ViVIX-S 1717S User Manual

CE 0434

Contents

1. Instruction

This section gives basic information of this manual and products with the safety guide.

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1.1 Document Guide

This User Manual explains how to use the **ViVIX-S 1717S Wired** detector made by Vieworks, X-ray interface unit and other peripheral equipment. With this manual, you can install, set and manage the **ViVIX-S 1717 S Wired** detector as well as use its various functions.

1.1.1 Caution

If the user is not fully aquainted with this manual, the products can be malfunctioned or unsuspected problem can be happened due to carelessness. To prevent any medical accidents, the user should fully understand the instructions of this manual before operating the products.

1.1.2 Target

This manual is intended for service enginneers who install and set the **ViVIX-S 1717S Wired** detector.

1.1.3 Symbols

Before attempting to use Vieworks' product, follow the safety instructions in this manual along with the caution symbol. It is important for you to read and understand the contents of this manual for operating the products safely.

Caution

- This symbol is used to indicate a potentially hazardous situation which may cause death, personal injury or substantial property damage if the instructions are ignored. Be sure to understand the instructions of this symbol for the safe operation.

Information

- This symbol is used to indicate references and complementary information. Users are recommended to read the sentences with this notice carefully.

1.1.4 Notations

Bold Types

We applied bold font style to the words which indicated products terms, or the words and sentences which are needed to transmit clear meaning to the customers. This helps you to easily distinguish the words from other technical ones for explaining functions.

1.1.5 Contact Department

For any inquiries regarding this document and relevant products, contact to the department in Vieworks.

Item	Contents
Department	Customer Support Team in Vieworks
E-mail	CustomerSupport@vieworks.com

1.2 Intended Use

ViVIX-S 1717S Wired detector is a digital X-ray imaging solution. It acquires images by exposing X-ray which has been penetrated the human body. When X-ray photons pass through scintillator in the detector, the photons convert to visible ray, and the visible ray is converted to electronic signals through TFT (a-Si). Then the detector digitalizes X-ray images and transfers them to workstation in a wired way for radiography diagnostics. Users can perform image diagnosis easily through the image display monitor with this process. Advanced digital image processing also allows considerably efficient diagnosis, all kinds of information management, and sharing of image information on network.

- This detector is used for the general-purpose diagnostic procedures, and it is intended to replace radiographic film / screen systems.
- This device is not intended for mammography applications.

1.2.1 Features

- Compatible with a conventional film cassette complying with ISO4090, enables digital radiography diagnosis instead of the existing analog radiography.
- The new sensor with 140 μm of pixel pitch produces high-resolution (approx. 9.5 Mega pixels) digital images.
- As Vieworks provide two types of scintillator, user can choose one of the detectors to use.
  - 1717SA – CsI (Cesium Iodide, 428.4㎜ x 428.4㎜)
  - 1717SB – Gadox (Gadolinium Oxysulfide, 430.08㎜ x 430.08㎜)

1.3 Product Use Guide

This chapter instructs about the use of product and disposal as well as the liability limit of Vieworks.

1.3.1 Product Usage

1 Only a physician or a legally certified operator should use the products.
2 The equipment should be maintained in a safe and operable condition by maintenance personnel.
3 Be sure to obey the guides in this manual when installing and using the products.
4 Use only computers and image display monitors recommended by this manual.
5 Use only the dedicated cables provided with the products.
6 For details about installation and use of the products, consult your sales representative or a distributor.

1.3.2 Disclaimer

1 In no event shall Vieworks be liable for damage or loss arising from fire, earthquake, any action or accident by a third party, any intentional or negligent action by users.
2 In no event shall Vieworks be liable for damage or loss arsing from any trial usage, or other usage under abnormal conditions.
3 In no event shall Vieworks be liable for personal physical harm or property damage that is sustained when the instructions are not followed.
4 In no event shall Vieworks be liable for direct or indirect consequential damages arising from the use or unavailability of this produt.
5 In no event shall Vieworks be liable for any damage arising from moving, alteration, inspection or repair by a person other than authorized service engineers.
6 Vieworks shall not be liable for loss of image data for any reason while using this product.
7 Roentgenography, image processing, image reading and image data storage must be performed in accordance with the laws of the country or religion in which the product is being used.
8 The user is responsible for maintaining the privacy of image data made from this product.
9 It is the responsibility of the attending physicians to provide medical care services. Vieworks will not be liable for faulty diagnoses.
10 Specifications, composition, and appearance of this product may change without prior notice.

1.3.3 Product Disposal

Disposal of this product in an unlawful manner may have a negative impact on health and on the environment. When disposing of this product, therefore, be absolutely sure to follow the procedure which is in conformity with the laws and regulations applicable in your area.

1.3.4 Trademark

The “Vieworks” name and logo are registered trademarks of Vieworks.

1.4 Safety Instruction

This product is designed and manufactured to ensure maximum safety of operation and to meet all the safety requirements applicable to electronic medical equipment. Follow these safeguards while using the products. If not, severe personal injury or substantial property damage can be happened. It is important for you to read and understand the contents of this manual before attempting to use the product.

1.4.1 Management and Authority

- The product should be installed, operated, and serviced according to Vieworks maintenance procedures and by personnel from Vieworks or distributor who providing purchase of the Vieworks' product.
- Operation and maintenance should be done in strict compliance with the operation instructions contained in the manual.
- The system, in whole or in part, cannot be modified in any way without prior approval from Vieworks.
- Before authorizing any person to operate the system, verify that the person has read and fully understood the User 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 made and maintained.
- It is important that this User Manual be kept at hand, studied carefully, and reviewed periodically by the authorized operators.
- If a malfunction occurs, do not use this device until qualified personnel corrects the problem.

1.4.2 Power Supply

- Do not operate the equipment using any type of power supply other than the one indicated on the rating label. Otherwise, it may result in a fire or electric shock.
- Do not supply power to more than one piece of equipment using the same AC outlet for this product. Doing so may result in a fire or electric shock.
- Do not connect a multiple portable socket-outlet or extension cord to the system. Doing so may result in a fire or electric shock.
- Always connect the three-core power cord plug to a grounded AC power outlet.
- Be sure to ground the equipment to an indoor grounded connector. Also, be sure to connect all the grounds for the system to a common ground.
- Do not use any power source other than the one provided with this product. Otherwise, a fire or electric shock may be caused due to a leakage.
- The owner should ensure continuous power supply to the system, with voltage and current according to the product specifications. If the system is powered unstably during its operation, we recommend you to install UPS (Uninterrupted Power Supply) to avoid loss of data.

- To make it easy to disconnect the plug at any time, avoid putting any obstacles near the outlet. Otherwise, it may not be possible to disconnect the plug in an emergency.
- Do not place heavy object such as medical equipment on cables and cords, or do not pull, bend, bundle or step on them to prevent their sheath from being damaged, and do not alter them neither. Doing so may damage the cords which could result in fire or electric shock.
- Securely plug the power cord into the AC outlet. If contact failure occurs, or if dust / metal objects come into contact with the exposed metal prongs of the plug, fire or electric shock may result.
- Be sure to turn off the power to each piece of equipment before connecting or disconnecting the cords. Otherwise, you may get an electric shock that could result in death or serious injury.
- Be sure to hold the plug or connector to disconnect the cord. If you pull the cord, the core wire may be damaged, resulting in fire or electric shock.
- Do not handle the product with wet hands. You may experience an electric shock that could result in death or serious injury.

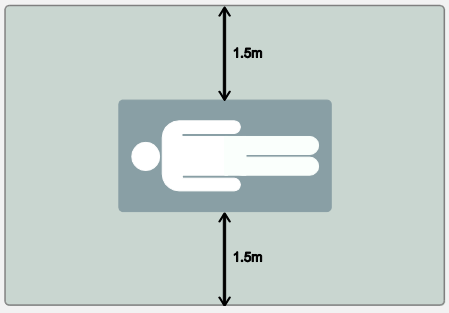
1.4.3 Handling

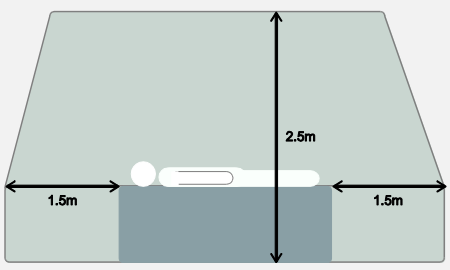
- Never disassemble or modify the equipment. Doing so may result in fire or electric shock. Also, since the equipment incorporates parts that may cause electric shock as well as other hazardous parts, touching them may cause death or serious injury.
- Do not connect the equipment with anything other than specified in this user manual.
- Do not place anything on top of the equipment. The object may fall and cause an injury. Also, if metal objects such as needles or clips fall into the equipment, or if liquid is spilled, it may result in fire or electric shock.
- Do not hit or drop the equipment. The equipment may be damaged if it receives a strong jolt, which may result in fire or electric shock if the equipment is used without being repaired.
- Do not place excessive weight on the detector. The internal image sensor may be damaged or the image quality can be affected.
- Have the patient take a fixed posture and do not let the patient touch parts unnecessarily. If the patient touches connectors or switches, it may result in electric shock or malfunction of the equipment.
- Do not spill liquid or chemicals onto the equipment or, in cases where the patient is injured, do not allow it to come in contact with blood or other body fluids.
- Turn OFF the power to each piece of equipment for safety when not being used.
- Do not submerge the equipment in water.
- Be sure to use the detector on a flat surface so it will not bend. Otherwise, the internal image sensor may be damaged. Be sure to securely hold the detector while using it in upright positions.

- Because the equipment cable is long, take care that cables do not become tangled during use. Also, be careful not to get your feet caught in the cable. It may cause a malfunction of the equipment or injury to the user from tripping over the cable.
- Do not block the ventilation ports of PSU to prevent overheating. Overheating can cause product's malfunctions and damages.

1.4.4 Environment of Use

- Do not install the equipment in any of the locations listed below. Doing so may result in failure or malfuction, equipment falling, fire, or injury
  - Close to facilities where water is used.
  - Where it will be exposed to direct sunlight.
  - Close to the air outlet of an air-conditioner or ventilation equipment.
  - Close to a heat source such as a heater.
  - Where the power supply is unstable.
  - In a dusty environment.
  - In a saline or sulfurous environment.
  - Where temperature or humidity is higher than the operating temperature.
  - Where there is freezing or condensation.
  - In areas prone to vibration.
  - On an incline or in an unstable area.
- The device malfunction can be occurred by EMI (Elecromagnetic wave Interference), released from wireless devices, radio and electronic equipment. To block out electromagnetic wave which affects to such devices, do not place any equipment around the device releasing electromagnetic wave. Also, change the direction and location of the device or move it to the shield place for reduce interference.
- It is not suitable for using this device in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Do not place liquid or food on the device. Otherwise, the conductive liquid can be flow in the ciruit of device and it may result in fire due to a short circuit.
- To prevent electric shock or fire due to using a wrong type of fire extinghisher, check if the fire extinguisher around the device has been approved for preventing electrical fire.
- Non-medical equipment such as PSU cannot be used in patient's vicinity.





1.4.5 Temperature

- The product is not intended to supply heat to a patient.
- The temperature of contact area with a patient will not be exceeded 48℃ under the normal user environment.
- Do not use the equipment beyond the range of recommended operating temperature.
- Be sure to monitor the internal temperature related to the patient contact area to avoid any adverse effect to the patient.

1.4.6 Problem Management

- Should any of the following occur, immediately turn off the power to each piece of equipment, unplug the power cord from the AC outlet, and contact our sales representative or distributor.
  - When there is smoke, an odd smell or abnormal sound.
  - When liquid is spilled into the equipment or a metal object is entered through an opening.
  - When the equipment has been dropped and is damaged.

1.4.7 Maintenance and Inspection

- Do not use or store the equipment near flammable chemicals such as acetone, benzene, thinner, etc. If chemicals are spilled or evaporate, it may result in fire or electric shock through contact with electric parts inside the equipment.
- If flammable disinfectant is used for cleaning the device, be sure to take care when using it.
- When the equipment is going to be cleaned, be sure to turn OFF the power of the equipment and unplug the power cord from the AC outlet. Never use acetone, benzene, thinner or any other flammable cleaning agent. Otherwise, it may result in fire or electric shock.
- Clean the plug of the power cord periodically by unplugging it from the AC outlet and removing dust or dirt from the plug, its periphery and AC outlet with a dry cloth. If the cord is kept plugged in for a long time in a dusty, humid or sooty place, dust around the plug will attract moisture, and this could cause insulation failure that could result in a fire.
- For safety reasons, be sure to turn OFF the power to the equipment when the inspections indicated in this manual are going to be performed. Otherwise, electric shocks may occur.

1.5 Product Usage Guide

- When using the equipment, take the following precautions. Otherwise, problems may occur and the equipment may not function correctly.

1.5.1 Calibration

- To ensure optimal performance of the system, it is important to verify that the system is calibrated.
- Check if the calibration is performed after the equipment is completed to be installed or repaired.
- Do not try to use the device if the calibration is not performed.
- You can process calibration with the calibration data CD (provided).

- The calibration result can be different through the use environment. Therefore, if the result performed by the provided calibration data is not satisfied, you can create the data in the field by using the calibration software (**Setup**) by yourself.

1.5.2 Distance Measurement

- Before taking any length measurement on an image, performing length calibration with a reference object and verifying its result for correct measurement.

1.5.3 Left/Right Marker

- Mark the information on the left/right side of image correctly and clearly.
- The software includes an option to mark the image with **L** (left) / **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.

1.5.4 Image Backup

- To avoid missing images which might result in patient being exposed to additional doses of radiation, it is important to send the images to PACS, or backup the images by filming or by using a CD or DVD option.
- If the hard disk of your workstation is about to full, the operator should backup images and delete the images to make room on the hard disk for new patient.

- The image backup should be done as a routine operation for every patient.

1.5.5 User Limitations

- The Vieworks software has the engineer mode which could only be operated with the inputting password.
- The engineer mode should be operated by the personnel who are qualified by Vieworks only.

1.5.6 Disposal

- Disposal of this product in an unlawful manner may have negative effects on health and on the environment.
- When disposing of this product, therefore, be absolutely sure to follow the procedure which is in conformity with the laws and regulations applicable in your area.

1.5.7 Pediatric Application

- Every request should be reviewed by the pediatric radiologist prior to beginning the examination to insure correct study is being performed.
- If the technologist notices an unusual request, they should contact the radiologist in charge. Examples include the orders- a Full Cervical, Thoracic, and Lumbar Spine series. The radiologist in charge should contact the ordering physician and decide which study is best for the pediatric patient.
- The technologist should use the proper technique for the patient's size to decrease the radiation dose when the technologist acquires diagnostic images.
- ALL pediatric patients shall be shielded for their x-ray examinations, except for when the shield will obscure the region of interest, as in a pelvic or SI joint X-ray for trauma or arthritis, or when it is physically or clinically unreasonable to shield the patient.
- For routine Hip X-Rays, ALL male children shall have their scrotum shielded using the small gonadal shield, females may not be shielded as this would obscure the hips.
- To minimize motion in infants and young children, swaddle the infant. Use distraction tools to improve cooperation and projectors with child-friendly themes, music, toys with flashing lights or music, child-friendly images on the ceiling or walls, singing, counting, and a parent reading and talking to the child through the console all can help reduce anxiety and comfort the child.
- A scoliosis series will consist of a single frontal standing view of the spine. No lateral view or supine view is needed, unless specifically asked for by the Orthopedist or Radiologist. If the female's breasts can be shielded without obscuring the spine, breast shields should be used.

1.5.8 Before Exposure

- Be sure to check the equipment daily and confirm that it works properly.
- Sudden heating of the room in cold areas will cause condensation to form on the equipment. In this case, wait until the condensation evaporates before performing an exposure. If the equipment is used while condensation is formed on it, problems may occur in the quality of captured images.
- When an air-conditioner is used, be sure to raise/lower the temperature gradually so that a difference in temperature in the room and in the equipment does not occur, to prevent condensation.

1.5.9 During Exposure

- This equipment is not protected (sealed) against liquids such as blood and medication in the operating room. If necessary, wrap the equipment in a disposable cover when using it.
- Do not use the detector near devices generating a strong magnetic field. Doing so may produce image noise or artifacts.

1.5.10 Operation and Storage Environment

- The equipment is mainly for use in X-ray exposure rooms and hospital wards. To use it in other places, consult our sales representative or a distributor.
- Do not expose this equipment to high temperatures and/or high humidity. Malfunctions may occur.
- When not in use, keep the equipment in a location where they are safe and cannot fall down.
- Be sure to use and store this equipment under the conditions described below.

Classification	Temperature	Humidity (Non-condensing)	Atmospheric Pressure
Operating environment	+10 ~ +35℃	30 ~ 85%	700 ~ 1060 hPa
Storage environment	-15 ~ +55℃	10 ~ 90%	500 ~ 1060 hPa

- The operating environment of this equipment is complied with **EN60721-3-3 Class 3K2**.
- The storage and shipping environment of this equipment is complied with **EN60721-3-2 Class 2K2**.

1.5.11 Others

- Do not use this equipment in combination with peripherals such as defibrillators or large electric motors as these may cause power-supply noise or power supply voltage variations. Doing so may prevent normal operation of this equipment and peripherals.

2. Product

This section gives an instruction about the product component and specifications

Components

Detector

PSU

Others

2.1 Components

2.1.1 Detector

Product Name		Model / Description
ViVIX-S 1717S Detector		• FXRD-1717SA / 1717SB : 11kg ▫ With a protective case: 18kg

2.1.2 PSU (Power Supply Unit)

Product Name		Model / Description
PSU		• FXRS-01A / 01B (2.0kg)
DC Power Cable		• 10m

2.1.3 Accessories

Type		Description
Cables		• AC Power Cable (2m)
		• Generator Interface Cable (15m)
		• Gigabit LAN Cable (15m, Direct) ▫ 1000BASE-T ▫ CAT5E or CAT6
CD		• Calibration data CD ▫ Pre-offset / Post-offset data ▫ Gain / Defect map data
		• Software (Viewer or SDK) • Manual

- The protective case for the **ViVIX-S 1717S** wired detector is sold separately.

- The use of accessories and cables other than those approved and sold by Vieworks Co., Ltd. may result in increasing emissions of electromagnetic waves or decreasing stability of the equipment.
- Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards. All combinations of equipment must be in compliance with **IEC 60601-1-1** system requirements.
- Any person who connects additional equipment to the signal input or signal output ports configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard **IEC 60601-1**.
- Consult your sales distributor or manufacturer if you have any concerns.

2.2 ViVIX-S 1717S Detector

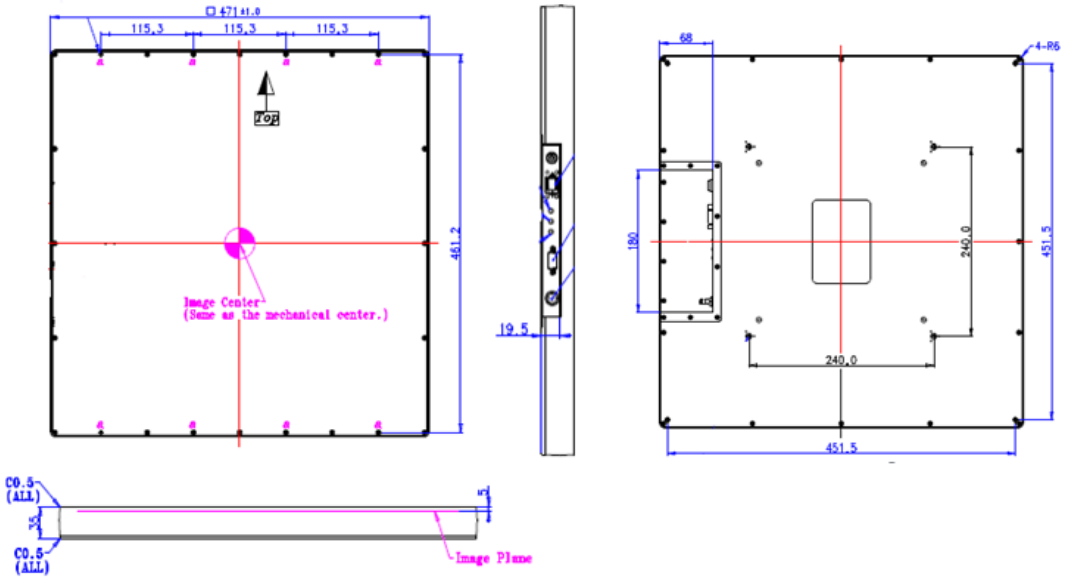
The detector is designed to acquire digital images through several conversion processes of X-ray. The images are sent to the workstation where the image acquisition program (viewer) is connected with cables.

2.2.1 Specifications

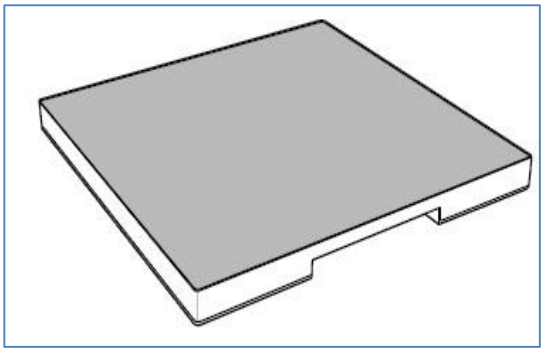
Item	Specifications
Model	• FXRD-1717SA (CsI) • FXRD-1717SB (Gadox)
Image Sensor	• a-Si (Amorphous Silicon) TFT
X-ray Scintillator Type	• FXRD-1717SA : CsI: TI (Thallium doped Caesuim Iodide) • FXRD-1717SB : Gd_2O_2S:Tb (Gadolinium oxysulfide)
Pixel Pitch	• 0.14㎜ (140㎛)
Field of View	• 17″ x 17″
Active Area (H x V)	• 430.08㎜ × 430.08㎜
Active Array	• 3072 x 3072 pixels
Effective Area	• FXRD-1717SA: 3428.4㎜ x 428.4㎜ • FXRD-1717SB: 430.08㎜ x 430.08㎜
Effective Array	• FXRD-1717SA : 3060 x 3060 • FXRD-1717SB : 3072 x 3072
Grayscale	• 14bit
Spatial Resolution	• Min. 3.5 lp/㎜
Dynamic Range	• 73dB or more
Image Acquisition Time	• 1 sec. (Image Acquisition and Transfer Time)
Recommended Cycle Time	• 15 sec.
X-ray Synchronization Control	• AED (Auto Exposure Detection) • DR Trigger (External line trigger) • Passive Trigger (External line trigger)
Rated Power Supply	• DC +24 V, Max. 0.5 A • The detector is powered by PSU with a DC power cable connection.
Power Consumption	• Max. 20 W
Dimensions (H × W ×D)	• 470㎜ × 470㎜ × 35㎜ (Without a protective case) • 520㎜ × 520㎜ × 75㎜ (With a protective case)
Weight	• FXRD-1717SA : 11 kg (Without a protective case) • FXRD-1717SB : 18 kg (With a protective case)
Image Transmission	• 16 bit Digital Output Ethernet(1000BASE-T)
Data Transmission Rate	• Max. 1Gbps

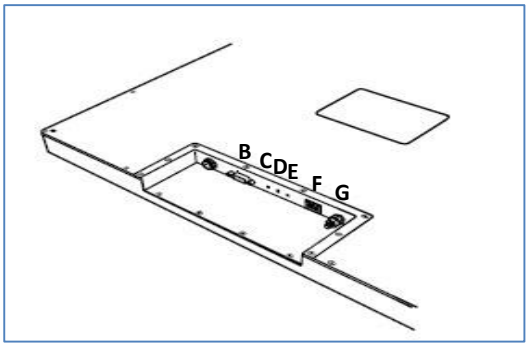
• X-ray exposure time is not included in the image acquisition time.

2.2.2 Drawing Sheet



2.2.3 Functions





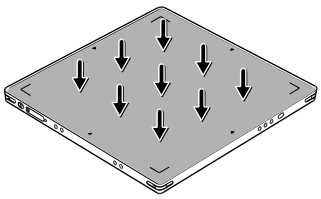
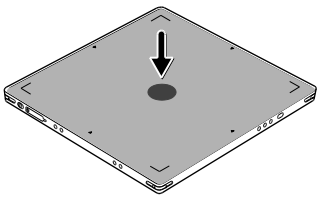
	Name	Description
A	**DC power connector**	• DC +24V input
B	**Generator interface connector**	• D-SUB 9 pin, Female
C	**Status indicator [EXP_OK]**	• Indicates data sending and communication. (Light green(blink))
D	**Status indicator [STATUS]**	• Standby status (Light green)
E	**Status indicator [POWER]**	• Power on/off status (Light green)
F	**LAN port**	• Gigabit Ethernet port (1000BASE-T) • Communication between the detector and PC
G	**Potential Equalization**	• Equipotentiality Ground

2.2.4 Use Environment

Item	Operation	Storage & Transportation
Temperature	• +10 ~ +35℃	• -15 ~ +55℃
Humidity	• 30 ~ 85% (Non-condensing)	• 10 ~ 90% (Non-condensing)
Atmospheric Pressure	• 700 ~ 1060 hPa	• 500 ~ 1060 hPa
Shock	• 1.6G	• 20G
Vibration	• 0.7G	• 0.7G

- The use environment of detector and PSU are same.

Load Limit of Detector

Uniform Load	Local Load
Over the whole surface	Center diameter 40mm
Max. 150kg	Max. 100kg
	

- Do not let the paitent or object heavier than load limit be on the detector. Then, detector can be damaged.
- Do not let the patient lie or get on the detector. Internal devices such as a sensor can be seriously damaged even if his/her weight is within the load limit.

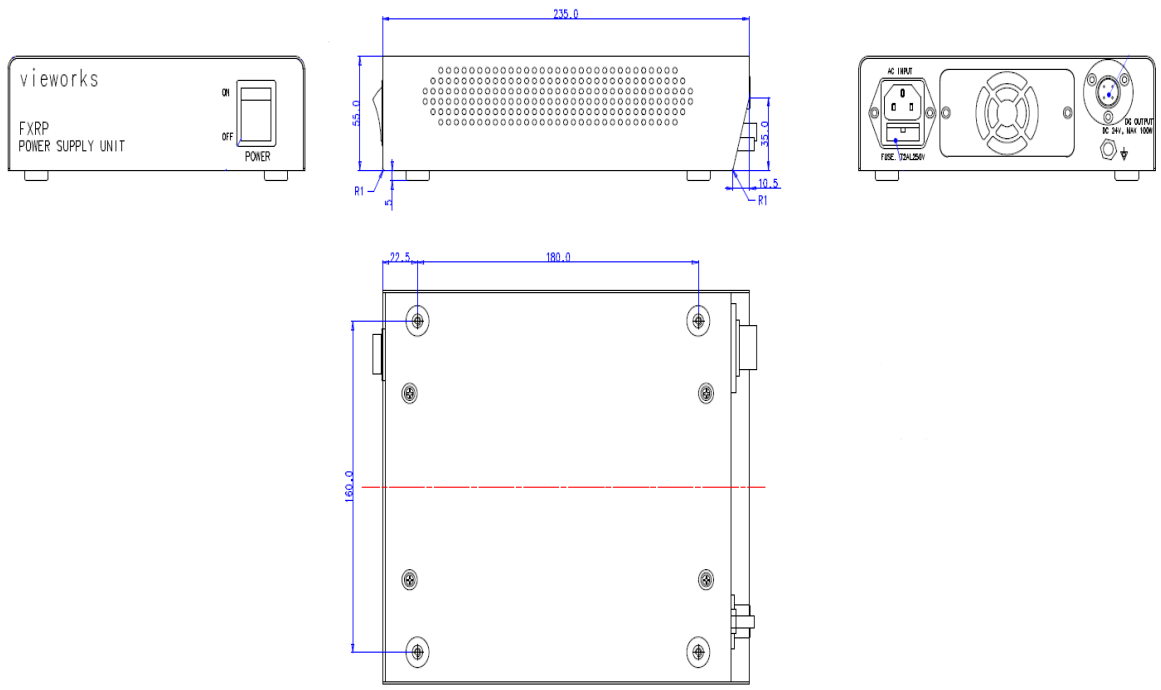
2.3 PSU (Power Supply Unit)

PSU supplies power to the detector.

2.3.1 Specifications

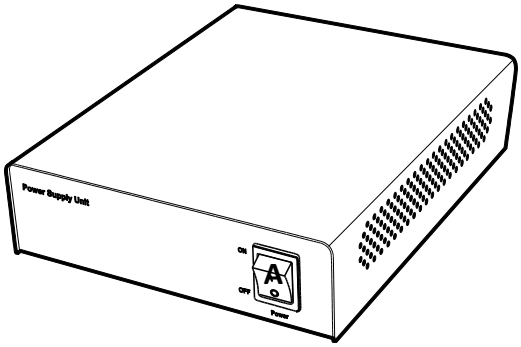
Item	Specifications
Model	• FXRP-01A/01B
Power Supply	• Input: AC100 to 240V, 50/60Hz, Max. 200VA • Output: DC +24V 3.3A, 80W
Dimension (H × W × D)	• 230㎜ × 190㎜ × 55㎜
Weight	• 2.0 kg

2.3.2 Drawing Sheet



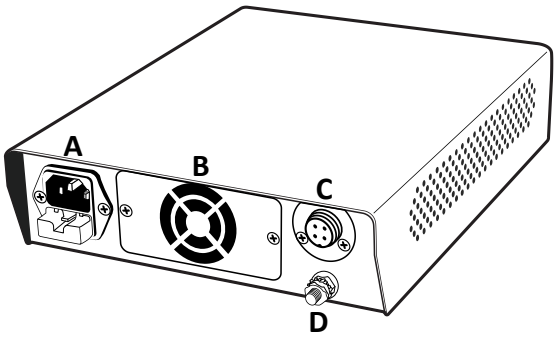
2.3.3 Functions

Front Side



No.	Name	Description
A	**Power Switch**	• PSU power swtich (ON or OFF) (Including green LED Lamp)

Rear Side



	Name	Description
A	**AC power input port**	• T2AL250V fuse (2 EA) ▫ 100 ~ 240V. ▫ 50/60Hz ▫ Supplies power to PSU
B	**FAN**	• Emits inside air of PSU to outside
C	**DC power output coonector**	• DC +24V Output • Supplies power to the detector
D	**Potential Equilization**	• Equipotentiality Ground

• P.E (Potential Equalization) port of PSU is used to maintain potential equalization between PSU and another grounded system. Use the conductor that can be detached without using a tool.

2.4 Others

2.4.1 X-ray Generator (Recommended Exposure Condition)

Item	Recommended condition
X-ray energy range	• 40 kVp ~ 150 kVp
Reliability (Lifetime Dose)	• 74 Gy or higher (35 uGy x 365days x 24hrs x 60min. x 60sec. / 15sec.)

2.4.2 Recommended Specifications of Workstation (PC)

Item	Recommended specification
Operating System	• **VXSetup** ▫ Windows 7 64bit SP1 (Professional Edition or higher) ▫ Windows 8 / Windows 8.1 64bit SP1 (Professional Edition or higher) • **Chameleon Setup** ▫ Microsoft Windows Vista Service pack 1 or higher (32bit / 64bit) ▫ Microsoft Windows 7 ▫ Microsoft Windows 8, Microsoft Windows 8.2 (32bit / 64bit)
CPU	• Intel Core i5 2600 or higher (or compatible CPU)
Memory	• 4GB or higher
Hard Disk	• 1TB or higher
LAN Card **(Only for detector communication)**	• Gigabit (for) • Intel® PRO 1000 Series (Gigabit LAN card for network interface) • Minimum requirements ▫ Speed: 1Gbps or faster ▫ Jumbo Frames: 9K ▫ Receive Descriptors: 2K (1024 or higher)
Monitor	• 1024 × 768 or larger
CD-ROM	• CD or DVD R/W

2.4.3 Recommended Specifications of Grid

Item	Recommended specification
SID	• 100 cm / 130 cm / 150 cm / 180 cm
Size	• 451mm X 365mm X 1.5mm
Ratio	• 8:1 / 10:1 / 12:1
Frequency	• 215 line/inch
INTER SPACER	• AL

• Check the recommended specifications by Vieworks first before buying the generator, workstation and grid.

3. System Configuration

This section gives information about the various connection / configuration ways among the detector, PSU, workstaton and X-ray generator. You can figure out the most suitable way of system configuration through this instruction.

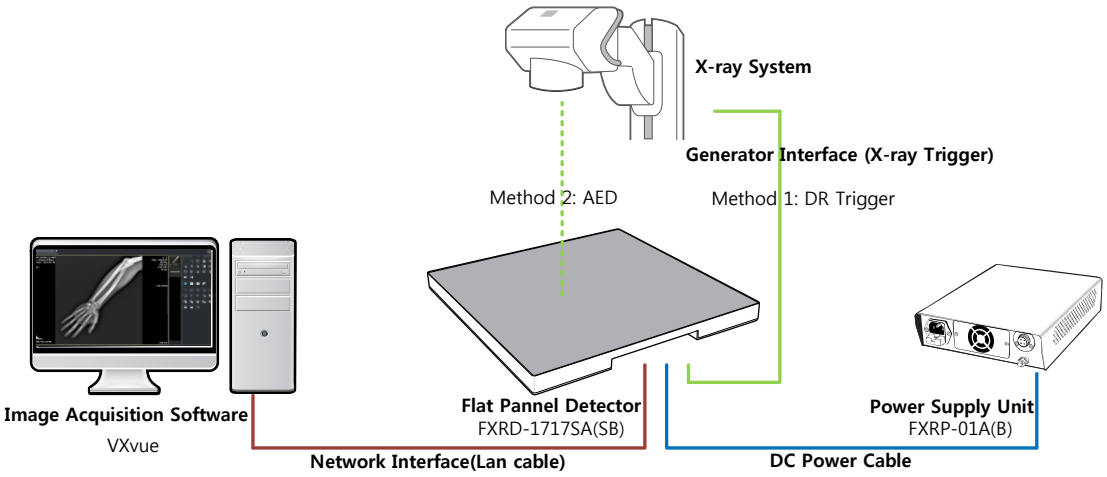
Detector Connection Method

Diagram

Generator Interface

Configuring Trigger Interface

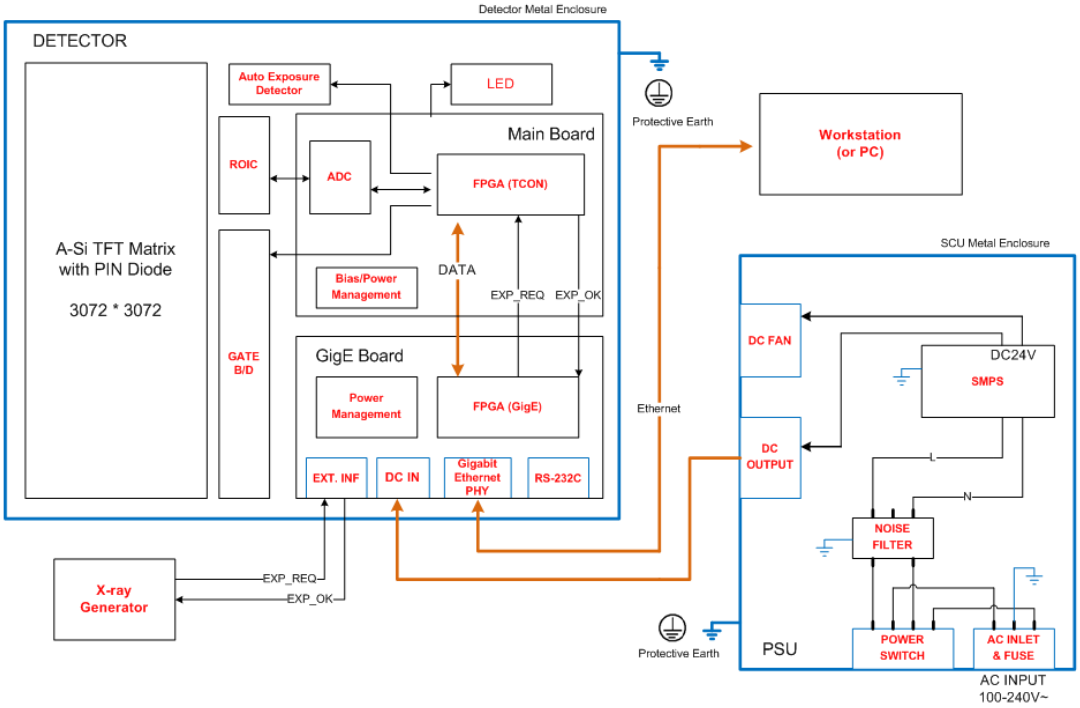
3.1 Detector Connection Method



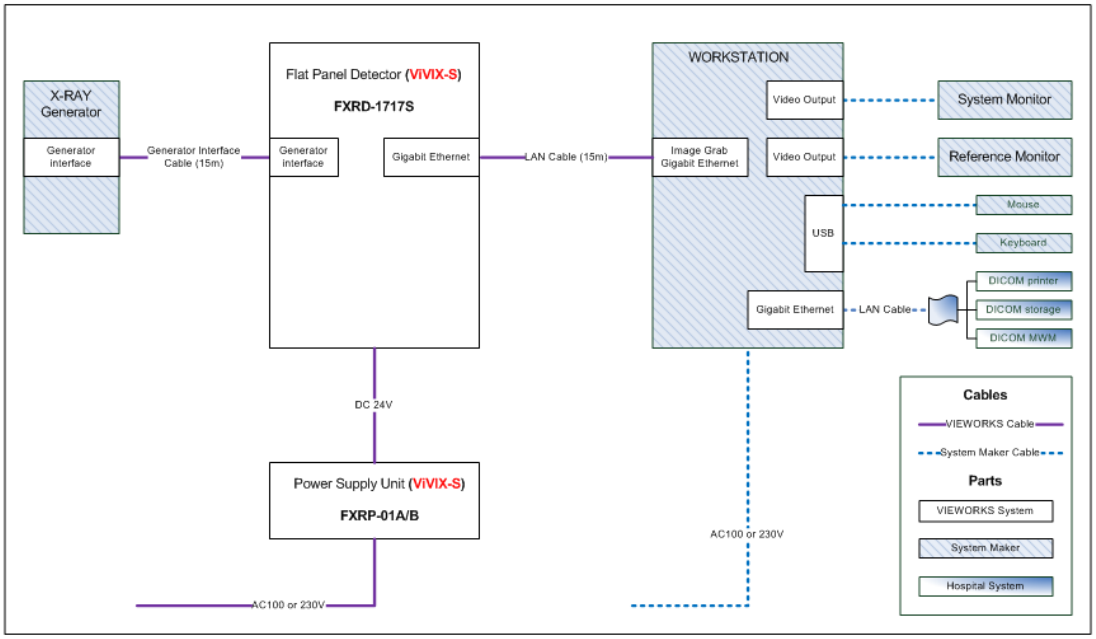
- The power of **ViVIX-S 1717S** wired detector is supplied from PSU.
- The **ViVIX-S 1717S** wired detector and workstation is connected with a wired LAN cable.
- You can use DR Trigger mode and Passive Trigger mode by connecting the X-ray generator with the **ViVIX-S 1717S** wired detector physically.
- You can use AED mode without connecting the X-ray generator with the **ViVIX-S 1717S** wired detector physically.

3.2 Diagram

3.2.1 Block Diagram



3.2.2 Wiring Diagram



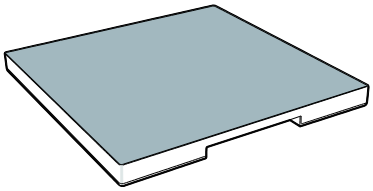
3.3 Generator Interface

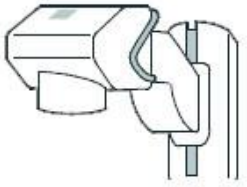
There are **AED** interface, **DR Trigger** interface and **Passive Trigger** interface that utilizing the **ViVIX-S 1717S** wired detector and X-ray genterator.

Mode	Description
AED	The detector detects X-ray exposure from the X-ray generator automatically and then performs image acquisition without any cable connection.
DR Trigger	The detector and X-ray generator receive and send their signal to each other for image acquisition. The detector and X-ray generator should be connected with a generator interface cable.
Passive Trigger	The X-ray generator generates X-ray right after it sends EXP_REQ signal to the detector. The detector then acquires an image. The X-ray generator and the detector should be connected with a generator interface cable.

3.3.1 AED (Auto Exposure Detection) Interface

If the **ViVIX-S 1717S** detector is used as the **AED** interface, you can acquire images without connecting the generator to the detector with a generator interface cable.





Cautions when using the AED mode

- Make sure to follow the operating environment requirements (Temp: **+10℃ ~ +35℃**).
- Do not give impact to the product. If it receives strong jolt, unwanted images may be acquired because of the malfunction of the sensor without the X-ray exposure.
- No image acquisition or horizontal artifacts may occur depending on using environment such as exposure condition, thickness of object or grid.
- When you set X-ray exposure area to the direction of the detector, the center of the detector should be included in the X-ray exposure area. Otherwise, you may not acquire an image.

3.3.2 DR Trigger Interface

Connect a detector and X-ray generator with a generator interface cable, and then acquire images after sending and receiving their signals for exposure.

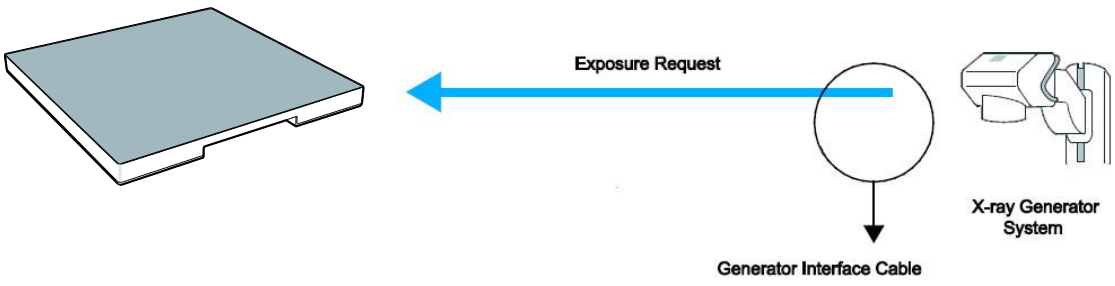
Signal Processing Steps

1 The detector receives **EXP_REQ** signal from the X-ray generator.
2 After the detector completes to prepare image acquisition, it sends **EXP_OK** signal to the X-ray generator.
3 The X-ray generator confirms **EXP_OK** signal and generates X-rays.
4 The detector acquires images and then transmits the image data.

- **EXP_REQ** is a signal sent from X-ray generator to detector for requesting exposure.
- **EXP_OK** is an exposure ready signal from the detector to X-ray generator.

3.3.3 Passive Trigger Interface

Connect a detector and X-ray generator with a generator interface cable, and then acquire images right after receiving EXP_REQ signal from the X-ray generator.



Signal Processing Steps

1 The detector prepares to acquire images righte after it receives **EXP_REQ** signal from the X-ray generator.
2 The X-ray generator generates X-rays.
3 The detector acquires images and then transmits the image data.

- **EXP_REQ** is a signal sent from X-ray generator to a detector for requesting exposure.

3.4 Configuring Interface

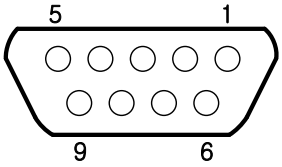
For exposure with **DR Trigger** or **Passive Trigger** interface, the detector and X-ray generator should be connected with a generator interface cable. Connect the one end of generator interface cable to D-SUB generator interface cable of the detector, and then connect the other end to X-ray generator.

- Up to one X-ray generator can be connected to D-SUB generator interface cable of the **ViVIX-S 1717S** wired detector.

- The engineer who understands about the X-ray generator device and interface technology well should be in charge of the connection between the detector and generator interface.

3.4.1 Generator Interface Connector Pin Map

D-SUB generator interface connector is the D-SUB 9 pin female connector.



Definition of D-SUB Generator Interface Connector pin map (1 ~ 9)

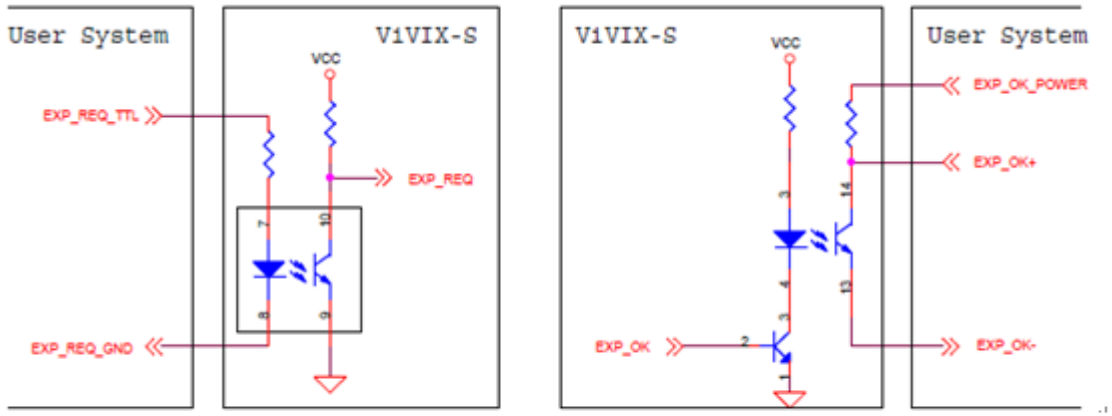
No.	Signal Name	I/O	Type	Description
1	**EXP_REQ_TTL**	Input	TTL	Receive **EXP_REQ** signal
2	**EXP_REQ+**	Input	Contact	Receive **EXP_REQ** signal
3	**EXP_OK+**	Output	-	Send **EXP_OK** signal
4	**PRE_SW**	-	-	Reserved for test only. Do not connect.
5	**EXP_OK_POWER**	Input	-	Power of **TTL** signal
6	**EXP_REQ_GND**	Input	TTL	Return signal of **EXP_REQ_TTL**
7	**EXP_REQ**	Input	Contact	Return signal of **EXP_REQ+**
8	**EXP_OK-**	Output	-	Return signal of **EXP_OK+**
9	**PRE_SW_RET**	-	-	Reserved for test only. Do not connect.

- Up to one X-ray generator can be connected to the D-SUB generator interface connector.

- There are **Contact** type (OPEN/ CLOSE) and **TTL** type (ON/ OFF) on signal in/output pin.
- TTL type information
  - ON : VCC / OFF : GND
  - Current: 5 mA ~ 10 mA / Voltage: 12 V ~ 24 V

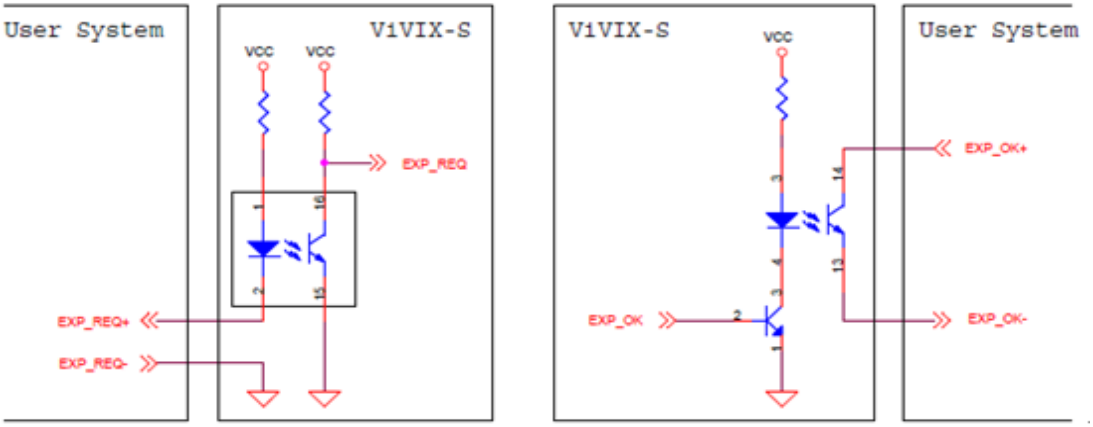
3.4.2 Input / Output Circuit

Input circuits of exposure request signal / Output circuits of exposure respond signal



<Request Input> <Request Output>

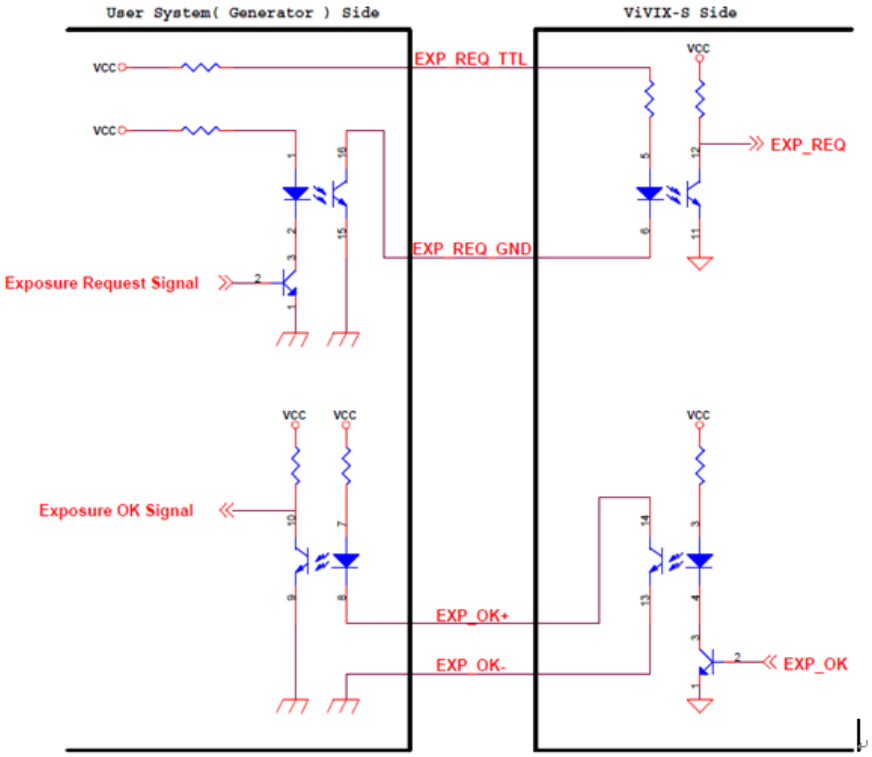
<TTL Type>



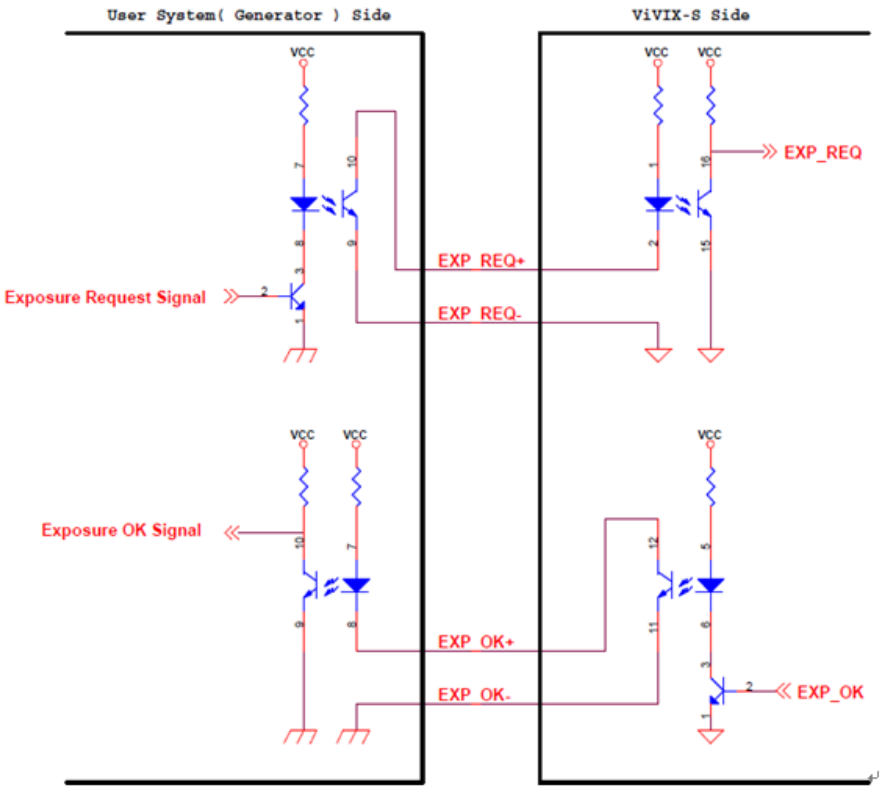
<Request Input> <Request Output>

<Contact Type>

Sample diagram between the detector and X-ray generator interface



< Example: TTL type >



< Example: Contact type >

4. Settings

This section gives information about the installation and setting method to use a detector/PSU.

Product Installation

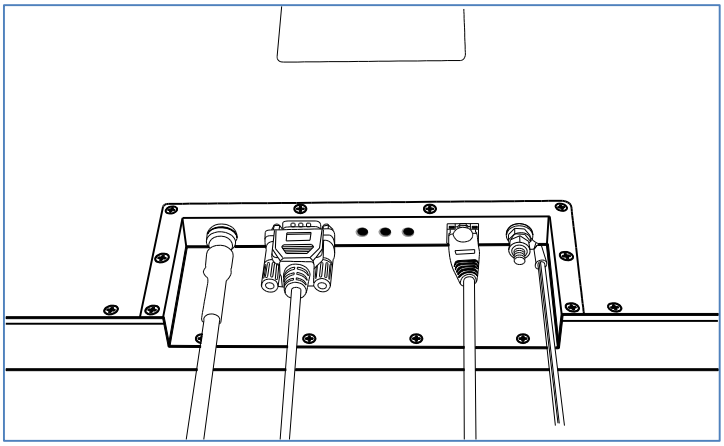
Device Setting

Diagnosis of Devices

4.1 Product Installation

4.1.1 Connecting Devices

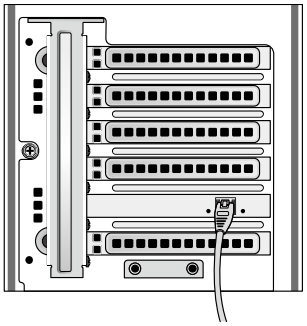
- Installation of this equipment should be made by licensed and authorized personnel by Vieworks.
- This equipment must only be connected to the power with protective earth.



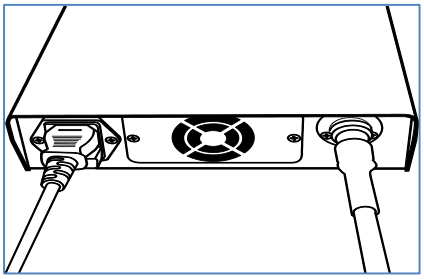
1 If you use the DR Trigger mode or the Passive Trigger mode, connect the one end of generator interface cable to D-SUB generator interface connector of the detector, and the other to the X-ray generator.

- If you use the AED mode, a generator interface cable is not needed as the detector is operated by detecting X-ray automatically.

2 Connect one end of the LAN cable to one of the LAN ports of the detector, and connect the other end to the LAN port of workstation assigned for data transfer.



3 Connect one end of the DC power cable to the DC power output connector of PSU, and connect the other end to the DC power connector of the detector.



- Make sure to connect the DC power cable when the power PSU is off.

4 To supply power, connect the AC power cable to the AC power input port of PSU.

5 If the DC power cable is longer than 10m, you should use it with connecting the ground wire. The ground terminal and ground wire shall be connected before operating the system. Connect the ground terminal and cable of the detector to ground marked as this symbol. ⏚ ıe resistance between the ground terminal and ground shall be less than 0.1 ohms.

4.1.2 Booting Up PSU and Detector

1 Turn on the power switch at the front side of PSU.
2 Check if the power switch of PSU lights up green n.
3 Check if the power LED of the detector lights up in light green.
4 Check if the stauts LED of the detector lights up in light green.

- When the power switch of PSU lights up green, it means that the power is approved normally.
- The detector starts booting up when you turn on the power of PSU.

- When the power LED of the detector lights up in light green, it means that the power is approved normally.
- When the status LED of the detector lights up in light green, it means that the detector boots up normally.
- If the power LED of the detector does not light up, check if the DC power cable is connected to port 5 of PSU correctly.

4.1.3 Checking Status LED of Detector

POWER LED

- The power LED indicates the information of power status which is approved to the detector in light green color.
- When the power is approved normally, POWER LED lights up.

ACTIVE LED

- The active LED indicates status information about the possibility that the detector can be used normally or not in light green.
- The active LED lights up when the detector is completed to boot up normally.

DATA LED

- The data LED indicates status information about the data processing in light green.
- The data LED lights up when the detector sends data.

Summary List of Detector Status LED

Information	POWER LED	ACTIVE LED	DATA LED
Color	Light Green	Light Green	Light Green
Power permitted	ON	ON	OFF
Boot-up completed	ON	ON	OFF
Image acquisition	ON	ON	Blinking
Power off	OFF	OFF	OFF

- Once the detector power is on, red and green colors of STATUS LED are turned on for a second at the same time. The STATUS LED is changed to a green color when the detector booting is finished.

- If the STATUS LED blinks abnormally, refer to <6 Troubleshooting> to check if communication or system error is occurred.

4.2 Device Setting

4.2.1 Software Installation

1 After connecting all devices, prepare the following softwares to set, calibrate and operate the detector / PSU.

Software	Description
VIVIX Device Driver (VDD)	Image filter driver for acquiring images from a detector.
VIVIX Setup	A program for setting and managing the detector / PSU.

2 Install **VIVIX Device Driver** and **VIVIX Setup** in sequence.

- It is not necessary to install **VIVIX Device Driver** and **VIVIX Setup** separately in case of installing the **VXvue** program made by Vieworks.

3 Configure environment for the workstation.

4.2.2 Setting Detector and PSU

1 After executing **VIVIX Setup**, access to the detector and PSU to set each device properly.
2 Perform detector calibration to acquire images suitable for the installation environment.
3 Take radiographic images to check if the shooting is conducted normally.

- Refer to **VIVIX Setup Operation Manual** for the detailed information about the device settings.

4.3 Diagnosis of Devices

Execute the **VIVIX Setup** program to check if threre is any problem to operate the detector / SCU after installing and setting devices.

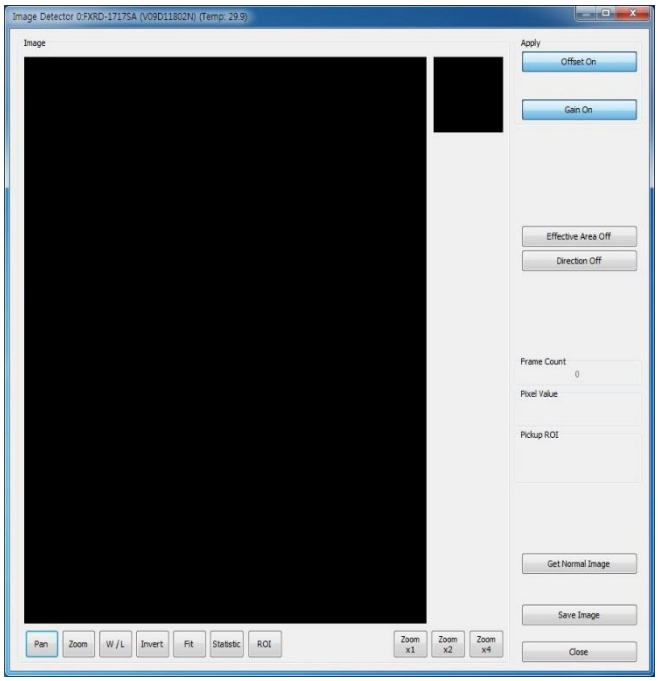
Diagnosis Items

Items	Description
Image	Diagnoses the acquired images.

- Set the devices and perform calibration again if any problem is found during the diagnosis. Contact the person in charge of service if the problem is not corrected.

4.3.1 Image Diagnosis

1 Execute **VIVIX Setup** and move to the **Image** dialog.
2 Take an image and check if it has any problem.
3 Take a dark image and check if it has any problem.
4 Check the effective area and whole area of the image.



- Refer to **VIVIX Setup Operation Manual** for the detailed information about the image diagnosis.

- If any problem is found on the image, check if it is caused by the surrounding environment and calibrate the detector again. Contact the person in charge of Vieworks if the problem is caused by the performance of a detector.

5. Inspection & Maintenance

This section gives information about inspection and maintenance of the product.

Product Inspection

Cleaning and Disinfection

Replacing the Fuse of PSU

5.1 Product Inspection

- To use products correctly and safely, make sure to check the products before use. If the problems occur during inspection or the product cannot be repaired, consult the sales representative in Vieworks or a relevant engineer.

5.1.1 Daily Inspection

Before or after using the detector and other surrounding equipment, check the items below daily.

Item	Description
Detector	• Ensure that there are no loose screws or breaks.
Cable	• Ensure that cables are not damaged and cable jackets are not torn. • Ensure that the power cord plugs are securely connected to both AC inlet and AC outlet of the equipment.

5.1.2 Performance Inspection

Check the detector and other devices periodically as follows.

Item	Period	Description
Resolution	Half-yearly	• Check the resolution of the detector through resolution chart or using a phantom.
Sensitivity	Half-yearly	• Evaluate the characteristic of the detector through checking gray value of the images made by X-ray dose amount reaching to the surface of the detector.
Calibration	Half-yearly	• Updating the calibration data by proceeding calibration in the order of Offset → Gain → Defect. • Proceed to calibrate when X-ray Generator, Tube, Collimator or exposure environment are changed.

- The resolution inspection can be conducted by a user or a service engineer.
- Sensitivity and calibration should be conducted by an authorized service engineer who Vieworks grants.

5.2 Cleaning and Disinfection

After using the detector and peripheral equipments for examination, use germicidal disinfecting wipes or cloth with mild diluted disinfectant detergent to clean surfaces of the product.

- In case the surface or narrow space of equipment is contaminated by contact with blood or other body fluids of a patient, make sure to clean and disinfect it to protect the patients and users from infection.

5.2.1 Recommended Detergent Foam

Recommended disinfectant wipe

- Super Sani-cloth Plus Wipes by PDI
- Sani-cloth Active Wipes multi Surface (Alchol Free/Sans alcool) by PDI
- Sani-cloth CHG 2% by PDI
- Cavi Wipes by Kerr Total Care
- Sporicidal Wipes by Clinell
- Universal Wipes by Clinell

Recommended disinfectant product

- Sulfa'safe by Anios
- Storage temperature: 5°C ~ 35°C

- Other Disinfectant detergent compliant to conditions listed below may be used following proper procedures according to its own manual.
  - European Biocidal Products designed for surface disinfection (Directive 98/8/EC)
  - Detergent with composition of Didecyldimethylammonium chloride, polyhexamethylene biguamide hydrochloride.

5.2.2 How to Use Detergent Foam

1 Prepare the disinfectant detergent and a clean and dry non-woven cloth.
2 Use the spray bottle to spray detergent to the cloth and clean the equipment.
3 Clean residue on the equipment with its power off.
4 Conduct cleaning once a week or in case of contamination.

- Do not re-use wipes.
- Be careful to use disinfectant detergent which can cause irritation to eyes and skin.
- Use in well-ventilated areas, and wear gloves at all times.
- Do not clean the equipment with its power on.
- Do not use abrasive brush and scraper to clean the product.
- Be careful not to make liquid soak when cleaning the connector on the side of products.

5.3 Replacing the Fuse of PSU

There are 2 fuses are attached on PSU for the purpose of electrical accident precaution, in case of over current from external power input. Stop using PSU immediately when the fuse is blown.

Fuse Information

Item	Specifications
Model	Littelfuse® 218002 (2ea)
Type	Time Lag Cartridge Fuse
Amp Rating	2A
Voltage Rating	250V

- Pull the plug out and turn all the devices off before changing the fuse.
- First, resolve the cause why the fuse is blown. Replace the fuse to the one provided as an option (1 set / 2 ea) or to the one with same specifications when the fuse is out.
- Be careful not to touch both the patient and the fuse holder at the same time or let the patient touch the fuse holder.

How to Replace the Fuse

No.		Description
1		Separate the fuse from the holder located power input port on the back side of PSU by pulling the fuse holder.
2		After checking, replace the fuse with correct specifications in case of need.
3	-	Insert the fuse holder again.

6. Troubleshooting

6.1 Troubleshooting

6.1.1 Troubleshooting Guide

When you encounter problems while using the equipment, search for the table below for the problem or error messages and try the solutions. If the problem persists, turn off the detector and consult your sales representative or a distributor. Please refer to the details of the following symptoms or error messages.

- Troubleshooting must be performed by service engineer who is authorized by Vieworks. If an unqualified person performs troubleshooting on the system resulting in damaging the detector, software or hardware, then the Vieworks or its representative is not responsible for the detector repair regardless of remain warranty. For more detailed information, refer to <8.1 Service Information> and <8.2 Warranty>.

6.1.1 Failure to Turn the Detector On

Category	Description
Symptom	• Failed to turn the power of the detector.
Expected Causes	• Poor power supply to PSU. • Faulty connection of the DC power cable. • The DC power cable is damaged.
Solutions	1 Check if the power is supplied to PSU properly. If not, replace PSU to another one. 2 Check if the DC power cable is connected corretly. If not, connect it in a right way. 3 Check if a DC power cable or ethercon cable is damaged. Replace the damaged cable to a new one. 4 Replace the detector to another one and check the result.

6.1.2 The Power Switch of PSU is not Working

Category	Description
Symptom	• The power switch of PSU is not working even though it is turned on.
Expected Causes	• The AC power cable is broken down. • Trouble in the fuse • The internal circuit is broken down.
Solutions	1 Check the connection between AC power cable and PSU. 2 Turn off the power switch and turn it on again. Check if the fan of PSU is working properly. 3 Replace the fuse of PSU. (Refer to <5.3 Replacing the Fuse of PSU>.) 4 Replace PSU to another one and check the result.

6.1.3 Communication Test is Failed

Category	Description
Symptom	• Errors in transmission. Communication test is failed.
Expected Causes	• Network connection problem • Network setting problm • PC environment setting probelm • Equipment failure
Solutions	1 Check the connection of network cable between Workstation and PSU. 2 Check if the accurate network cable is used or not. (CAT 5E or 6) 3 Use the recommended network card. 4 Set the network information of Workstation and detector again. 5 Set the whole workstation environment again such as firewall setting and release the power save mode. 6 Replace a detector to another and check the result.

6.1.4 Errors in Detector LED

Category	Description
Symptom	• All LEDs of a detector are blinking. • Two LED lamps of a detector are blinking and the remaining one is blinking slowly. • Other errors occur excepting the two cases above.
Expected Causes	• Internal hardware errors of a detector. • Registration error of the detector • Data transmission error
Solutions	1 Reboot the detector and check the result. 2 Replace the detector to another one.

7. Regulatory Information

This section gives explanation about regulatory related information including labels and symbols.

Medical Equipment Safety Standards

Labels and Symbols

Guidance and Manufacturer Declaration for EMC

7.1 Medical Equipment Safety Standards

7.1.1 Medical Equipment Classification

Item	Description
Type of protection against electrical shock	Class I
Degree of protection against electrical shock	Type B applied parts
Degree of protection against ingress of water	IPX0
Operation mode	Continuous operation
Flammable anesthetics	NOT suitable for use in the presence of flammable anesthetic mixture with air / oxygen / nitrous oxide.

7.1.2 Product Safety Standard

South Korea

전기, 기계적 안전성에 관한 시험: IEC 60601-1과 식품의약품안전청고시 제 2009-137호에 따른다.
전자파장해방지에 관한 시험: IEC 60601-1-2에 따른다.

전자파 간섭 (EMI)	
전자파 전도	식품의약품안전청 고시 2009-54호 1종 A급 기기로서 별표 1의 5.1 식품의약품안전청 고시 2009-54호 별표 1의 전자파장해 (간섭)
전자파 방사	식품의약품안전청 고시 2009-54호 1종 A급 기기로서 별표 1의 5.2 식품의약품안전청 고시 2009-54호 별표 1의 전자파장해(간섭)

전자파 내성 (EMS)	
정전기방전(ESD) 시험	식품의약품안전청 고시 2009-54호 별표 2의 36.202/36.202.2/KN61000-4-2
방사성 RF 전자기장 시험	식품의약품안전청 고시 2009-54호 별표 2의 36.202/36.202.3/KN61000-4-3
전기적 빠른 과도현상 (EFT) 시험	식품의약품안전청 고시 2009-54호 별표 2의 36.202/36.202.4/KN61000-4-4
서지(Surge) 시험	식품의약품안전청 고시 2009-54호 별표 2의 36.202 및 36.202.5/KN61000-4-5
전도성 RF 전자기장 시험	식품의약품안전청 고시 2009-54호 별표 2의 36.202/36.202.6/ KN61000-4-6
전원주파수자기장 시험	식품의약품안전청 고시 2009-54호 별표 2의 36.202/36.202.8/ KN61000-4-8
전원공급 입력선의 전압 강하, 순간정전 및 전압변동 시험	식품의약품안전청 고시 2009-54호 별표 2의 36.202/36.202.7/KN61000-4-11
전원주파수 변동	IEC 60601-1(1995) 10.2.2 power supply 및 식품의약품안전청 고시 2009-54호 별표2의 36.202.14

USA / Canada

Item	
IEC 60601-1(ed.2 am1+ am2+ co1)	Medical electrical equipment- Part 1: General requirements for safety
IEC 60601-1:2005(ed.3)+co1+co2	Medical electrical equipment- Part 1: General requirements for safety
UL 60601-1(ed.1)	-
CSA-C22.2 No. 601-1-M90 (R2006)	Medical electrical equipment –Part 1: General requirements for safety (adopted amendment 2:1995 to IEC 601-1:1990)
IEC 60601-1-2: 2007(ed.3)	Medical electrical equipment-Part 1-2: Collateral standard: Electromagnetic compatibility
IEC 60601-1-4: 2000(ed.1.1)	Medical electrical equipment- Part 1-4: Collateral Standard: Programmable electrical medical systems
IEC 62304:2006-Ed.1.0	Medical device software-software life cycle processes
ISO 14971:2012	Medical device – Application of risk management to medical devices

European Union

Item	
MDD (Medical Device Directive)	(93/42/EEC as amended by 2007/47/EC) Medical Device Directive
EN ISO 13485:2012	Medical devices – Quality Management systems – Requirements for regulatory purposes
EN 60601-1: 2006	Medical electrical equipment - Part 1: General requirements for safety
IEC 60601-1: 2005(ed.3)+CO1+CO2	Medical electrical equipment- Part1: General requirements for safety
IEC 60601-1-2: 2007(ed.3)	Medical electrical equipment -Part 1-2: Collateral standard: Electromagnetic compatibility-Requirements and tests
IEC 60601-1-4: 2000(ed.1.1)	Medical electrical equipment - Part 1-4: Collateral Standard: Programmable electrical medical systems
IEC 62304:2006	Medical device software-Software life cycle processes
ISO 14971: 2012	Medical device – Application of risk management to medical devices

7.2 Labels and Symbols

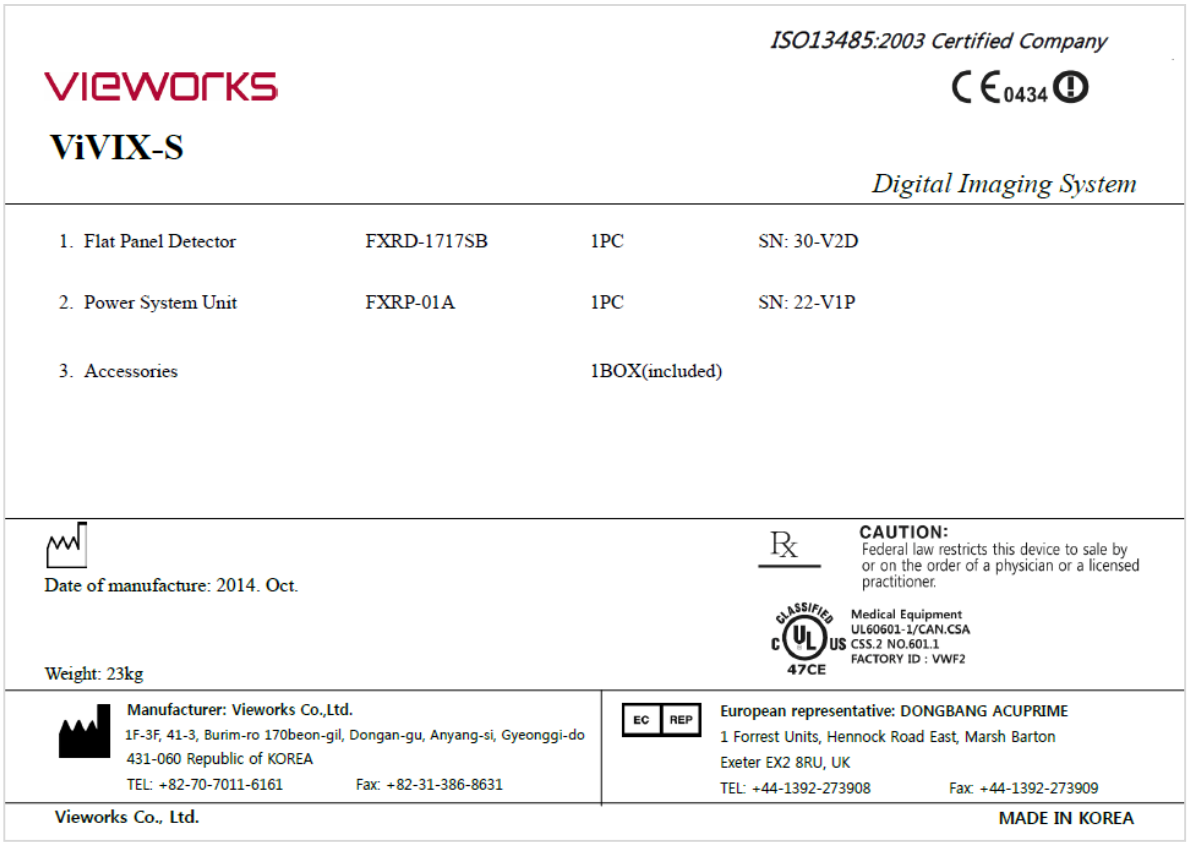
The **ViVIX-S 1717S** wired detector and other components have labels and markings on them. Their contents and locations are indicated below.

7.2.1 Label

Detector

PSU (Power Supply Unit)

Outer Box (Example)



7.2.2 Product Serial Number

Serial Number Composition

The serial number of each product and components are composed as follows.

V	1	D	A	B	J	0	0	1
Revision		Composition		Year	Month		Serial number	

- Revision will be updated as the following cases.
  - Mass production or big order.
  - Exterior alterations of the product
- Item code will be produced based on internal management standard of vieworks.
- Composition code is as follows.
  - **D**: Detector
  - **P**: PSU
- Range of Serial Number is 001 ~ 999.

Initials per Year

11	12	13	14	15	16	17	18	19	20
AA	AB	AC	AD	AE	AF	AG	AH	AI	BJ

Initial per Month

1	2	3	4	5	6	7	8	9	10	11	12
A	B	C	D	E	F	U	V	W	X	Y	Z

Composition of Serial Number for Each Product (Example)

Model	Composition	Serial Number
FXRD-1717SA	Detector	V1DAEA001
FXRD-1717SB	Detector	V2DAEA001
FXRS-01B	PSU	V1PAEA001

7.2.3 Product Symbols

Symbol	Description
	Direct current
	Alternating current
	Protective earth (Ground)
	Equipotentiality
	Power on
	Power on for part of the equipment
	Power off
	Power off for part of the equipment
	Attention, consult accompanying documents
	General warning sign
	Warning sign for electricity
	This Mark shows compliance with both Canadian and U.S. safety requirements. With Respect to electric shock, fire, and mechanical hazards only. In accordance with UL60601-1 and CAN/CSA C22.2 No. 601.1.
	This mark shows compliance of the essential requirement and other relevant provisions of Directive 93/42/EEC as amended by 2007/47/EC.
	Non-ionizing radiation
	Read and understand all instructions and warning labels in the product documentation before using the equipment. Keep manual for future reference.
	Dealing with a medicine that can only be given by a prescription from a doctor and you should use a certain medication that a doctor recommended.
	General mandatory action sign
	This mark indicates that this equipment must be handled with care.
	Do not jolt or apply excessive load to the equipment.
	This is a Type B Applied Part according to UL 60601-1 and EN 60601-1.
	This mark indicates that the equipment must be collected separately under the Directive on Waste Electrical and Electronic Equipment 2002/96/EC (WEEE) in the European Union. (For European Union)

7.3 Guidance and Manufacturer's Declaration for EMC

- This device has been tested for EMI/EMC compliance, but interference can still occur in an electromagnetically noisy location. Attempt to maintain a suitable distance between electrical devices to prevent malfunction.

7.3.1 Electromagnetic Emissions

Equipment Under Test (EUT) is intended for use under the electromagnetic environment specified below. The customer or user of the EUT should assure that it is used in such an environment.

Immunity Test	Compliance	Electromagnetic Environment
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 all establishments other than domestic 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	

7.3.2 Electromagnetic Immunity

The **ViVIX-S 1717S** wired system is intended for using in the electromagnetic environment specified below. The user of this system should assure that it is used in the following environment.

Electrostatic Discharge (ESD) IEC 61000-4-2

Item	Description
Immunity test	• Electrostatic discharge (ESD) IEC 61000-4-2
IEC 60601 test condition	• Contact ±6kV • Air ±8kV
Compliance Level	• Contact ±6kV • Air ±8kV
Electromagnetic Environment - Guidance	• 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

Item	Description
Immunity test	• Electrical fast transient/Burst IEC 61000-4-4
IEC 60601 test condition	• Power supply lines ±2kV • Input/Output lines ±1kV
Compliance level	• Power supply lines ±2kV • Input/Output lines ±1kV
Electromagnetic Environment (Guidance)	• Main power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5

Item	Description
Immunity test	• Surge IEC 61000-4-5
IEC 60601 test condition	• Differential mode ±1kV • Common mode ±2kV
Compliance Level	• Differential mode ±1kV • Common mode ±2kV
Electromagnetic Environment - Guidance	• Main 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

Item	Description
Immunity test	• Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11.
IEC 60601 test condition	• <5% UT (>95% dip in UT) for 0.5 cycle • 40% UT (60% dip in UT) for 5 cycles. • 70% UT (30% dip in UT) for 25 cycles. • <5% UT (<95% dip in UT) for 5 sec.
Compliance Level	• <5% UT (>95% dip in UT) for 0.5 cycle • 40% UT (60% dip in UT) for 5 cycles. • 70% UT (30% dip in UT) for 25 cycles. • <5% UT (<95% dip in UT) for 5 sec.
Electromagnetic Environment - Guidance	• Main 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.

• UT is AC power prior to the application of the test level voltage.

Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8

Item	Description
Immunity test	• Power frequency (50/60 Hz) magnetic field IEC 61000-4-8
IEC 60601 test condition	• 3 A/m
Compliance Level	• 3 A/m
Electromagnetic Environment - Guidance	• Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Conducted RF IEC 61000-4-6 / Radiated RF IEC 61000-4-3

Item	Description	
Immunity test	• Conducted RF IEC 61000-4-6	• Radiated RF IEC 61000-4-3
IEC 60601 test condition	• 3 Vrms 150 kHz to 80 MHz	• 3 V/m 80 MHz to 2.5 GHz
Compliance Level	• 3 Vrms 150 kHz to 80 MHz	• 3 V/m 80 MHz to 2.5 GHz
Electromagnetic Environment - Guidance	• Portable and mobile RF communications equipment should be used no closer to any part of the EUT, including cables, than the recommended separation distance calculated from the below equations applicable to the frequency of the transmitter. $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{3.5}{V_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz • 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  .	

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- 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 EUT is used exceeds the applicable RF compliance level above, EUT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating EUT.
- Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

8. Information

This section gives overview information for service and warranty of the product.

Service Information

Warranty

Revision History

8.1 Service Information

8.1.1 Product Liftime

The estimated product lifetime is up to seven (7) years under the appropriate regular inspection and maintenance.

8.1.2 Regular Inspection and Maintenance

In order to ensure the safety of patients, operating personnel and third parties, and to maintain the performance and reliability of the equipment, be sure to perform regular inspection at least once a year. If necessary, clean up the equipment, make adjustments, or replace consumables.
There may be cases where overhaul is recommended depending on the conditions. Contact your sales representative or distributor for regular inspections or maintenance.

8.1.3 Repair

If a problem cannot be solved even after taking the measures indicated in Troubleshooting and contact your sales representative or a distributor for repairs. Please refer to the name label and provide the following information.

- Priduct name: **ViVIX-S 1717S** Wired Detector
- Serial number: 12 digit-number on the product label
- Explanation of problem: Describe it as detailed as possible.

8.1.4 Replacement Support

Performance parts (parts required to maintain the functioning of the product) of this product will be stocked for seven years after discontinuance of production, to allow for repair.

8.2 Warranty

Vieworks warrants that this product will be free from defects in materials and workmanship for a period of 24 months from the date of delivery. If any such product proves defective during this warranty period, Vieworks 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 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 with shipping charges prepaid.

Vieworks shall pay for the return of the product to customer if the shipment is to a location within the country in which Vieworks 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 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 WITH RESPECT TO THIS PRODUCT IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED. VIEWORKS AND ITS VENDOR DISCLAIM ANY IMPLIED WARRANTIES OF MERCHANTABLILITY OR FITNESS FOR A PARTICULAR PURPOSE. VIEWORKS 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 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.

8.3 Revision History

Version	Date	Description
2.0	2013-03-06	• (Added) Initial release
2.1	2013-04-05	• (Changed) 2.4 Product Components
	2013-04-16	• (Changed) 7.1 Detector Specifications and Use Environments
	2013-04-26	• (Changed) 3.2.1 PSU/SCU Components
	2013-06-03	• (Changed) 8.2 Labels and Symbols
	2013-06-12	• (Changed) 3.2.1 PSU/SCU Components • (Changed) 7.2 PSU/SCU Specifications and Use Environments
2.2	2013-08-29	• (Changed) Overall technical information and certification • (Changed) Some titles of each section/chapter • (Changed) Document form
2.3	2013-11-08	• (Changed) Image of the generator interface cable • (Changed) Product lables • (Changed) Product safety standards • (Changed) Warranty
3.0	2014-03-11	• (Added) 4.5.1 VXvue User • (Added) 4.5.2 SDK User • (Modified) 1.3 Product Instruction • (Modified) 2.4 Product Usage Guide • (Modified) 7. Specifications • (Deleted) 4.5.1 VXvue Installation • (Deleted) 4.5.3 Wi Allowing VXvue to communicate through Windows Firewall on Windows 7
3.1	2014-03-25	• (Changed) 6.3 Maintenance • (Changed) 7. Specifications
4.0	2014-07-23	• Overall Revised • (Added) 1. Instruction • (Changed) 2.6 Product Specifications • (Changed) 3. Settings • (Changed) 4. Calibration • (Changed) 5. Calibration • (Added) 5.5 Direct Calibration • (Added) 6. Diagnosis, Inspection, and Maintenance • (Added) 7. Troubleshooting • (Changed) 8. Regulatory Information
4.1	2014-08-22	• Applied the new corporate logo • (Added) 2.6.1 Detector • (Added) 3.1.3 Checking Satus LED of Detector
4.2	2014-10-30	• (Changed) Contact address and fax number

		• (Changed) 5.5 Direct Calibration • (Changed) 6.2.2 Performance Inspection • (Changed) 8.2.1 Label
4.3	2014-12-16	• (Changed) Contact address • (Changed) 8.2.1 Label
5.1	2015-09-25	• (Revised) Separated the guidance of VIVIX Setup from this manual. • (Changed) 4 Settings • (Changed) 5 Inspection and Maintenance • (Changed) 7.1 Medical Equipment Safety Standards • (Changed) 8.1.1 Product Life
5.3	2016-01-29	• (Added) 5.2 Cleaning and Disinfection

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