Digital Imaging System

TFlatXR

Service Manual

(For veterinary use)

Vieworks Co., Ltd.

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Revision History

Rev 0.0	27 Mar. 2010	first release (Draft)

Accident Reporting

The FDA Medical Device Reporting regulation, 21, CFR 803 and the CE Council Directive 93/42/EEC concerning Medical Devices require that "the manufacturer of medical devices submit a report to the FDA or 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

IEC/EN/UL 60601-1 CSA C22.2 No. 601.1 KFDA No. 2009-1377	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
IEC/EN 60601-1-2	Medical electrical equipment Part 2: electromagnetic compatibility–requirements and tests

Authorized representatives

If you have any accident, please contact the authorized representatives

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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 maintenance 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.

10) This product must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that exits the shielded locations, a minimum RF filter attenuation of shielding effectiveness.

11) This product is intended for use by healthcare professionals only. This product may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the product or shielding the location.

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 turns on the system in hazardous substances are detected in the environment.

If flammable substances are detected after the system has 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 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 anyone 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 TFlatXRCalibration software runs a system diagnostic. Run TFlatXRCalibration 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 (see operation manual).

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 losing 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 QXvue 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 are 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

Guidance and manufacturer's declaration - electromagnetic emissions		
The X-ray Flat Panel Imager (hereafter called FPI) is intended for use in the electromagnetic specified below. The customer or the user of the FPI should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group1	The FPI users 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 FPI is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Not applicable	
Note	The FPI is not allowed to use the cables or components differ from the originally attached. If the different cables or components are used, they may deteriorate the performance of electromagnetic emissions.	

The limited length of cables for conforming EMC (IEC60601-1-2 Ed2, 2001+AMD.1, 2004))

Cables	Cable length (Max.)
DC Cable	2m
GND Cable	3m

1.14.2 Guidance and manufacturer's declaration - electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The FPI is intended for use in the electromagnetic specified below. The customer or the user of the FPI should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC61000-4-2	±6kV contact ±2/4kV contact ±8kV air ±2/4kV air	±6kV contact ±2/4kV contact ±8kV air ±2/4 kV 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 IEC61000-4-4	±2 kV 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 IEC61000-4-5	±1kV differential mode ±0.5kV differential mode ±2kV common mode	±1kV differential mode ±0.5kV differential mode ±2kV common mode	Mains power quality should be that of a typical hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	< 5 % U_T (> 95 % dip in, U_T) for 5 sec	< 5 % U_T (> 95 % dip in, U_T) for 5 sec	Mains power quality should be that of a typical hospital environment. If the user of the FPI requires continued operation during power mains interruptions, it is recommended that the FPI be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in atypical commercial or hospital environment.
Note: (1) U_T is the a.c.mains voltage prior to application of the test level. (2) This angiography X-ray system can only allow to use the designated cables and components. If the different cables or components are used, they may deteriorate the performance of recommended separation distance between portable and mobile RF communications equipment and this system.			

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.

Guidance and manufacturer's declaration – electromagnetic immunity			
The FPI is intended for use in the electromagnetic environment specified below. The customer or the user of the FPI should assure that it is used such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the FPI, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150kHz to 80MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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 determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
Note: (1) At 80MHz and 800MHz, the higher frequency range applies. (2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, object and people. (3) This angiography X-ray system can only allow to use the designated cables and components. If the different cables or components are used, they may deteriorate the performance of electromagnetic immunity.			
[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 FPI is used exceeds the applicable RF compliance level above, the FPI should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the FPI. [b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/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.

Recommended separation distances between portable and mobile RF communications equipment and the FPI.

The FPI is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FPI can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the FPI 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		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power 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.
(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption by absorption and reflection from structures objects and people.
(3) The FPI can only allow to use the designated cables and components.
If the different cables or components are used, they may deteriorate the performance of recommended separation distance between portable and mobile RF communications equipment and this system.

⚠ Caution

DO NOT USE THE ELECTROMAGNETIC DEVICE, SUCH AS (CELLULAR/CORDLESS) TELEPHONES AND RADIO CONTROLLED TOYS, CLOSE TO THIS SYSTEM. OTHERWISE, IT MAY CAUSE MALFUNCTION OF THE SYSTEM.

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 (UL)

1) CLASS I EQUIPMENT
2) NO APPLIED
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 Oxide

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

TFlatXR system is indicated for digital imaging solution designed for general radiographic system for human or veterinary anatomy. 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

TFlatXR system consists of detector, power supply unit, software and its accessories.

TFlatXR system components

Sensor Unit	16kg×1
Power Supply Unit	1kg(approx.)×1
AC Cable	1.8m×1
DC Cable (Sensor Unit – Power Supply Unit)	10m×1
D-Sub Cable	10m×1
Ethernet Cable (Crossover, 1000BASE-TX)	15m×1
Ground (GND) Cable for Sensor Unit	3m×1
Ground (GND) Cable for Power Supply Unit	3m×1
Dongle Key	1
Software	
Viewer	QXvue
Configuration	QXvue_Configure
	QXvue_Configure_DICOM
Calibration and Diagnostic	TFlatXRCalibration
Workstation (option)	
OS	Windows XP professional
CPU	Minimum Pentium 4, 3.0 GHz
Memory	Minimum 2G Byte
Hard Disk	Minimum 80G Byte
Ethernet	Minimum 1000 Mbit/s(2EA)
Monitor	1600x1200, Color
CD Rom	CD or DVD R/W
X-ray grid (option)	10:1, 215lines/inch

Caution

Power Supply Unit & Sensor Unit – It should be used in the Patient Environment.

AC/DC Adapter – AC/DC Adapter connected to QXR should be tested by IEC 60950-1

Power Cord Set (for US) – Type SJT or SVT, 18AWG, 3-Conductor, VW-1 125V or 250V, 10A, max 3.0m long; One end with Hospital Grade Type, MENA 5-15P or 6-15P. Other end with appliance coupler. "CAUTION Grounding reliability can only be achieved when the equipment is connected to an equipment receptacle marked "Hospital Only" or "Hospital Grade"

Power Cord Set (Other Countries) – For connection to supply not in USA, make sure the power cord is the correct type that is required in your area

2.3 Environment

	Under delivery and stock	Under operating
Temperature	-15 ~ 55 ℃	+10 ~ 35 ℃
Humidity	10 ~ 90 % (Non-Condensing)	30 ~ 85 % (Non-Condensing)
Pressure	50 ~ 106 kPa	70 ~ 106 kPa

2.4 Component description

1) Sensor Unit

Creates X-ray image by using flat panel detector.

2) Power supply unit

Supplies DC-power to sensor unit.

3) QXvue

Software to view X-ray image.

Get image from detector, process it to ease the diagnostic, save it in database and manage it.

4) TFlatXRCalibration

Diagnostic detector and report the result. Calibrate the system.

5) QXvue_Configure & QXvue_Configure_DICOM

Configure parameters for TFlatXR Digital Imaging System

2.5 Others

Caution

Accessories and Cables provided by Vieworks should be used.
Other cables and accessories may negatively affect EMC performance.

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective EN and IEC standards (for examples, EN 60950 and IEC 60950 for data processing equipment and EN 60601-1 and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standards EN 60601-1-1 and IEC 60601-1-1. Anyone who connects additional equipment to any signal input or signal output ports configures a medical system and is therefore responsible that the system complies with the requirements of the system standards EN 60601-1-1 and IEC 60601-1-1.

3. System Specification

3.1 Pixel Matrix

Effective Pixel Number	3008 × 3072
Pixel pitch	143 ㎛ ×143 ㎛

3.2 Effective field of view (FOV) size

Horizontal : 430 mm(16.9")

Vertical : 439 mm(17.2")

3.3 X-ray detection method

Cesium Iodide (CsI) scintillator + Amorphous Silicon (a-Si) Photodiode

3.4 Time of capture and transmission

Shorter than 6 second

3.5 Image Specification

1) Image Format

3072(W) X 3072(H)

2) Effective Field of View

Horizontal : 430 mm(16.9")

Vertical : 439 mm(17.2")

3.6 Resolution

It should be more than 3.5 LP 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 are the resolution.

3.7 Electrical Specification

3.7.1 Flat Panel Sensor Unit

1) Input Voltage

DC 24V

2) Power consumption

20W

3.7.2 Power Supply Unit

1) Input Voltage

AC 100 to 240V, Single phase 50/60Hz

2) Maximum power
60VA
3) Output power standard
DC + 24 Vdc ± 10 %

3.8 Interface

1) Image data	16 bit Digital Output Ethernet (1000BASE-T)
2) System control	Ethernet (1000BASE-T)
3) X-ray sync signal	External

3.9 Image Acquisition Mode Table

Mode	Frame rate (Frame/s)	Binning/Non-Binning	X-ray period (ms)
3072 lines Full Scan mode	1(approx)	Non-binning	Standard: 500 (Variable between 50 to 500) Optional: 1000, 2300, 3200 or 4000

4. System Installation

4.1. Introduction

4.1.1 Objective

This document describes the connection method of the X-ray Flat Panel Imager (FPI) model FDX4343R.

4.1.2 Definitions, Abbreviations and Shortened Forms

FPI : Flat Panel Imager (X-ray flat surface detector)

EXP_REQ : Image acquisition (X-ray exposure) request signal. Input from the user side to the D-Sub connector on the FPI.

EXP_OK : Exposure-OK. Image acquisition (X-ray exposure enabled) period signal. Outputs the X-ray exposure enabled time from the FPI. Output from the D-Sub connector on the FPI.

4.2 Before Getting Started

4.2.1 Environmental conditions

For the operating environment, the ambient temperature is +10oC to +35oC.

For the storage environment, the ambient temperature is -15oC to +55oC.

4.2.2 Operating environments

Windows XP SP2

4.2.3 Wiring for the D-Sub pin

Wiring is required for external control. D-Sub connector pin assignment and signal names on the side of the FPI are described below. The EXP_OK signal notifies you of the X-ray exposure enabled timing.

4.2.4 Ethernet environments

Although the FPI system can be remote-controlled from the user-created FPI system driving software via Ethernet, it is limited to the communication between this FPI system and user system on a 1:1 basis. The FPI system cannot be used in the universal network environment. Do not connect it to the universal network environment.

Followings are requirement for Ethernet.

- Ether Crossover Cable
- Ethernet (1000BASE-TX)

4.3 Installing Housing in Apparatus

Use the screw holes 16-M4 (Depth 8).

The screws should be fixed all screw holes of each part. Also, the screw thread length entering the screw holes should be each depth of holes.

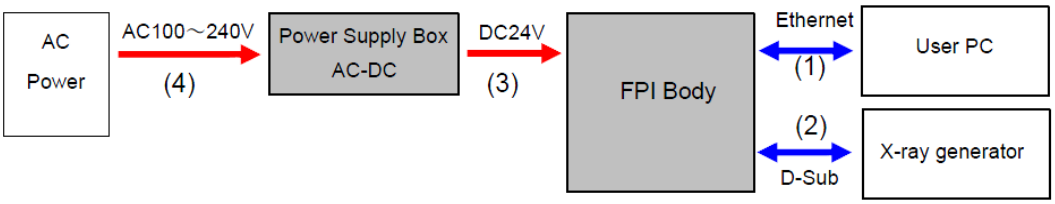
Installation respect of the device that installs FPI should be smooth.

It is necessary to clean installation respect of the device before FPI is installed.

Tightening torque of screw; 1.35 - 1.65 [Nm]

4.4 Sensor Unit Installation

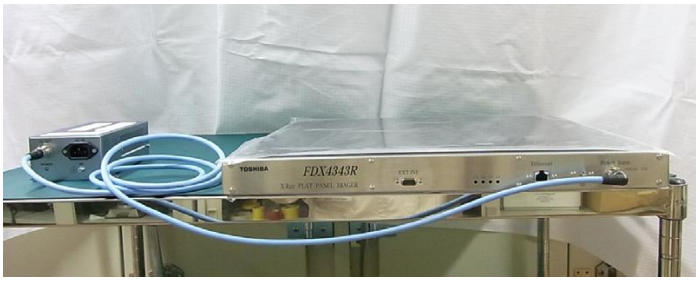
For connection, connect according to this item as shown in a figure below.



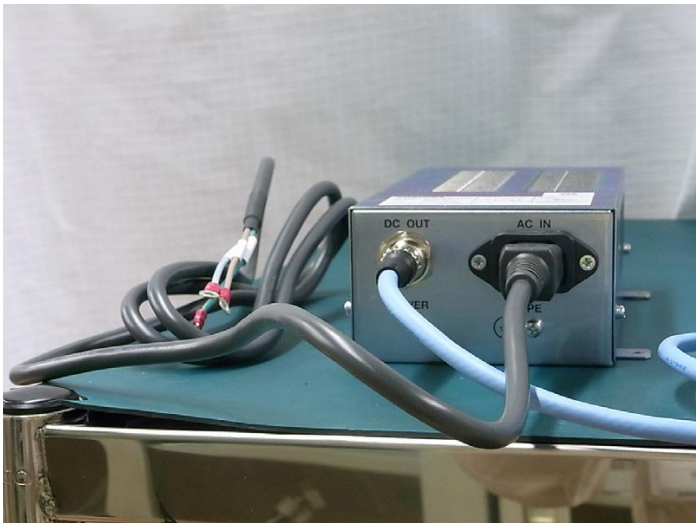
1) Connect the Ethernet terminal on the FPI and User PC via the Ether Crossover Cable. This system requires a dedicated local line. If Internet is in use on the user PC, two lines; the Global Ethernet that goes through the DNS server and the Local Ethernet for connecting this system, are required. For the Ethernet line with this system, please allocate a proper address for the user PC's local IP address. The local IP address of this system is 192.168.95.30 or 192.168.95.31(TBD). The IP address of this system can be selected.

2) Connect the FPI to the X-ray generator
Please refer to "OPERATION MANUAL OF FDX4343R" for more details

3) Connect the FPI to power supply (AC-DC) via the attached power cable



4) Connect the AC power cable to the power box and connect the terminal of the attached AC power cable to the AC power supply



⚠ Caution

Do not disconnect Ethernet connection while DC24V is operating and supplying to FPI.

4.5 Dongle Key Installations

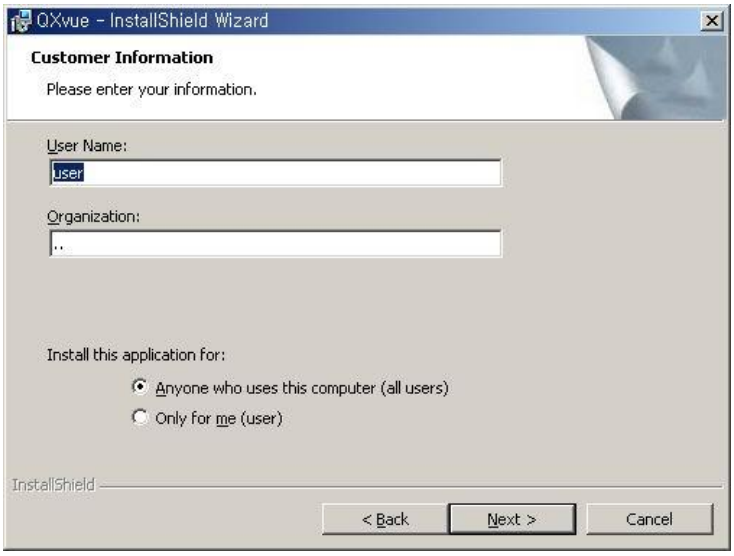
QXvue software checks for USB-type dongle key to run. Please plug the dongle key into any free USB port on PC.

4.6 QXvue Installation

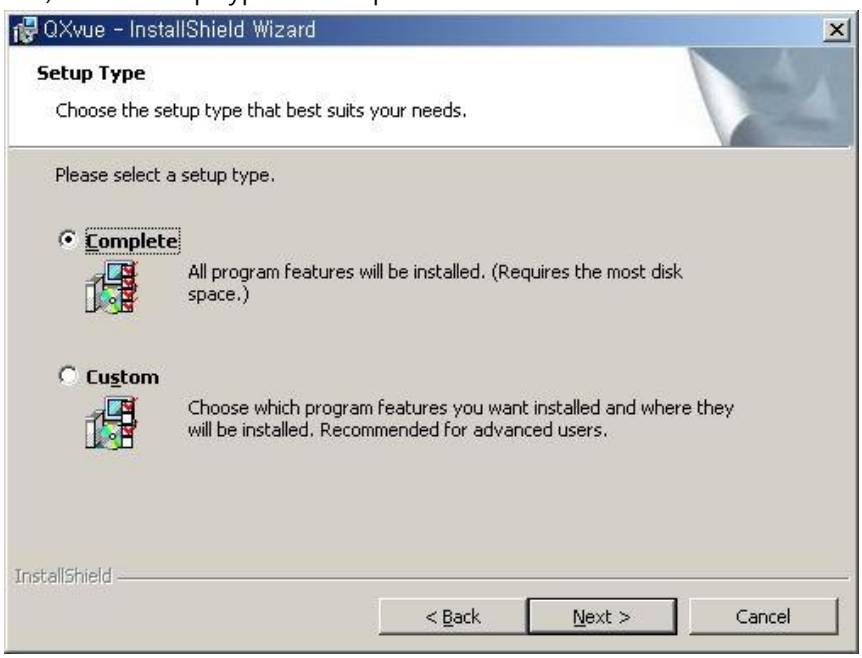
1) Insert QXvue CD in CD Drive

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

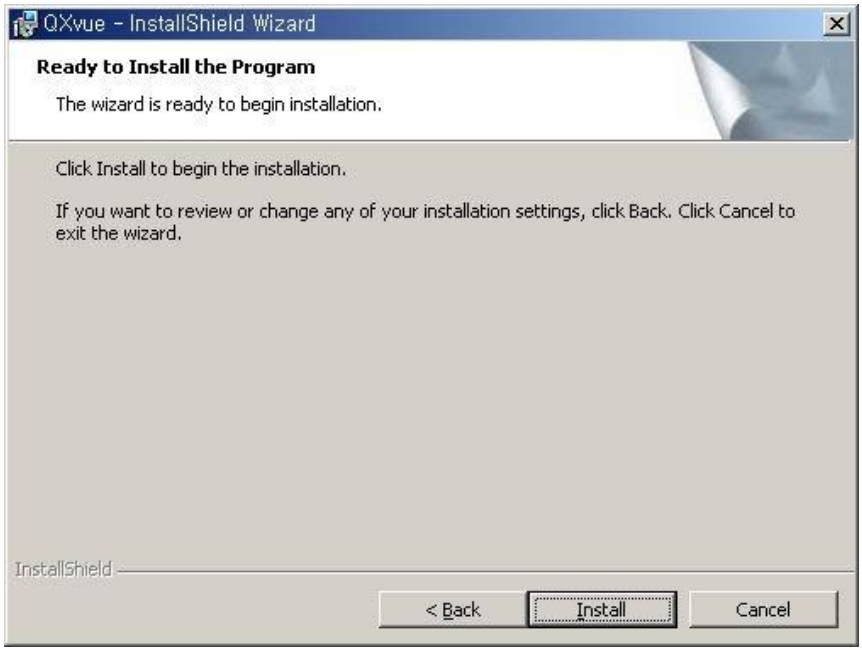
3) Input User Name and Organization, and select user, then click "Next" button



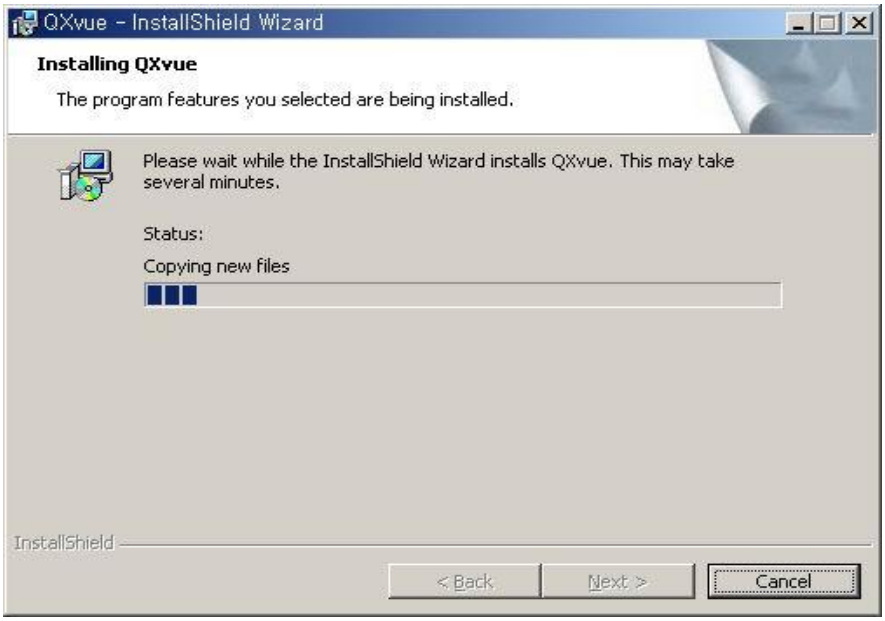
4) Select setup type as Complete then click "Next" button



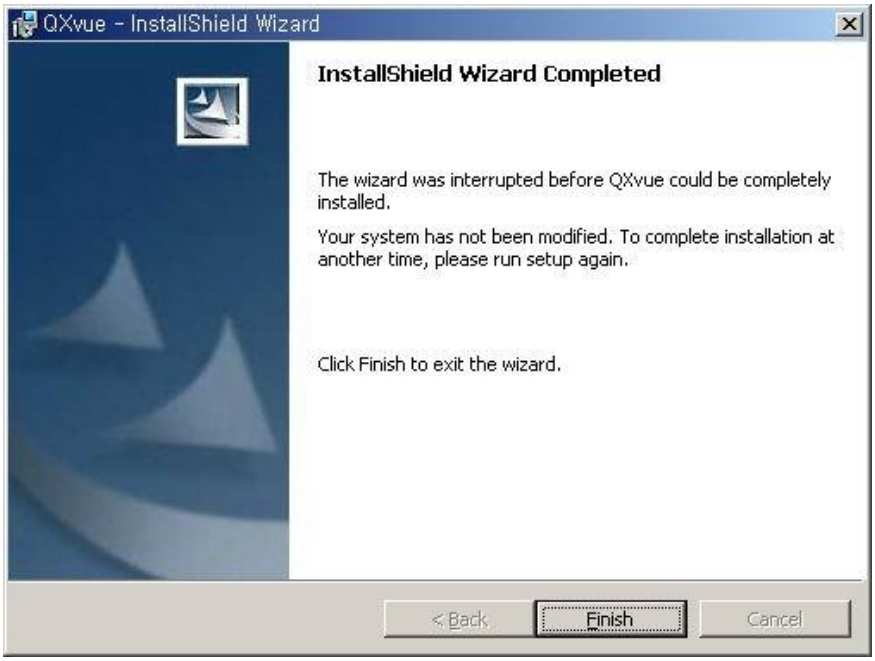
5) "Ready to Install the Program" window will be displayed, press "Install" Button



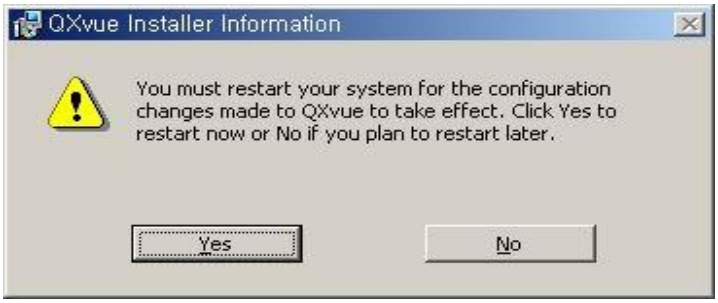
6) "Installing QXvue" will be displayed, now the InstallShield is installing QXvue.



7) After finishing installation of QXvue, "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 QXvue software is successfully installed to the following directory.

Software	C:₩Program Files₩QXvue
Data	D:₩QXvueData

Executable File List

QXvue.exe	Viewer program
TFlatXRCalibration.exe	Calibration program
QXvue_Configure.exe	General Configure program
QXvue_Configure_DICOM.exe	DICOM Configure program

⚠ To run QXvue, "East Asian Language" option in windows should be selected, if not , "Selected collating sequence not supported by the operating system" or "the selected order is not supported by this operating system" message will be displayed.

To select this option

1. Start->Control Panel-> Regional and Language...
2. Check "Install files for East Asian languages" option and click "OK" button to install

4.7 Sensor unit specific files installation

1) Please check the following files are included in a separately provided CD-ROM disk.
   Defective pixel map: "TETD_Defect_YYYYMMSNSNSN.map"
   License key code file: "YYYYMMSNSNSN.key"
2) Copy "TETD_Defect_YYYYMMSNSNSN.map" into the folder "D:₩QXvueData₩Reference"
3) Copy "YYYYMMSNSNSN.key" into the folder "D:₩QXvueData₩Config"

4.8 FPI Start

(1) Power on and boot the user PC.
(2) Check the connection between units and input the AC power to the AC power supply.
DC24V is input to the FPI and the FPI is started.
(3) If the FPI starts successfully, LED1, 2, and 3 on the side of the FPI are lit in green.

For the LED's, refer to 8.2

If power is turned on for the first time, the FPI starts with the settings made upon shipping from the factory. For the second time onward, the FPI starts with the settings saved by the setting status save command. If the settings are not saved by the setting status save command, the FPI starts with the most recently saved settings.

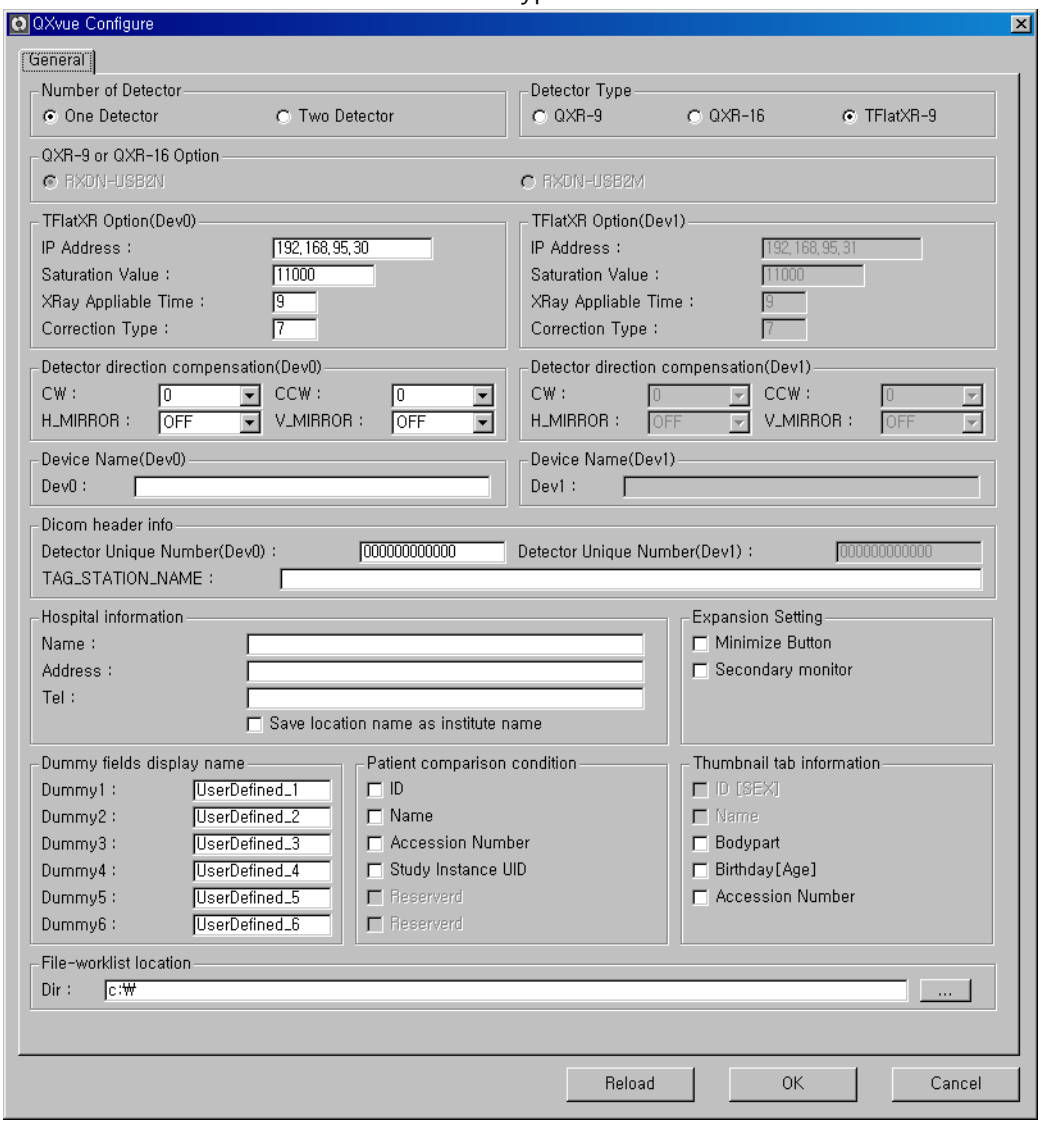
5. Preparation for operating TFlatXR system

To operate TFlatXR system, following step should be executed

1) Run QXvue_Configure
2) Select Number of Detector with one Detector and Detector type with TFlatXR-9
   Supporting "Two detector" is TBD.
3) Do Configuration of general
4) Exit QXvue_Configure
5) Run TFlatXRCalibration
6) Diagnosis and calibrate
7) Exit TFlatXRCalibration
8) Run QXvue_Configure_DICOM
9) Do Configuration of DICOM
10) Exit QXvue_Configure_DICOM

5.1 Select Number of Detector and Detector type

1) Run QXvue_Configure in "C:₩program files₩QXvue" folder
2) Select Number of Detector and Detector type



5.2 General Configuration of QXvue

Refer to clause 7.2

5.3 Diagnosis and calibration

Refer to clause 6 for diagnosis and clause 6 for calibration

5.4 DICOM Configuration of QXvue

Refer to clause 7.3

6. Calibration

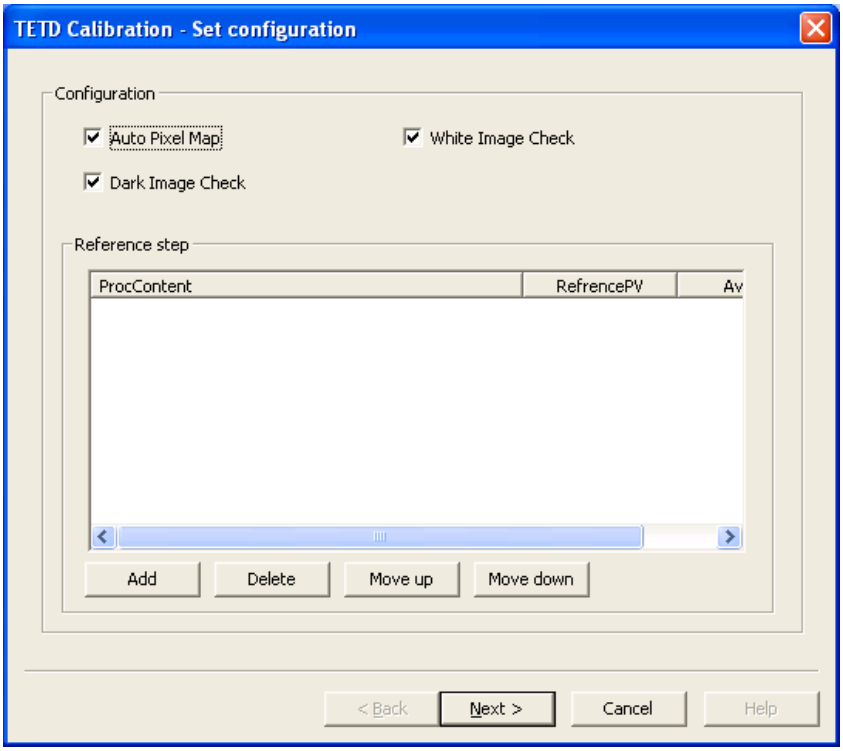
Calibration procedure calibrates pixel gain using the installed x-ray generator and x-ray tube.

The calibration should be performed on the following case

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

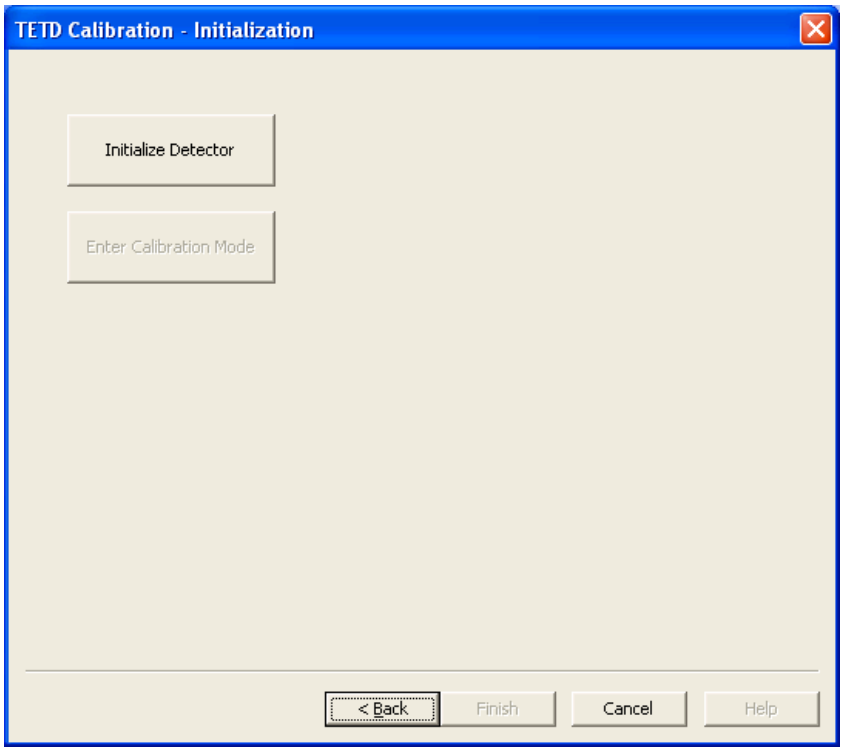
6.1 Description of tabs and dialogs

6.1.1 Set configuration tab



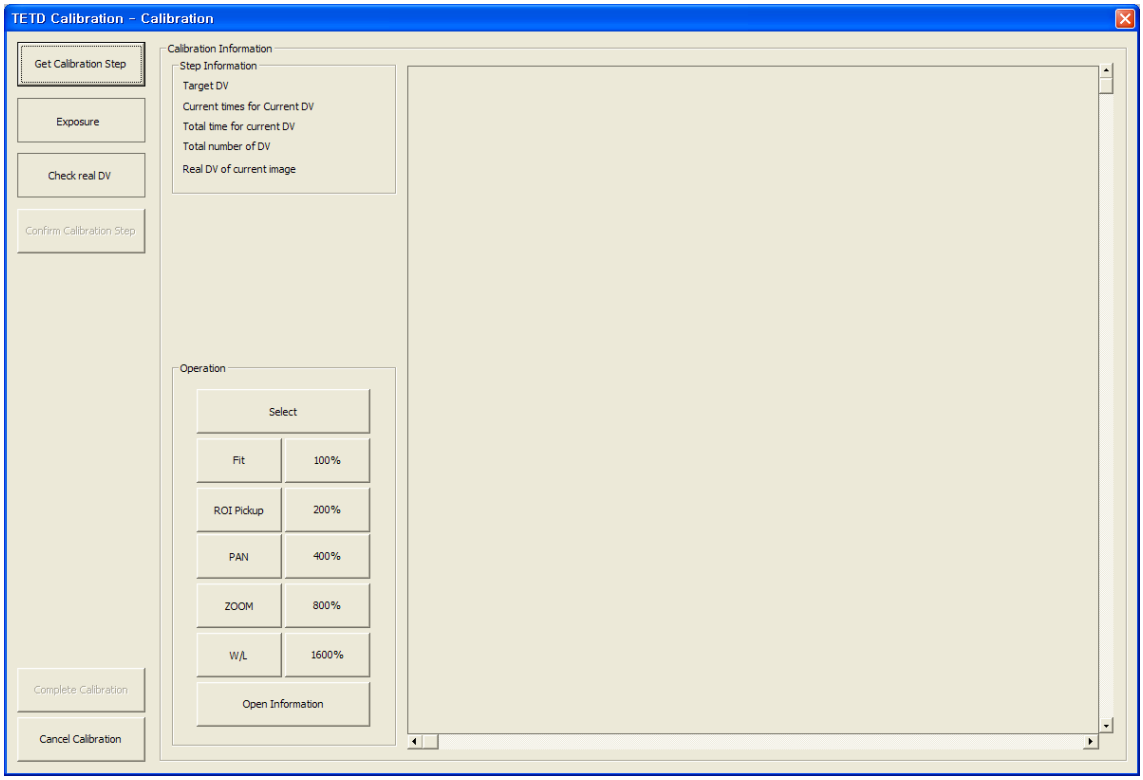
1) When this tab is activated
   The program reads current configuration from the XML file.
2) 'Next' button
   Saves any modified configurations to the XML file.
3) Other buttons
   A. Auto Pixel Map
   B. White Image Check
   C. Dark Image Check
   D. Buttons in 'Reference Step' group
      i. Add – Adds a reference calibration step.
      ii. Delete – Deletes selected reference calibration steps.
      iii. Move up – Moves up selected reference calibration step.
      iv. Mode down – Moves down selected reference calibration steps.

6.1.2 Initialization tab



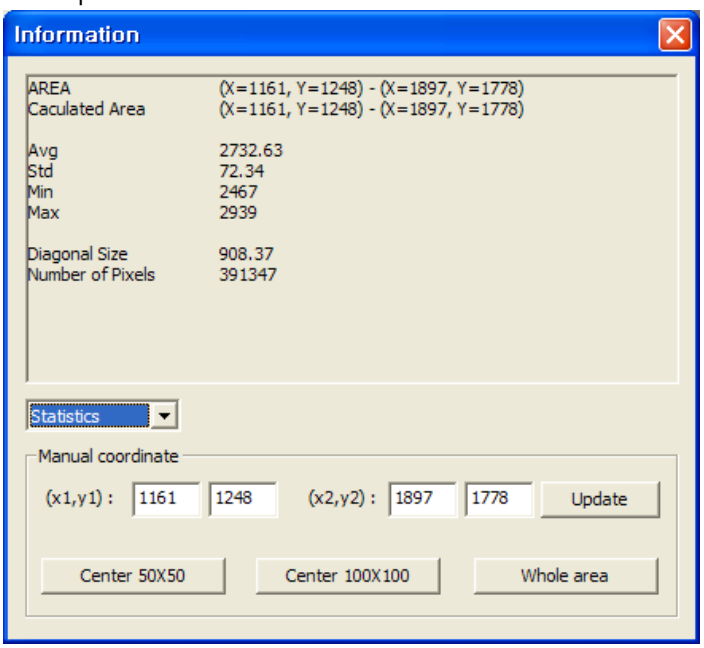
1) 'Initialize Detector' button
   Initializes the detector. It may take several seconds to initialize the detector.
2) 'Enter Calibration Mode' button
   Let the detector enter calibration mode. If the detector enters calibration mode successfully, a dialog will pop up for calibration procedures.

6.1.3 Calibration dialog



1) 'Get Calibration Step' button
   'GetCalibrationStep' command is sent to the detector.
2) 'Confirm Calibration Step' button
   Finishes the current step for the calibration. 'ConfirmCalibrationStep' command is sent to the detector.
3) 'Complete Calibration' button
   Completes the calibration procedures. 'CompleteCalibrationStep' command is sent to the detector. Also 'ExitCalibrationMode' command is called. This command let the detector enter the intial state. The dialog will be closed.
4) 'Cancel Calibration' button
   Cancels out whole calibration procedures. 'AbortCalibration' is sent to the detector
   Also 'ExitCalibrationMode' command is called. This command let the detector enter the intial state. The dialog will be closed.
5) Other buttons
   A. Select – Enters the region selection mode. To select region to see statistics of the rigion in 'Information' dialog, this mode should be selected.
   B. Fit – Adjust the size of image to fit in the image display area.
   C. ROI Pickup – If you select a region in this mode, W/L is adjusted according to the pixel values in the region.
   D. PAN – Enters the mode adjusting the image position in the display area.
   E. ZOOM – Enters the mode enlarging or shrinking the image size.
   F. W/L – Enters the mode adjusting W/L(Window/Level). W/L can be adjusted by dragging the mouse with right mouse button pressed at any time.
   G. 100%, 200%, 400%, 800%, 1600% - Adjusts the image size as the selected ratio.

H. Open Information



The dialog displays statistics of the selected region or pixel level of the pixel where the cursor is pointing. If you select the 'Statistics' from the Combo box, the former is displayed. If you select the 'Pixel' from the Combo box, the latter is displayed.

To select a region by dragging the mouse, 'Select' mode should be selected as current mode. Or you can select a region by putting coordinates in the edit boxes and clicking 'update button'.

i. Center 50X50 – displays statics of the 50 by 50 wide rectangular region located at the center of the image.

ii. Center 100X100 – displays statics of the 100 by 100 wide rectangular region located at the center of the image.

iii. Whole area – displays statistics of the whole image.

6.2 Preparation for Calibration

- Run Calibration software
- Set SID to 1.8m or 1m.

⚠ Caution

Do not use x-ray grid when do calibration.

6.3 Configure

Select options referring to 6.1.1 clause and adds/removes/modifies calibration steps.

6.4 Initialization

Initialize the detector by clicking 'Initialize Detector' button. It takes several seconds to initialize the detector. If the initialization is done, 'Enter Calibration Mode' button is enabled. By clicking 'Enter Calibration Mode' button, you can let the detector enter the calibration mode. If the detector successfully enters the calibration mode, a 'Calibration' dialog will pop up.

6.5 Calibration

If the 'Calibration' dialog is displayed, this means that the detector successfully has entered the calibration mode.

The procedures of calibration are as follows.

1) Get Calibration Step – gets information for current calibration step.

2) Exposure & Check real DV – After taking the image, you should adjust SID, KVP and mAs to make the value 'Current DV' close to the value 'Target DV'. A couple of more shots should be made to get an appropriate 'Current DV' value.

3) Confirm Calibration Step – If you succeeded in getting the desired 'Current DV' value in step 0, click 'Confirm Calibration Step' to finish the current calibration step.

4) Repeat 1)~3) until the necessary number of calibration steps has been executed.

5) Complete Calibration – If the necessary number of calibration steps has been executed, 'Complete Calibration' button will be enabled. By clicking the 'Complete Calibration' button, you can complete the calibration process.

7. QXvue Configuration

7.1 What is Configuration?

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

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

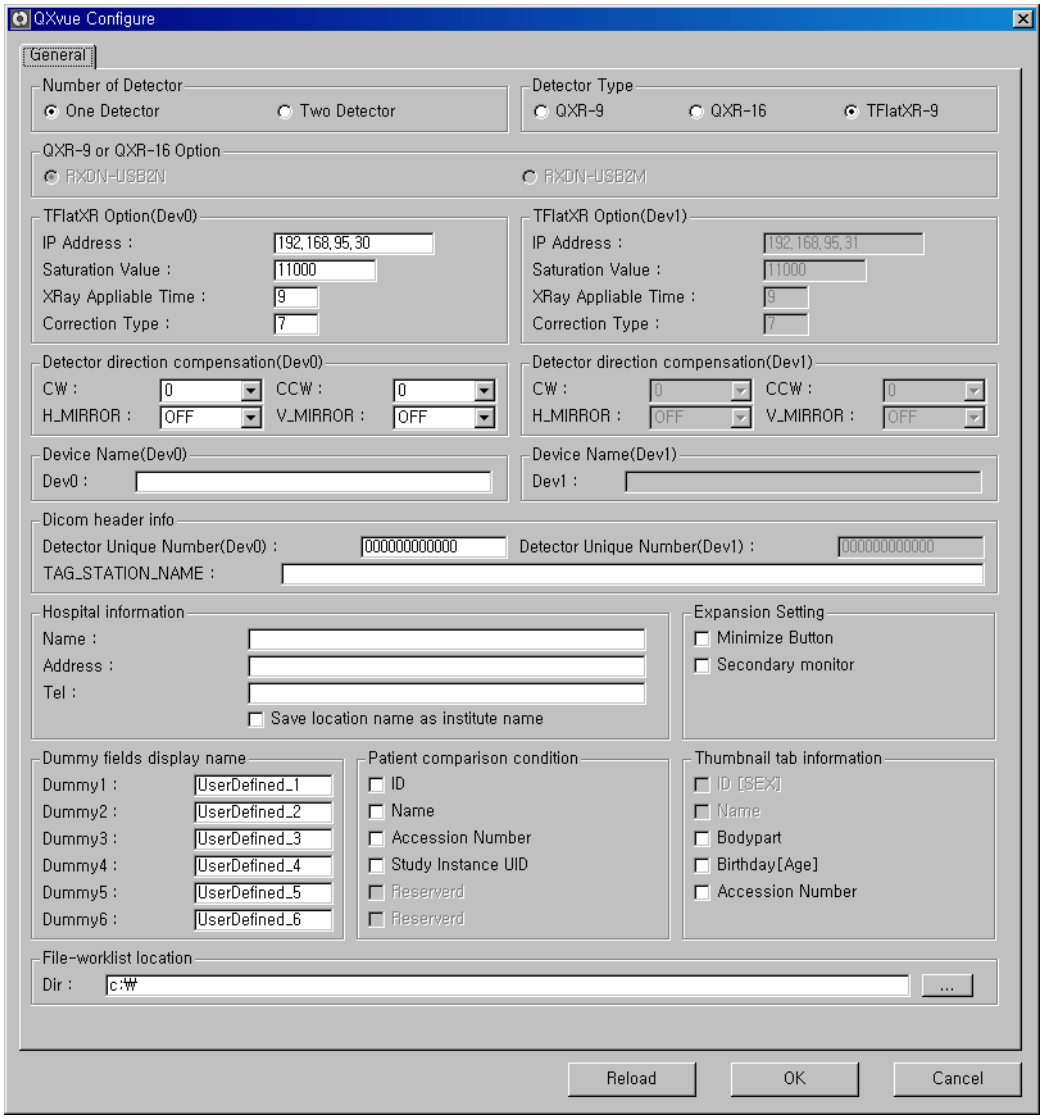
Configuration of QXvue is consist of two parts

General parameter setting by QXvue_Configure : Basic information used by QXvue

DICOM parameter setting by QXvue_Configure_DICOM : Worklist related DICOM header setting

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

7.2 General parameter setting



7.2.1 Hospital information

- They are the name, address and telephone number of the hospital in which the QXR 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.

7.2.2 Number of Detector

- Select "One Detector"
- Supporting "Two detector" is TBD.

7.2.3 Detector type

- Select TFlatXR-9

7.2.4 TFlatXR Option(Dev0)

- IP Address : The IP address of FPI
  "192.168.95.30" or "192.168.95.31"(TBD)

> **Note**
> FPI address is fixed with "192.168.95.30". "192.168.95.31" is not available now.
> PC's network setting has to be changed with same class of FPI address for cross-connection.
> Ex) IP Address : 192.168.95.10
> Basic Gateway : 192.168.95.1

- Saturation Value : The Saturation value for digital value
  "11000"(default)
- XRay Appliable Time : "9" (default)

> **Note**
> 0: 50ms, 1: 100ms, 2: 150ms, 3: 200ms, 4: 250ms, 5: 300ms, 6: 350ms,
> 7: 400ms, 8: 450ms, 9: 500ms, 19: 1000ms, 45: 2300ms, 63: 3200ms,
> 79: 4000ms ,others: 500 milli-second

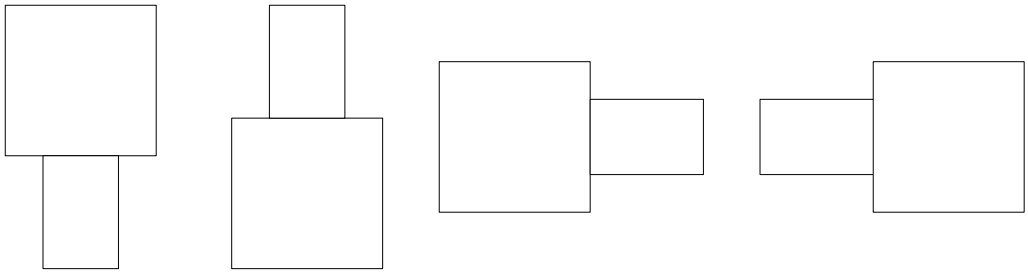
- Correction Type : "7" (default)

> **Note**
> 0: without any correction,
> 1: Only apply offset correction
> 3: apply offset and gain correction
> 7: Apply offset, gain, bad pixel correction

7.2.5 Detector direction compensation

This is used to set the image direction

Set direction according to installed state of detector



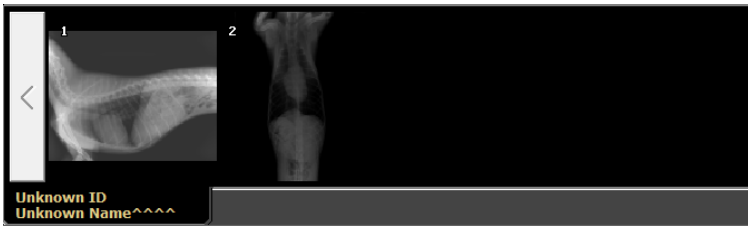
CW : 0
CCW : 0
H-Mirror : 1
V-Mirror : 0

CW : 0
CCW : 0
H-Mirror : 0
V-Mirror : 1

CW : 1
CCW : 0
H-Mirror : 0
V-Mirror : 1

CW : 1
CCW : 0
H-Mirror : 1
V-Mirror : 0

7.2.6 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

7.2.7 Expansion setting

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

7.2.8 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 QXvueCalibration, 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

7.2.9 Dummy fields display name

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

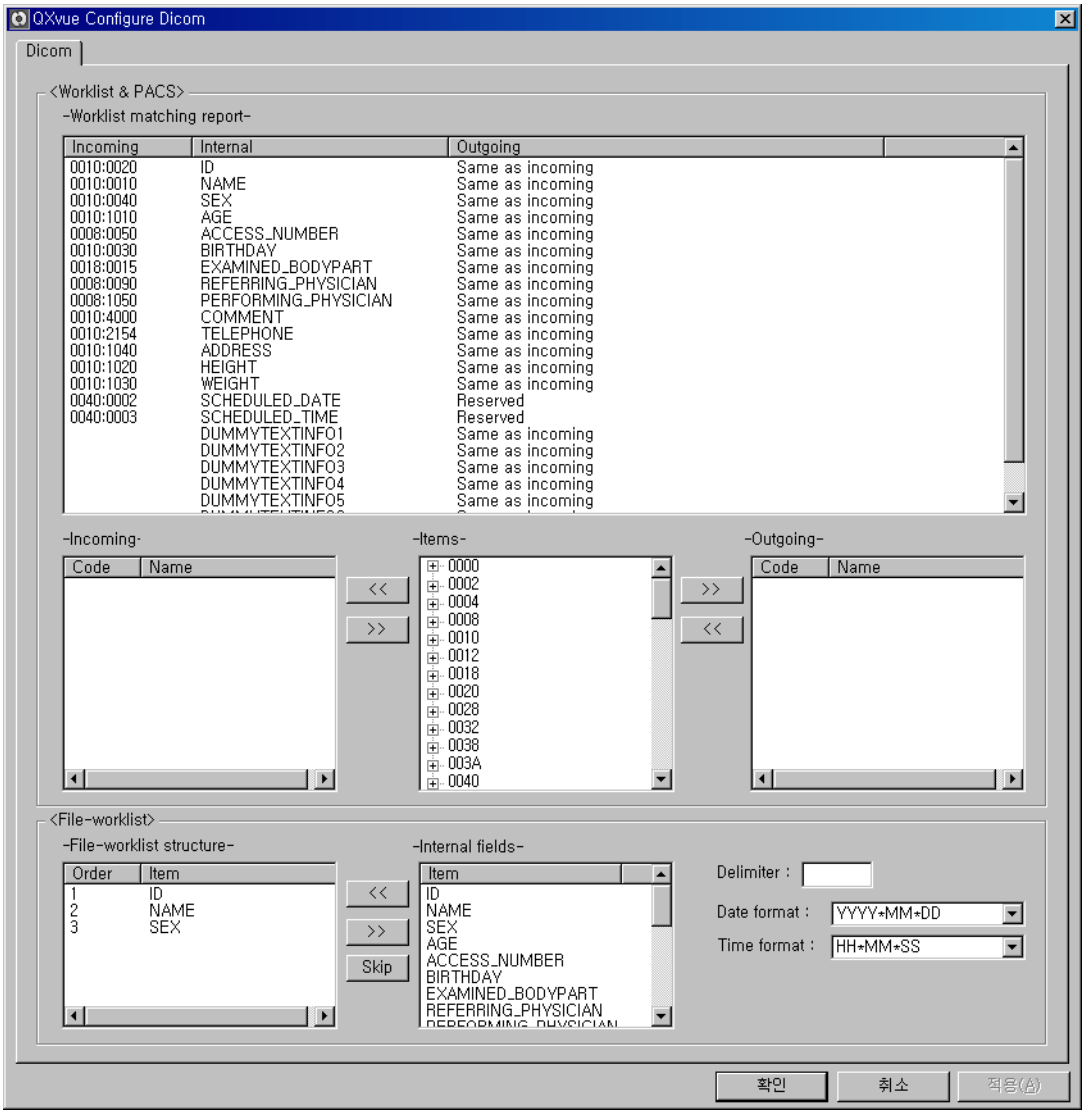
7.2.10 Patient comparison condition

- QXvue 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, QXvue 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

7.2.11 File-worklist location

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

7.3 DICOM parameter setting



QXvue use internally defined tag name related patient information for DICOM, this 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 QXvue receive order from the worklist server that might not be the standard DICOM tag, so QXvue has DICOM tag converting function to make standard DICOM file.

7.3.1 Worklist & PACS

1) Definition

- Incoming : Receiving tag from the worklist server
- Internal : Internally defined field name of the patient information and study order in QXvue
- 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

7.3.2 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

8. 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 9 of this manual for more details.

8.1 Failure Mode

Failure Mode	Repairing Procedure
LED is not lit	Refer to 8.2

8.2 Check the FPI Failure

Explanation of details on LED's on the side of the FPI

<LED1 POWER – Green>

Lit in green: When +24V is input

<LED2 HEALTHY – Green>

Lit in green: FPI retains the normal status.

<LED3 NETWORK – Green>

Lit in green: Normal communication status

<LED4 IMAGING – Green>

Lit in green, Radiography status, EXP_OK output period

Lit in green: READOUT

9. 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 its 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 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)

Appendix B Components and Characteristics

B.1 Flat Panel Sensor Unit

Sensor Protection Plate ..... Carbon Fiber Plate
Cooling ..... Natural Air Cooling
Input ..... DC24V (from AC/DC Power Supply)
Power Consumption ..... Maximum 20W
Overall Dimensions ..... 512×495×43mm (W(H)×D(V)×H))
Weight ..... 16 kg

B.2 Power Supply Unit

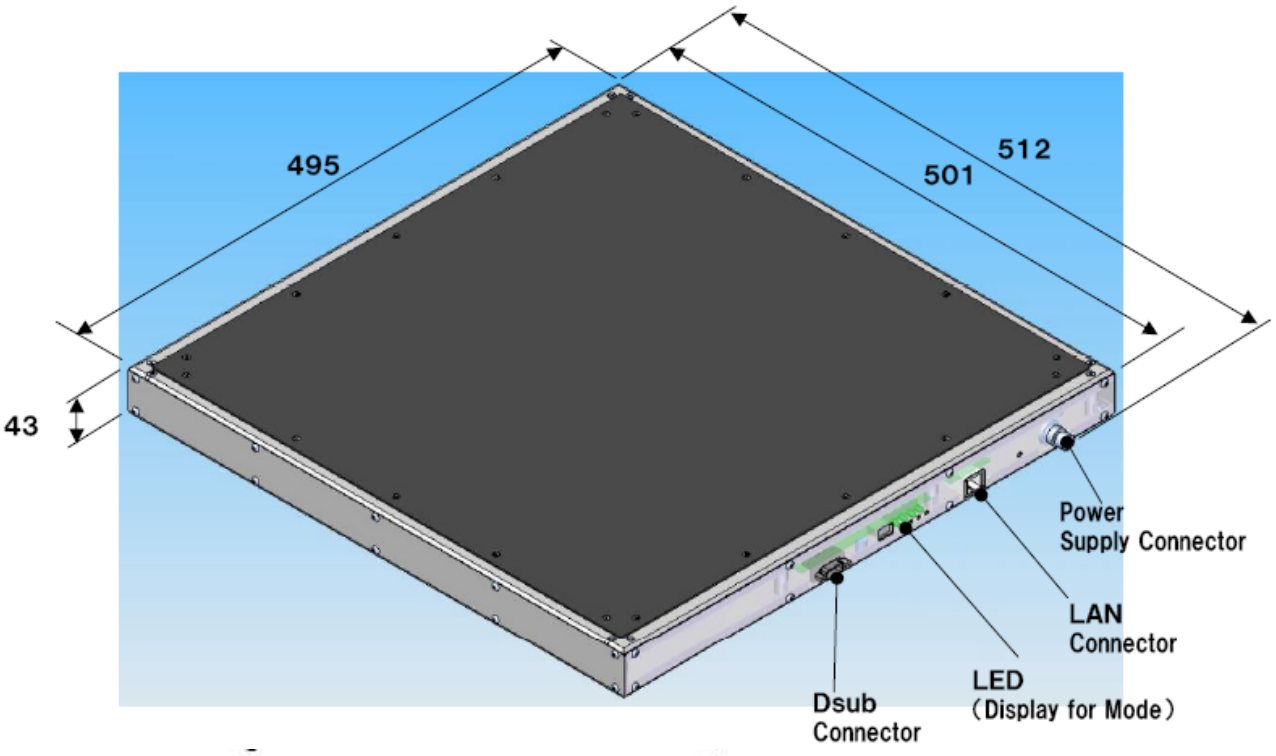
Input ..... AC100 to 240V, 50/60Hz
Output DC24V 1.3A 60W
Overall Dimensions ..... 126×200×60mm (W(H)×D(V)×H))
Weight ..... 1 kg (approx.)

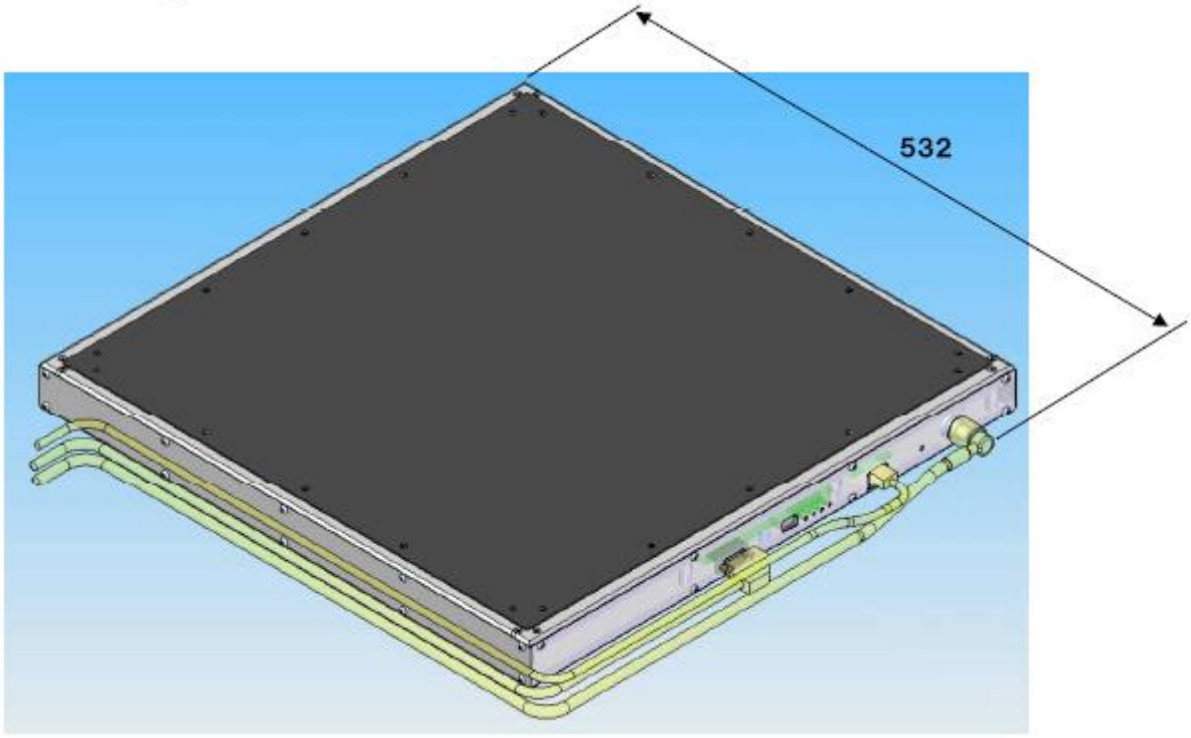
B.3 Dimensional Outline

Refer to Appendix C

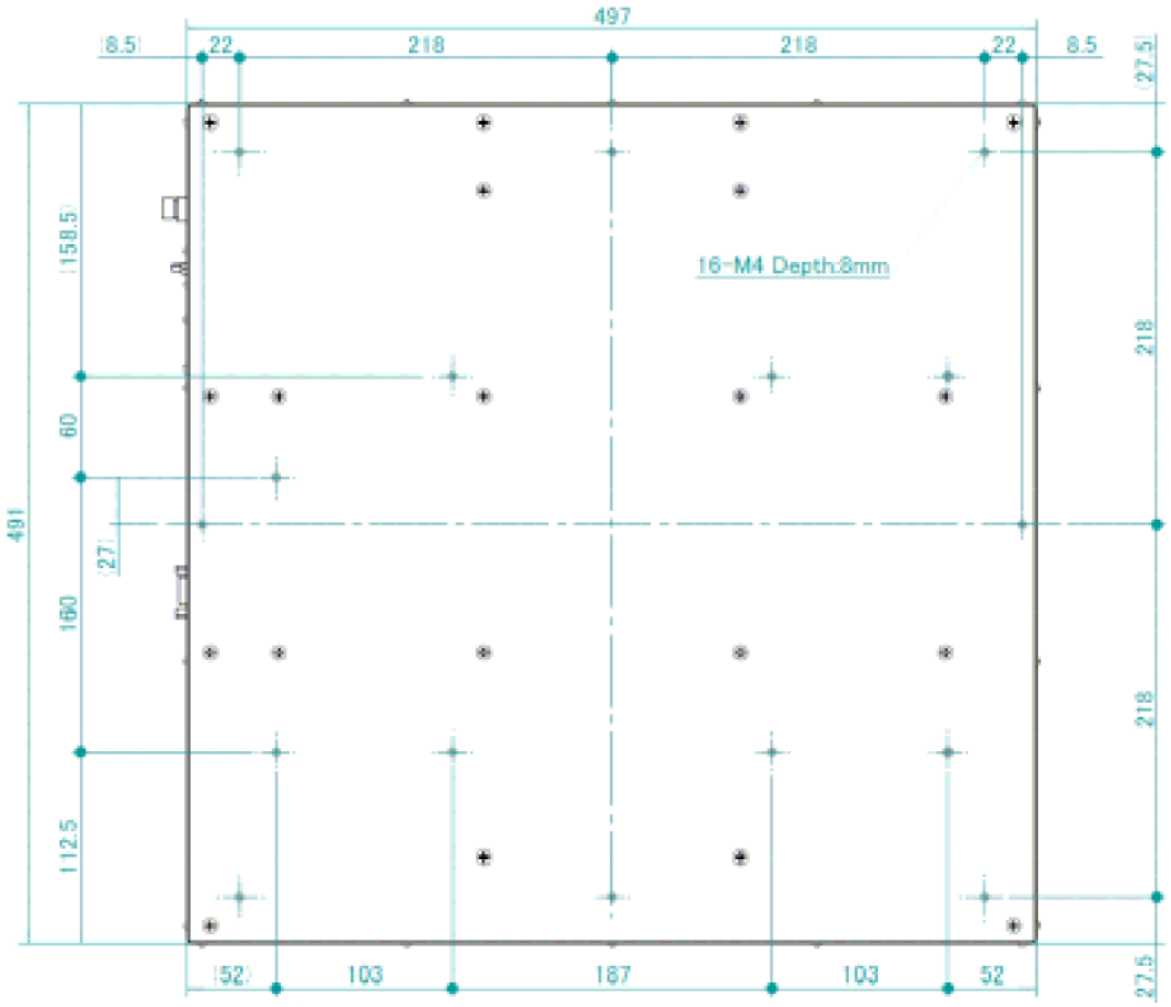
Appendix C Drawings

1) Flat Panel Sensor Unit (Unit: mm)

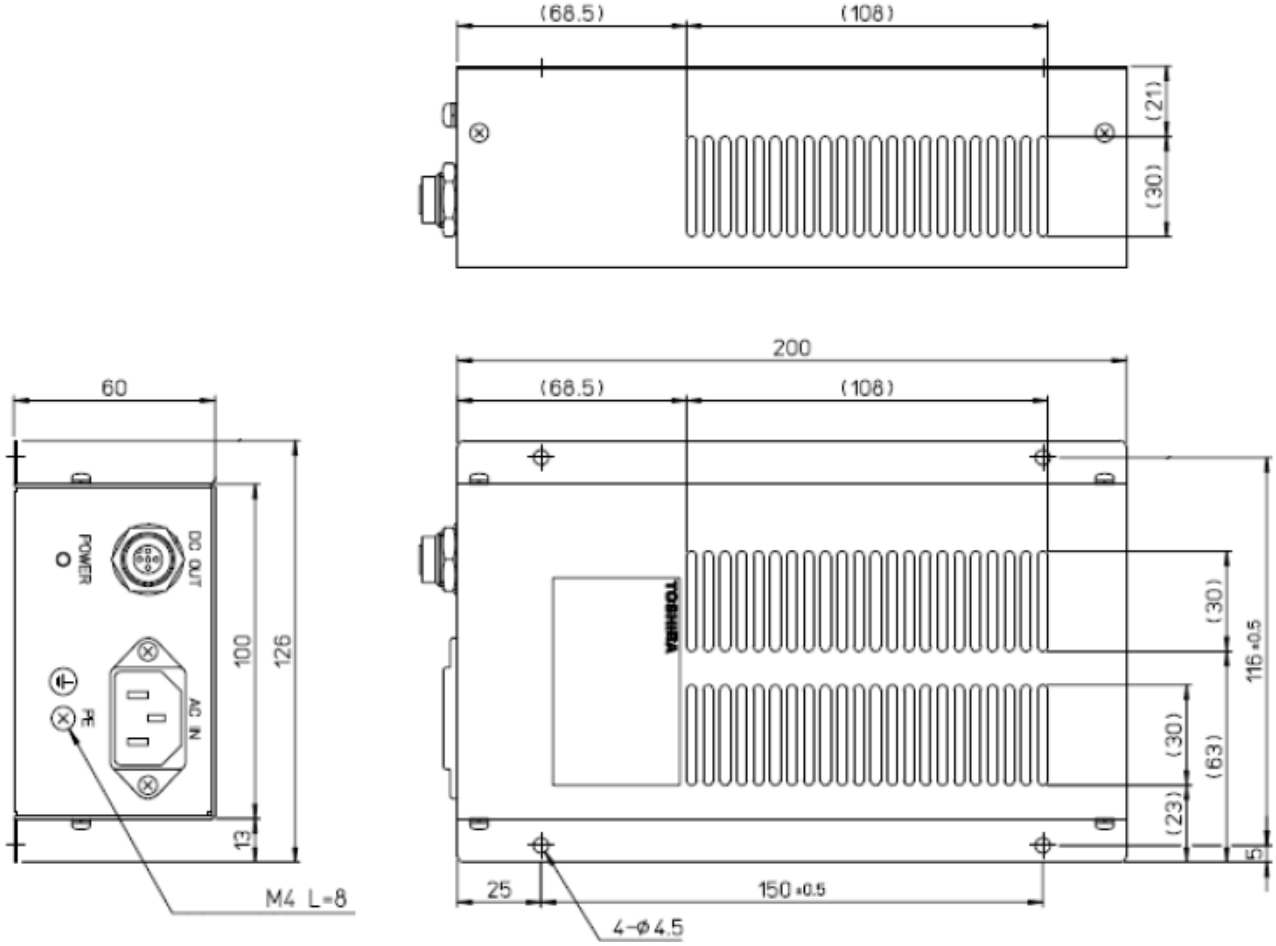




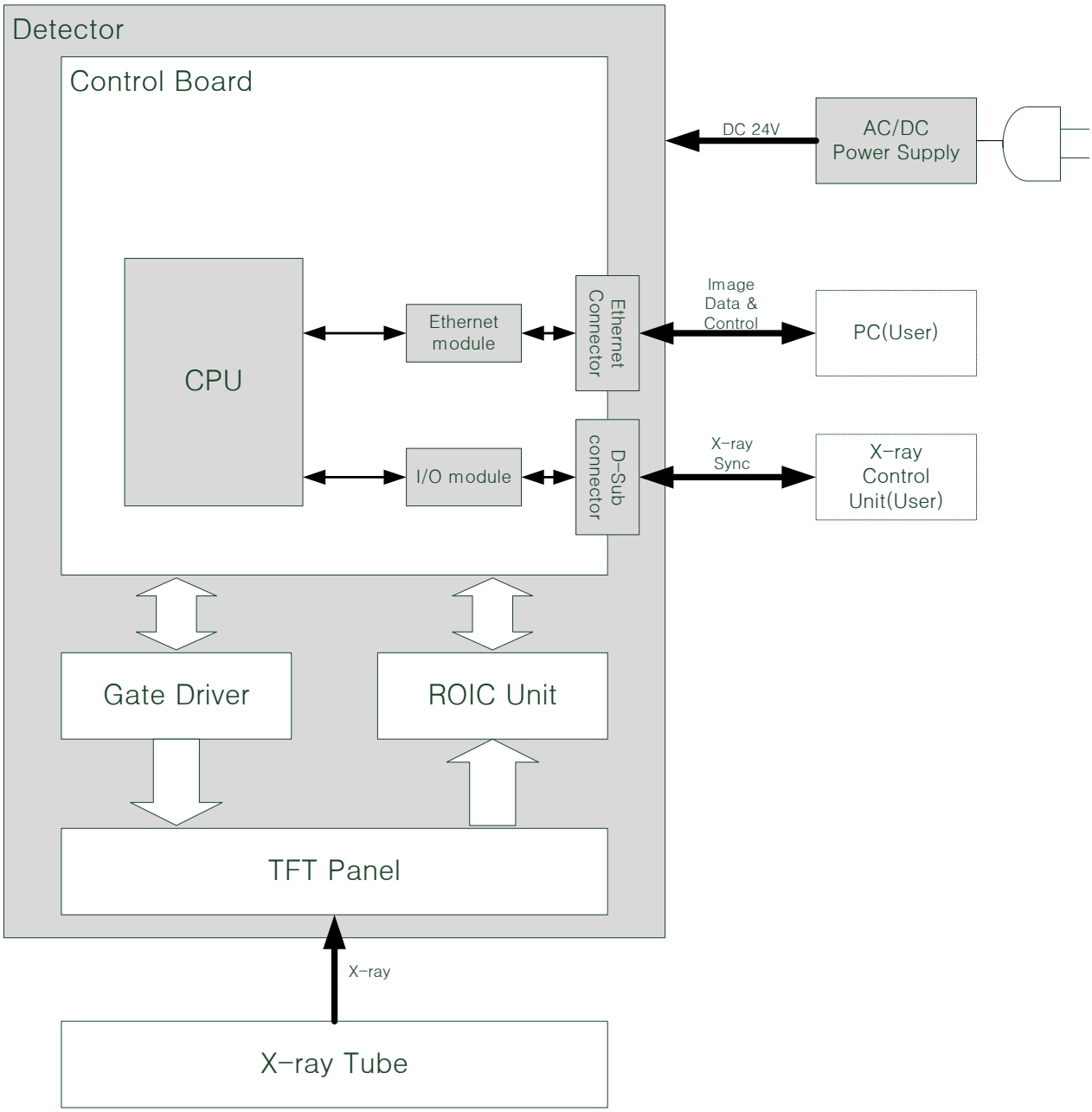
(Wired Image)


497
8.5
22
218
218
22
8.5
27.5
158.5
16-M4 Depth:8mm
218
60
491
27
160
218
112.5
52
103
187
103
52
27.5

2) Power Supply Unit (Unit: mm)



Appendix D Interconnection Diagram

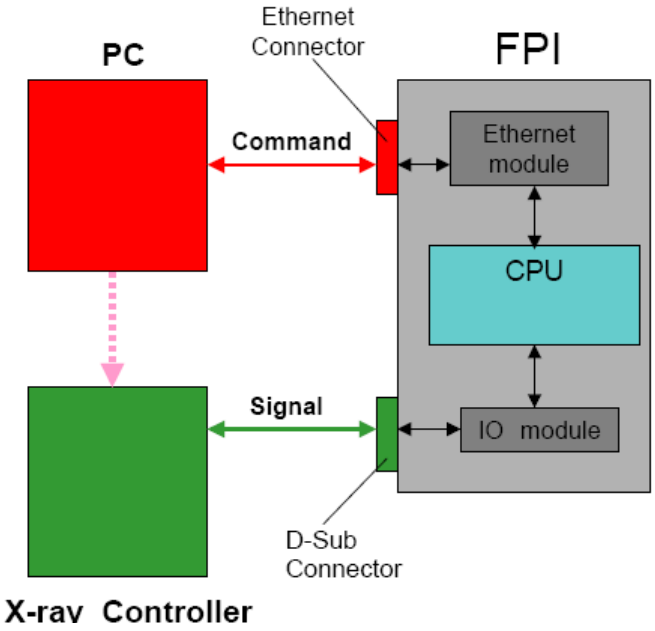


Caution

Do not disconnect Ethernet connection while DC24V is operating and supplying to FPI.

Appendix E Image Acquisition Interface

E.1 Communication Block Diagram



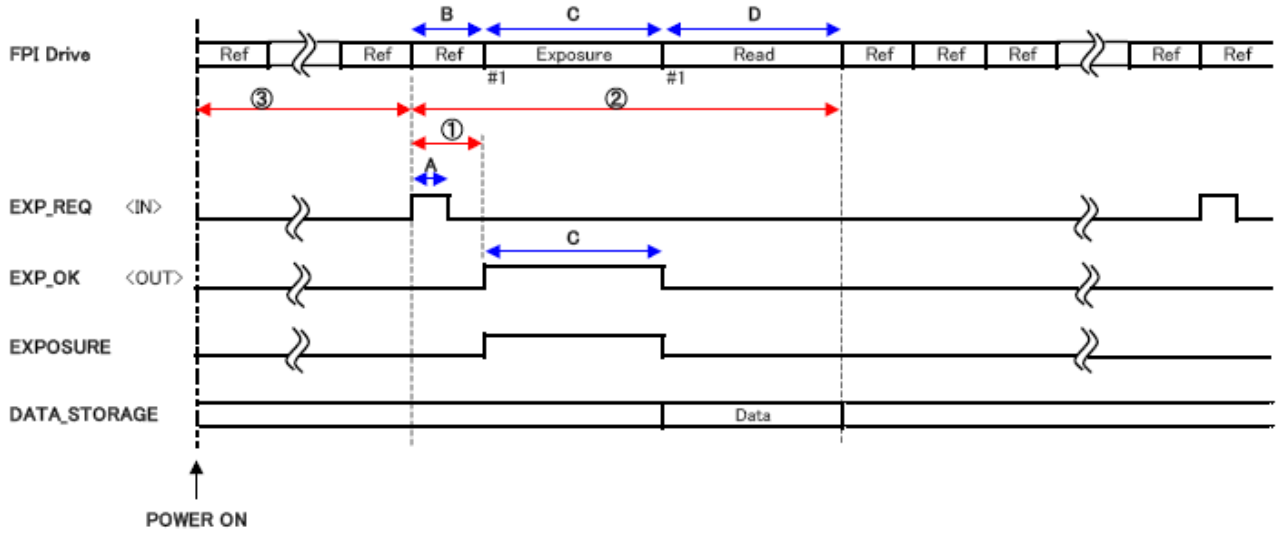
Communication Availability

Signal Name	Type	Ethernet Command Control (PC)	D-Sub Signal Control (X-ray Controller)
EXP_REQ	INPUT	OK	OK
EXP_OK	OUTPUT	N.A	OK

* EXP_REQ Command Response

E.2 Control Interface (D-Sub)

D-Sub Signal Control Interface Operation Sequence



A: EXP_REQ width

Minimum 1ms

B: Refresh period

For line drive (3072 Line scan), 36.9ms

C: EXP period

Set value: see the Image Acquisition mode table (50 to 500ms, 1000ms, 2300ms, 3200ms & 4000ms, Standard 500ms)

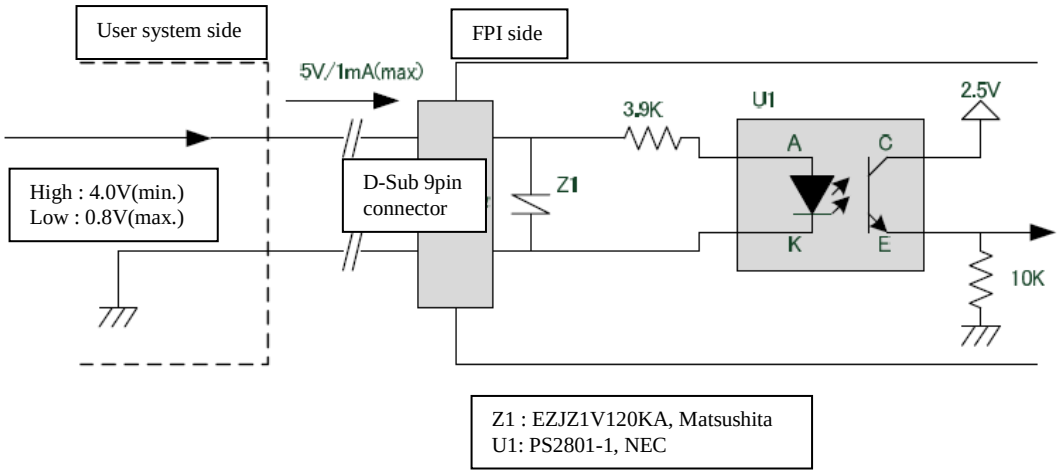
When you want to change EXP period, put in some period Command.

D: Read period

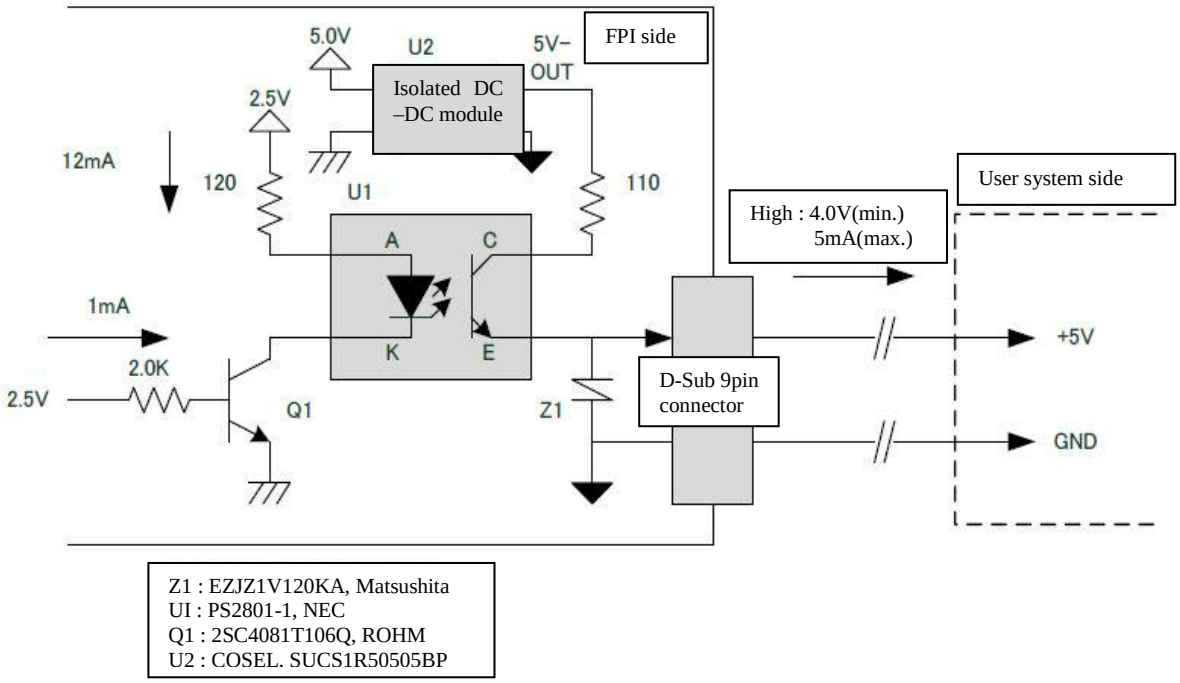
For line drive (3072 Line Scan) 1222ms

E.3 External Control (D-Sub)

(1) Input circuit

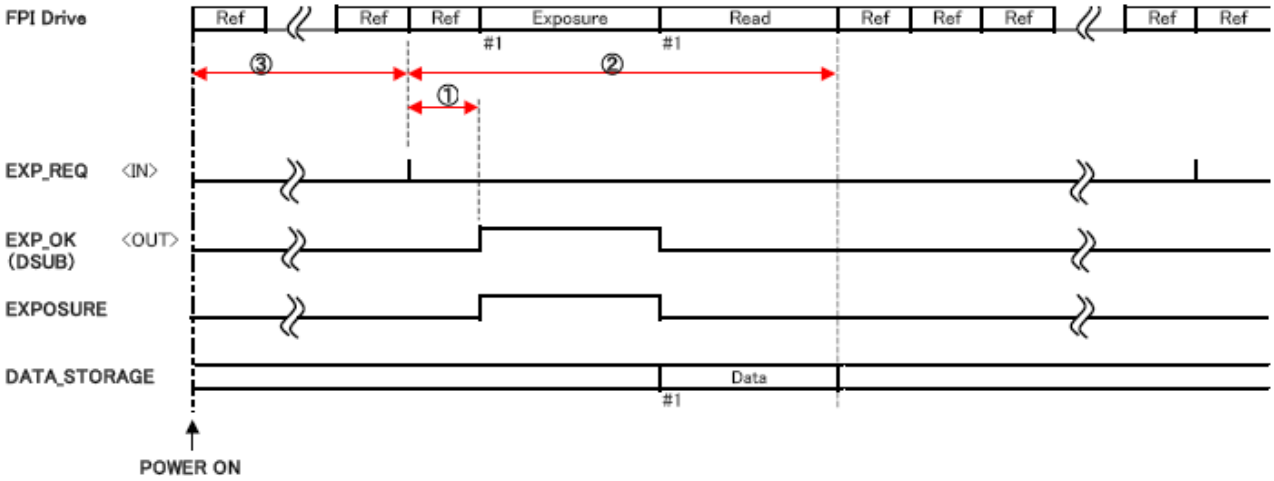


(2) Output circuit



E.4 Control Interface (Ethernet)

Ethernet Interface Command Control Operation Sequence



① : EXP_REQ - EXP_OK period Maximum 40ms

② : EXP_REQ - DATA STORAGE period Maximum 2,000ms (case EXPOSURE 500ms)

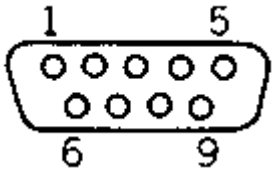
③ : POWER ON - EXP_REQ period Minimum 520ms

Description of the sequence

- By receiving "EXP_REQ" during "Refresh" status, proceeds to "Exposure" after completion of "Refresh".
- Continues "EXP_OK" signal ON during "Exposure". ON period is defined by Image Acquisition mode table.
- Proceeds to "Data Read" after completion of Exposure.
- After "Read", FPI proceeds to status of "Refresh".

Appendix F Pin Assignment

F.1 D-Sub pin (Image Acquisition Control interface)



Number viewed from insertion port side

D-Sub connector pin assignment on the side of the FPI.

Pin No	Signal name	I/O	Contents
1	TEST+	-	Don't connect. This pin is used for TEST.
2	EXP_REQ+	Input	Image acquisition (X-ray exposure) Request signal +
3	EXP_OK+	Output	Image acquisition (X-ray exposure) Period signal +
4	NC	-	Not connected
5	NC	-	Not connected
6	TEST-	-	Don't connect. This pin is used for TEST.
7	EXP_REQ-	Input	Image acquisition (X-ray irradiation) Request signal +
8	EXP_OK-	Output	Image acquisition (X-ray irradiation) Period signal +
9	NC	-	Not connected

F.2 Power Supply Connector

Pin No	Signal name	I/O	Contents
1	DC INPUT +	Input	DC 24V Positive Voltage Input
2	DC INPUT +	Input	DC 24V Positive Voltage Input
3	DC INPUT -	Input	DC 24V Negative Voltage Input
4	DC INPUT-	Input	DC 24V Negative Voltage Input
5	FG	-	Frame Ground