication Test Failure	Refer to 9.3
CCD Cooling Test Failure	Refer to 9.4
Black Level Test Failure	Refer to 9.5
Flat Field Test Failure	Refer to 9,6
Resolution Test Failure	Refer to 9.7

11.2 Repairing Power Failure

Check AC cable of Power Supply Unit is plugged securely, if not plug securely

Check power switch in turned on, if not turn on power switch

If not repaired, then replace Power Supply Unit

11.3 Repairing Serial communication Failure

Check Control Cable is installed securely, if not secure screw of cable tightly

Run calibration program and perform Serial Communication Test procedure

If the failure is not repaired, Check RS232 port of workstation.

If RS232 port of workstation id OK, replace Control Cable

If still the failure is not repaired, replace main PCB.

If still the failure is not repaired, replace Detector.

11.4 CCD Cooling Test Failure

Check fan is operating.

if fan is not operating, check connector of fan is plugged correctly.

If still the failure is not repaired, Check connector of TEC fan is plugged correctly.

If still the failure is not repaired, , replace main PCB.

If still the failure is not repaired, replace Detector.

11.5 Black Level Test Failure

Check cable between main PCB and CCD Block, if not plug connector and lock screw tightly

If not repaired, replace main PCB.

If still the failure is not repaired, replace Detector.

11.6 Flat Field Test Failure

Check x-ray is exposed properly

If x-ray is exposed properly

Check Generator Interface Cable is connected properly

If not repaired, replace main PCB.

If not repaired, replace Detector.

11.7 Resolution Test Failure

If resolution is less than specification, then the detector cannot be repaired in the field, so in this case please contact Vieworks Co., Ltd

12. WARRANTY

Vieworks Co. warrants that this product will be free from defects in materials and workmanship for a period of twelve (12) months from the date of delivery. If any such product proves defective during this warranty period, Vieworks Co., at it's option, either will repair the defective product without charge for parts and labor, or will provide a replacement in exchange for the defective product. In order to obtain service under this warranty, Customer must notify Vieworks Co. of the defect before the expiration of the warranty period and make suitable arrangements for the performance of service. Customer shall be responsible for packaging and shipping the defective product to the service center designated by Vieworks Co. with shipping charges prepaid. Vieworks Co. shall pay for the return of the product to Customer if the shipment is to a location within the country in which the Vieworks Co. designated service center is located. Customer shall be responsible for paying all shipping charges, duties, taxes, and any other charges for products returned to any other locations.

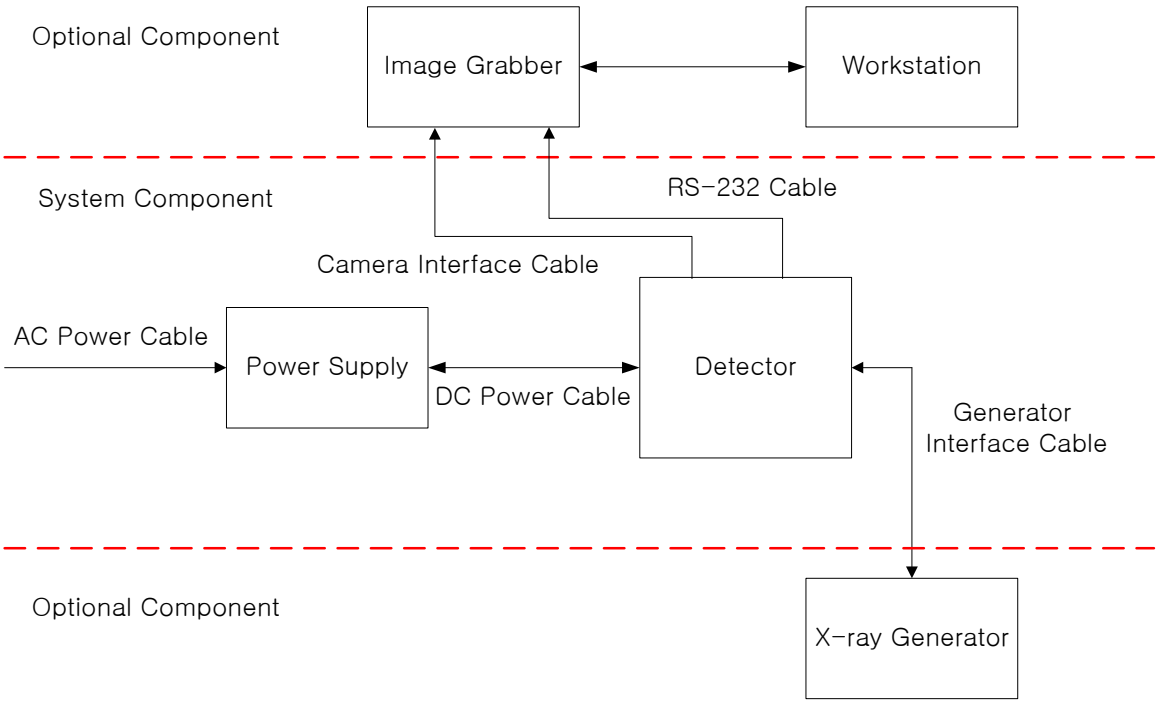
This warranty shall not apply to any defect, failure, or damage caused by improper or inadequate maintenance and care. Vieworks shall not be obligated to furnish service under this warranty to repair damage resulting from attempts by personnel other than Vieworks Co.; or its representatives to install, repair, or service this product, to repair damage resulting from improper use or connection to incompatible equipment or power source; or to service a product that has been modified or integrated with other products when the effect of such modification or integration increases the time or difficulty of servicing the product.

THIS WARRANTY IS GIVEN BY VIEWORKS CO. WITH RESPECT TO THIS PRODUCT IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED. VIEWORKS CO. AND ITS VENDOR DISCLAIM ANY IMPLIED WARRANTIES OF MERCHANTABLILITY OR FITNESS FOR A PARTICULAR PURPOSE. VIEWORKS CO. RESPONSIBILITY TO REPAIR OR REPLACE DEFECTIVE PRODUCTS IS THE SOLE REMEDY PROVIDED TO THE CUSTOMER FOR BREACH OF THIS WARRANTY. VIEWORKS AND ITS VENDORS WILL NOT BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES IRRESPECTIVE OF WHETHER VIEWORKS CO. OR THE VENDOR HAS ADVANCE NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

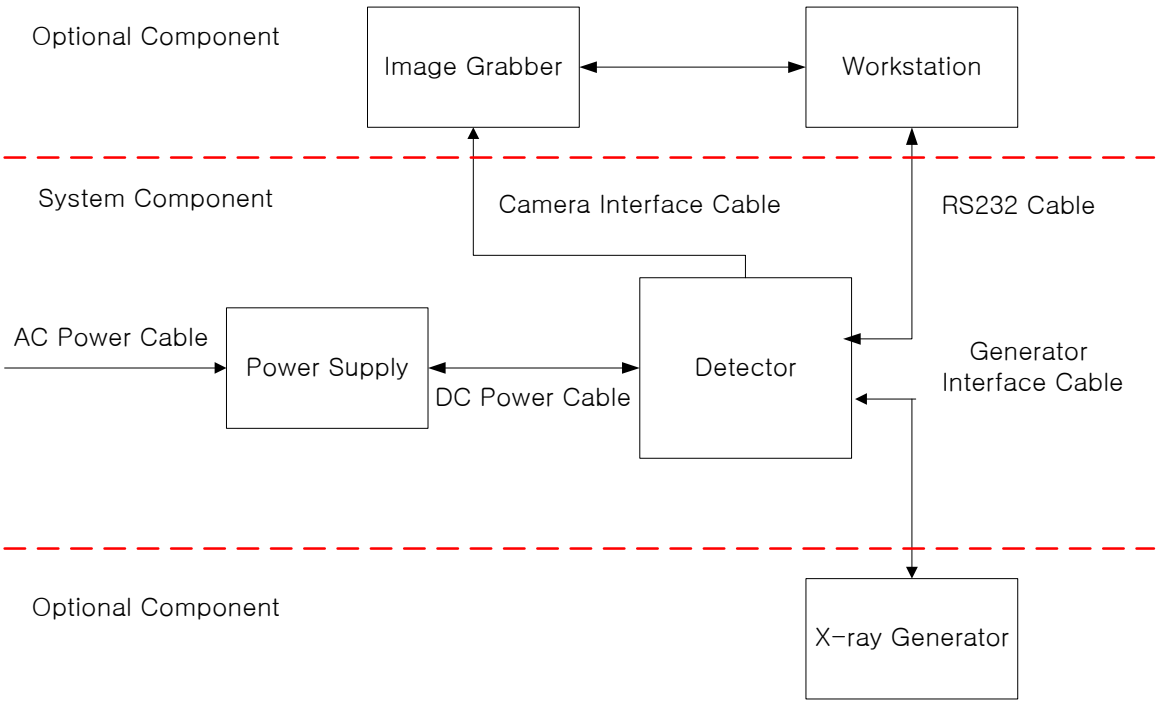
There are no warranties which extend beyond the description mentioned in this document.

Appendix A MAXXray Interconnection Diagram

Using RXDN-USB2M Image Grabber



Using RXDN-USB2N Image Grabber



Appendix B Symbols

DIRECT CURRENT

ALTERNATING CURRENT

PROTECTIVE EARTH (GROUND)

EQUIPOTENTIALITY

OFF (POWER : DISCONNECTION FROM THE MAINS)

ATTENTION, CONSULT ACCOMPANYING DOCUMENS

ON (POWER : CONNECTION FROM THE MAINS)

TYPE BF APPLIED PART

Appendix C How to use line trigger

1. Scope

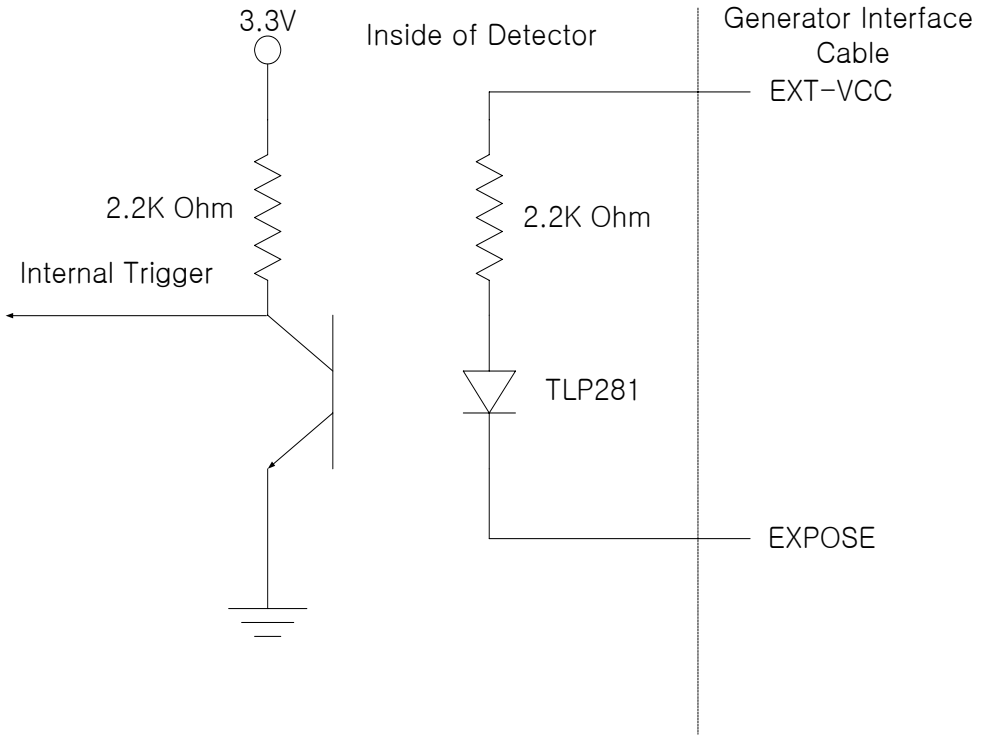
This document explain how to operate QXR using external trigger.

To take a picture of patient the x-ray will be exposed to the patient and at the same time the CCD in the QXR should be operated to receive the light from the screen.

For the CCD to receive light and generate an image of patient, QXR should know the starting time, and the ending time of the x-ray exposure.

The external trigger function is used for the QXR to know the starting time, and the ending time of the x-ray exposure.

2. Interface Circuit



Note : To activate trigger function, the current through LED of TLP281 should be in the range of 5.5mA to 16mA, so the voltage between VCC-EXT and Expose pin should be in the range of 12V to 36V .

3. Operation mode of trigger function

1) Active Low Mode

A. Standby : x-ray is not exposing, so the detector is waiting x-ray exposure

- Do not flow current through the LED(TLP281).
- To make above condition, do not apply voltage between *VCC_EXT* and *Expose*

B. Exposure : X-ray is exposing

- Flow current through the LED(TLP281) while x-ray is exposing
- To make above condition, apply voltage between *VCC_EXT* and *Expose* while x-ray is exposing

2) Active High Mode

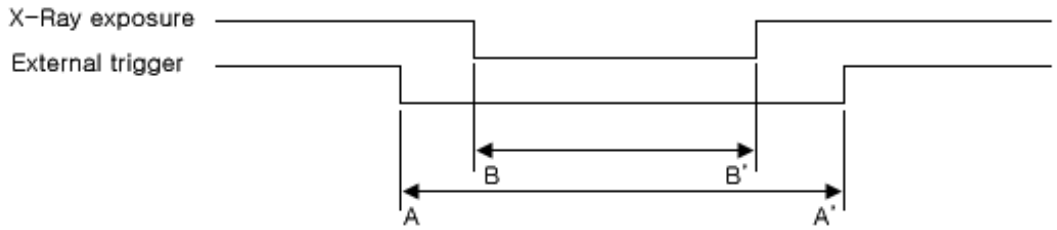
A. Standby : x-ray is not exposing, so the detector is waiting x-ray exposure

- Flow current through the LED(TLP281) while x-ray is exposing
- To make above condition, apply voltage between *VCC_EXT* and *Expose* while x-ray is exposing

B. Exposure : X-ray is exposing

- Do not flow current through the LED(TLP281).
- To make above condition, do not apply voltage between *VCC_EXT* and *Expose*

4. External trigger timing



<Fig. 5-1>

A. *A* should begin before or concurrently with *B* and *A'* should be terminated after or concurrently with *B'*

5. Software setting

Run QXvueCalibration and select line trigger polarity.

Appendix D Quality Control

SECTION I Quality Control testing

Quality Control Test and Frequency

Test Item	Frequency	Purpose
Check Cabling	Daily	Confirms the connections of the cables to make sure the system is ready to operate
Visual Inspection	Daily	Confirms that no parts are damaged
Fan Filter Cleaning	Daily	Confirms that the filter in front of ventilation fan is clean to ensure cooling of CCD
Check Hard Disk free space	Daily	Confirms that free space of hard disk is enough
Worklist Connection	Daily	Confirms Worklist connection
PACS Server Connection	Daily	Confirms PACS Server connection
Printing Test	Daily	Confirms Printer connection
Study Performing	Daily	Confirms that new study can be performed normally
Serial Communication Test	Monthly	Confirms serial communication between Detector and workstation is working
Cooling Test	Monthly	Confirms CCD Cooling
Black Level test	Monthly	Confirms black level of image
Flat Field Test	Monthly	Confirms flat image
Resolution Test	Monthly	Confirms resolution
Calibration	Annually	Calibrate system

Check Cabling

Objective:

To confirm that the system is properly installed and the system is ready to use

Frequency:

Daily

Equipment:

Daily Report Form

Procedure:

1. Check AC Power Cable is connected firm
2. Check DC Power Cable is connected firm
3. Check Camera Interface Cable is connected firm.
4. Check Control Cable is connected firm

Performance and Corrective Action:

Connect cables firm and record result on the Daily Report Form

Visual Inspection

Objective:

To confirm that there is no defect or damages of the parts that is visible, and that the system is ready to use.

Frequency:

Daily

Equipment:

Daily Report Form

Procedure:

1. Confirm that Detector is installed firm on the X-ray stand or table
2. Confirm that the skin of detector is not damaged
3. Confirm that the screen has no defect or has not damaged

Performance and Corrective Action:

Install detector firm

Record result on Daily Report Form

If some parts is damaged require service assistance

Fan Filter Cleaning

Objective:

To confirm that air ventilation for cooling CCD has no problem .

Frequency:

Daily

Equipment:

Vacuum cleaner

Daily Report Form

Procedure:

1. Confirm that fan filter is clean.
2. Clean fan filter using vacuum cleaner

Performance and Corrective Action:

Record result on Daily Report Form

Check Hard Disk Free Space

Objective:

To confirm that new study can be performed and stored to hard disk drive of workstation.

Frequency:

Daily

Equipment:

MAXXvue S/W

Daily Report Form

Procedure:

1. Turn on the power of system
2. Run MAXXvue
3. Check hard disk free space indication is not red light

Performance and Corrective Action:

If the hard disk free space indication is not red, new study can be performed.

If the hard disk free space indication is red, delete old study to make free hard disk space enough to perform new study.

Record result on Daily Report Form

Worklist Connection

Objective:

To confirm that MAXXvue is connected normally with Worklist and can register study by querying from Worklist server

Frequency:

Daily

Equipment:

MAXXvue S/W

Worklist Server

Daily Report Form

Procedure:

1. Turn on the power of system
2. Run MAXXvue
3. Select Exposure Mode
4. Select Registration Menu
5. Select Worklist Menu
6. Select Configure Menu
7. Select Worklist server
8. Click Test button

Performance and Corrective Action:

Check the connection status that is displayed in test result window.

If connection test failed, check Worklist server is operating and configuration of Worklist server connection is correct.

If still Worklist connection fail, then require service assistance

Record result on Daily Report Form

PACS Server Connection

Objective:

To confirm that MAXXvue is connected normally with PACS Server and can send performed study data to PACS server.

Frequency:

Daily

Equipment:

MAXXvue S/W

PACS Server

Daily Report Form

Procedure:

1. Turn on the power of system
2. Run MAXXvue
3. Select Database Mode
4. Select Dicom transfer Menu
5. Select Configure Menu
6. Select PACS Server
7. Click Test button

Performance and Corrective Action:

Check the connection status that is displayed in test result window.

If connection test failed, check PACS server is operating and configuration of PACS server connection is correct.

If still PACS server connection fail, then require service assistance

Record result on Daily Report Form

Printing Test

Objective:

To confirm that MAXXvue is connected normally with Printer and can print images.

Frequency:

Daily

Equipment:

MAXXvue S/W

Dicom Printer or Paper Printer that is installed

Daily Report Form

Procedure:

1. Turn on the power of system
2. Run MAXXvue
3. Select Database Mode
4. Search database and open patient
5. Select Viewer mode
6. Select image and click Add to Document mode menu
7. Print image

Performance and Corrective Action:

Confirm that the image is printed normally.

If printing failed, check printer is operating and configuration of printer

If still printing fail, then require service assistance

Record result on Daily Report Form

Image Acquisition

Objective:

To confirm that MAXXvue is running normally and system is operating with no error.

Frequency:

Daily

Equipment:

MAXXvue S/W

Daily Report Form

Procedure:

1. Turn on the power of system
2. Run MAXXvue
3. Select Exposure Mode
4. Register patient
5. Expose X-ray with the condition of 50KV 5 mAs
8. Check flat Image is acquired and displayed on monitor

Performance and Corrective Action:

Confirm that system is operating normally.

If image acquisition failed, check the X-ray is exposed normally and the triggering with x-ray generator is properly configured.

If still image acquisition fail, then require service assistance

Record result on Daily Report Form

Serial Communication Test

Objective:

To confirm that interface of serial communication between workstation and Detector is running normally.

Frequency:

Monthly

Equipment:

MAXXrayCalibration S/W

Monthly Report Form

Procedure:

1. Turn on the power of system
2. Run MAXXrayCalibration
3. Click port open button
4. Select Communication Test menu
5. Click Serial communication test button
6. Check the result displayed is OK and the parameter of the system is displayed

Performance and Corrective Action:

Confirm that serial communoication between workstation and detect is operating normally.

If serial communication test failed, check the RS232 on workstation is operating and the control cable connection.

If still serial communication test fail, then require service assistance

Record result on Monthly Report Form

Cooling Test

Objective:

To confirm that CCD cooling is operating normally

Frequency:

Monthly

Equipment:

MAXXrayCalibration S/W

Monthly Report Form

Procedure:

1. Turn on the power of system
2. Run MAXXrayCalibration
3. Click port open button
4. Select Cooling Monitor menu
5. Click Start temp monitor button
6. Check that CCD temperature is under -4℃ within 15 minutes

Performance and Corrective Action:

Confirm that CCD cooling is operating normally.

If CCD temperature is not under -4℃ even though 15 minutes passed, confirm that the fan filter is clean and x-ray generator interface is correct.

If still CCD Cooling test fail, then require service assistance

Record result on Monthly Report Form

Black Level Test

Objective:

To confirm the dark level of image

Frequency:

Monthly

Equipment:

MAXXrayCalibration S/W

Monthly Report Form

Procedure:

1. Turn on the power of system
2. Run MAXXrayCalibration
3. Click port open button
4. Select Pre-resolution test menu
5. Click get test dark frame button
6. Confirm that dark image is captured and center level of avg value is between 0 - 1000

Performance and Corrective Action:

Confirm that dark image is captured and the center level is within . 0 - 1000

If dark image is not captured then confirm cable connection.

If still dark image is not captured or center level of dark image is not in the spec then, require service assistance

Record result on Monthly Report Form

Flat Field Test

Objective:

To confirm the flat image is captured and the artifact is compensated

Frequency:

Monthly

Equipment:

MAXXrayCalibration S/W

Monthly Report Form

Procedure:

1. Turn on the power of system
2. Run MAXXrayCalibration
3. Click port open button
4. Select Post-resolution test menu
5. Expose X-ray with the condition of 60Kv, 5mAs
6. Confirm that flat image is captured and artifact is not appeared

Performance and Corrective Action:

Confirm that flat image is captured and artifact is compensated.

If flat image is not captured then confirm cable connection.

If still flat image is not captured, require service assistance

If artifact is appeared, then do calibration and test again

If still artifact is appeared, then require service assistance.

Record result on Monthly Report Form

Resolution Test

Objective:

To confirm the resolution of the detector

Frequency:

Monthly

Equipment:

MAXXrayCalibration S/W

Resolution Chart (Nuclear Associate, model 07-523-2)

Monthly Report Form

Procedure:

1. Turn on the power of system
2. Run MAXXrayCalibration
3. Click port open button
4. Select Post-resolution test menu
5. Attach resolution chart (Nuclear Associate, model 07-523-2) on the center of a detector in diagonal direction Set x-ray generator to 60KV 10mas and SID to 1m
6. Expose X-ray
7. Confirm that the resolution is over 2.8lp/mm

Performance and Corrective Action:

Confirm that the resolution is over 2.8lp/mm.

If the resolution is under 2.8lp/mm, then test again with adjusting mAs from 5mAs to 20mAs.

If still resolution is under 2.8lp/mm, then require service assistance.

Record result on Monthly Report Form

Calibration

Objective:

To compensates defect pixels and calibrates pixel gain using the installed x-ray generator and x-ray tube.

Frequency:

Annually

When X-ray generator replaced

When X-ray tube rreplaced

Equipment:

MAXXrayCalibration S/W

Annual Report Form

Procedure:

1. Turn on the power of system
2. Run MAXXrayCalibration
3. Click port open button
4. Acquire Black image
5. Acquire 20% flat field image
6. Acquire 40% flat field image
7. Acquire 60% flat field image
8. Generate calibration data
9. Do flat field test

Performance and Corrective Action:

Confirm that calibration data is generated by testing flat field test

If flat field test after calibration failed , then require service assistance.

Record result on annual Report Form

SECTION II The maintenance guides for USER and the forms

MAINTENANCE

Contact VIEWORKS CO., LTD at the following number:

TEL: +82-70-7011-6161 / FAX: +82-31-737-4954

For optimal performance, VIEWORKS recommends that the working area be kept clean. There are no specific cleaning requirements for the MAXXray beyond normal care and attention for aesthetic appearances.

Caution: Federal law restricts this device to sale by or on the order of a physician.

PRODUCT COMPLAINT

Any health care professional (e.g., customer or user of this system of products) who has any complaints or has experienced any dissatisfaction in the quality, durability, reliability, safety, effectiveness, and/or performance of this product should notify Vieworks. If the device malfunctions and may have caused or contributed to a serious injury of a patient, Vieworks should be notified immediately by telephone, fax, or written correspondence.

CARE and CLEANING

Wipe external surface with an approved cleaning liquid from the list below

Use a non-abrasive soft cloth.

Wipe the cleaned surface with a cloth lightly moistened with clean water to remove residual cleaner and dirt.

The outer surface and patient contact surfaces may be cleaned with the one of the following preferred materials:

- most alcohol and ammonia based cleaners
- mild, non-abrasive cleaners

Note: Never use the following cleaning tools chemicals:

- hard brushes or scrapers of any kind
- strong acids or alkaloids

Daily Report Form

Installation Site Information : _____

_____

Date : _____ Operator : _____

Check Cabling : Check and record result as OK/NG AC Power cable : _____ DC power Cable : _____ Camera Interface Cable : _____ Control Cable : _____ Comment : _____
Visual Inspection : Check and record result as OK or describe the result and Activity done Visual Inspection : _____ Activity Done : _____
Fan Filter Cleaning : Record Fan filter status and record activity done Fan Filter Status : _____ Activity Done : _____
Hard Disk Free Space : Record Indication and record activity done Indication : _____ Activity Done : _____
Worklist Connection : Record result and activity done Result : _____ Activity Done : _____
PACS Server Connection : Record result and activity done Result : _____ Activity Done : _____
Printing Test : Record result and activity done Result : _____ Activity Done : _____
Study Performing Test : Record result and activity done Result : _____ Activity Done : _____

Monthly Report Form

Installation Site Information : _____

_____

Date : _____ Operator : _____

Serial Communication test : Record result and Activity Done Result : _____ Error Message : _____ Activity Done : _____ Comment : _____
Cooling Test : Record result and Activity Done CCD Temperature after 15 Minute : _____ Activity Done : _____ Comment : _____
Black Level Test : Record result and Activity Done Dark Image Acquisition(OK/NG) : _____ Black Level : _____ Activity Done : _____ Comment : _____
Flat Field Test : Record result and Activity Done Flat Field Acquisition(OK/NG) : _____ Flat Level : _____ Activity Done : _____ Comment : _____
Resolution Test : Record result and Activity Done Resolution(lp/mm) : _____ Activity Done : _____ Comment : _____

Annual Report Form

Installation Site Information : _____

_____

Date : _____ Operator : _____

Calibtration : Record equipment,result and Activity Done

X-ray Generator : _____

X-ray Tube : _____

X-ray Exposing Data

20% Flat Image : _____ KV _____ mAs

40% Flat Image : _____ KV _____ mAs

60% Flat Image : _____ KV _____ mAs

Result : _____

Comment : _____

Flat Field Test after Calibration : Record result and Activity Done

Flat Field Acquisition(OK/NG) : _____

Flat Level : _____

Activity Done : _____

Comment : _____

System Discrepancy Form

Installation Site Information : _____

_____

Date : _____ Published by : _____

System Information

X-ray Generator : _____

X-ray Tube : _____

X-ray grid Information : _____

Model of Detector : ☐ RXDN-6000D ☐ RXDN-6500D

Serial Number of Detector : _____

Serial Number of Power Supply Unit : _____

Version of MAXXvue : _____

Version of MAXXvueConfigure : _____

Version of MAXXrayCalibration : _____

Comment : _____

_____

System Discrepancy

Date of finding : _____

Operator : _____

How is it found : _____

_____

_____

_____

Comment : _____

_____

_____

Contact Information

Address : Vieworks Co., Ltd
#604 Suntechcity II, 307-2 Sangdaewon-dong,
Jungwon-gu, Seongnam-city, Gyeonggi-do
462-806 South Korea

Phone : +82-70-7011-6161

Fax : +82-31-737-4954

e-mail : vieworks@vieworks.com

Modification Request Form

Date : _____ Published by : _____

System Information

X-ray Generator : _____

X-ray Tube : _____

X-ray grid Information : _____

Model of Detector : ☐ RXDN-6000D ☐ RXDN-6500D

Serial Number of Detector : _____

Serial Number of Power Supply Unit : _____

Version of MAXXvue : _____

Version of MAXXvueConfigure : _____

Version of MAXXrayCalibration : _____

Comment : _____

_____

Modification Request

Software Name : _____

Request _____

_____

_____

_____

_____

Comment : _____

_____

_____

Contact Information

Address : Vieworks Co., Ltd
#604 Suntechcity II, 307-2 Sangdaewon-dong,
Jungwon-gu, Seongnam-city, Gyeonggi-do
462-806 South Korea

Phone : +82-70-7011-6161

Fax : +82-31-737-4954

e-mail : vieworks@vieworks.com