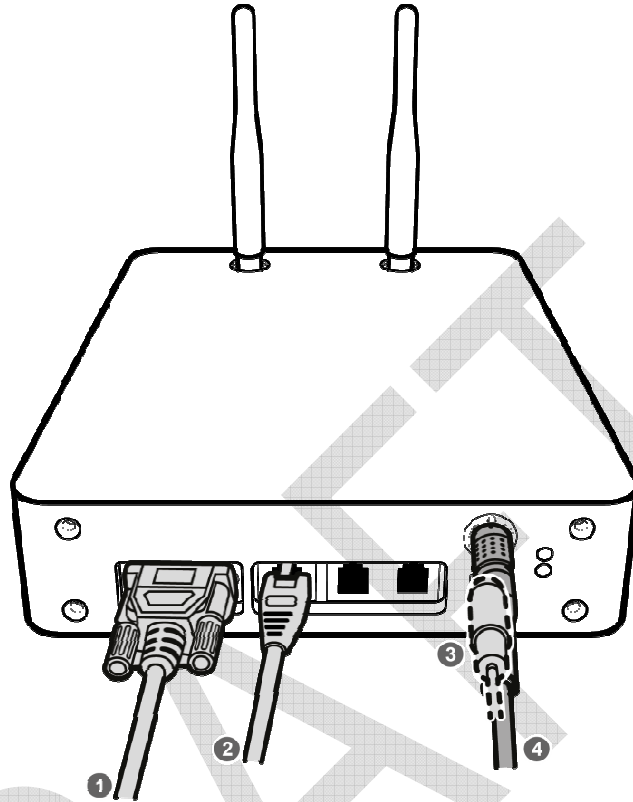


Mini SCU  [TBD]



- 1 If you use the **DR Trigger** mode, connect the one end of generator interface cable to the **EXT_INF** port of SCU, and the other to the X-ray generator.



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

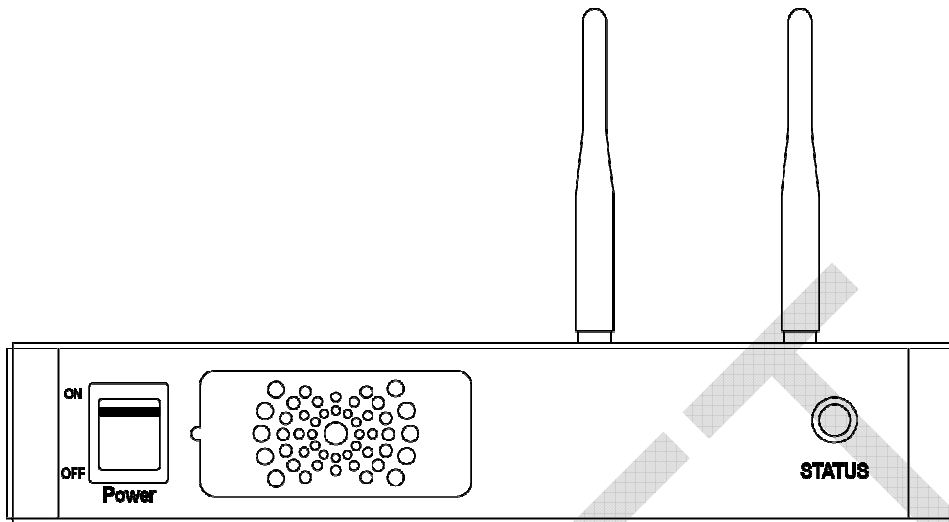
- 2 Connect one end of the LAN cable to one of the LAN ports of SCU, and the other to the LAN Card Connector of workstation assigned for data transfer.
- 3 To transmit image data using a Tether Interface, connect the one end of the tether interface cable to the port of Mini SCU and the other to the detector.



- If you use the wireless communication method, a tether interface cable is not needed as the image is transmitted wirelessly.

- 4 To supply power, connect the DC power cable to the DC power input port of SCU.

4.2.2 Booting up SCU



- 1 Turn on the power switch at the front side of SCU.
- 2 Check if the power switch of SCU lights up green.
- 3 Check if the status indicator is blinking in green after the power switch of SCU is permitted.
- 4 Check if the status indicator of SCU is blinking in green and turns to light up in the same color.
- 5 Check if the status indicator of SCU is blinking in green and turns to light up in blue.



- When the power switch lights up green, it means that the power is applied normally.
- When the status indicator is blinking in green, the SCU is booting.
- If the status indicator lights up green, it indicates that the SCU is being operated normally after booting up.
- If the status indicator lights up blue, SCU's preparation for communication is completed.

4.2.3 Booting up the Detector



- The procedures in this chapter are explained according to the default setting status of a detector (factory reset) and the use of wireless connection.
- Refer to <Product Initialization 오류! 참조 원본을 찾을 수 없습니다.> for the detailed information about the default setting status of a detector.

- 1 Attach a charged battery pack to the detector.
- 2 Press the power button of the detector for 1 second until the power LED is turned on.
- 3 When the power LED is on, check if it is lit green.
- 4 Check if the active LED is lit orange on the detector.



- If the power LED lights up green, the DC power is permitted normally.
- If the active LED lights up orange, the detector is completed to boot up normally.



4.2.4 Checking Status LED of Detector [TBD]

Power LED

- The power LED indicates the power status information which is permitted to the detector in green.
- The power LED lights up when the power is permitted normally.
- If the detector is connected with a tether interface, the power LED lights up when power is permitted to SCU because the detector is supplied power from SCU.
- The power LED is blinking when the detector is in the **sleep** mode.




Active LED

- The active LED indicates status information about the possibility that the detector can be used normally or not in orange.
- The active LED is blinking when the detector is completed to boot up normally.
- If the detector AP is on, the LED blinks for 5 times right after the booting.

Data LED

- The data LED indicates status information about the data processing in blue.
- The data LED lights up when the detector is available to make data communication.
- If the detector is in the **sleep** mode, the data LED lights up.
- The data LED is blinking while the detector transmits or saves data.
- If the detector **AP** is **on**, the LED blinks for 5 times right after the booting.

Summary List of Detector Status LED

Information	Power lamp	Active lamp	Data lamp
Color	Green 	Orange 	Blue 
When power is permitted	On	Off	Off
Boot-up completed (AP ON)	On	Blinking 5 times	Blinking 5 times
Boot-up completed (AP OFF)	On	On	Off
Ready for communication	On	On	On
Sleep mode	Blinking	On	On
Data communication (Send or Store)	On	On	Blinking
In process of wireless initialization	On	Blinking	Off
Power Off	Off	Off	Off



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

4.3 Software Installation

This section gives information about how to install the software on the workstation (PC) and how to configure the environment for software operation and communication.



- Check suitability of acquiring, processing and adjusting of images by referring to the recommended workstation specifications before the software installation.

4.3.1 Software Classification [TBD]

Vieworks provides clients who purchase our detector system with software as below. You can choose and use one of our softwares below.

Software	Description
VXvue	<ul style="list-style-type: none"> • A program for acquiring and adjusting images developed by Vieworks. <ul style="list-style-type: none"> ▫ Used for ViVIX-S detectors only. • Unnecessary to develop a separate viewer program.
VIVIX Setup	<ul style="list-style-type: none"> • A program for setting and managing the detector and SCU.
VXvue (Viewer)	<ul style="list-style-type: none"> • Software for acquiring, adjusting and managing the image.
XIPL	<ul style="list-style-type: none"> • Image processing program
Document	<ul style="list-style-type: none"> • VXvue Operation Manual • XIPL User Manual
VIVIX SDK	<ul style="list-style-type: none"> • Software development kit for ViVIX-S detector only, provided by Vieworks. • You can develop your own software dedicated to ViVIX-S by using this kit.
SDK Package	<ul style="list-style-type: none"> • Development package
VIVIX Setup	<ul style="list-style-type: none"> • A program for acquiring, adjusting and managing the image.
Document	<ul style="list-style-type: none"> • VIVIX SDK Developer Manual

4.3.2 Software Installation

- For a client who uses **VXvue**, install the **VXvue** program after reading **VXvue Operation Manual** carefully.
- For a client who uses **VIVIX SDK**, install the **Setup** program after reading **VIVIX SDK Developer Manual**.



- Be sure to install the software first with reading this manual before configuring Windows environment.



- Apart from the detector and SCU, the software can be installed separately.

4.4 Windows Environment Setting

This section gives information about configuring Windows to communicate with the detector and SCU after installing the **Setup** program or Viewer.



- The contents in this chapter are made on the basis of **Windows 7**.
- Configuration environment can be different depending on network adaptor manufacturer or models.

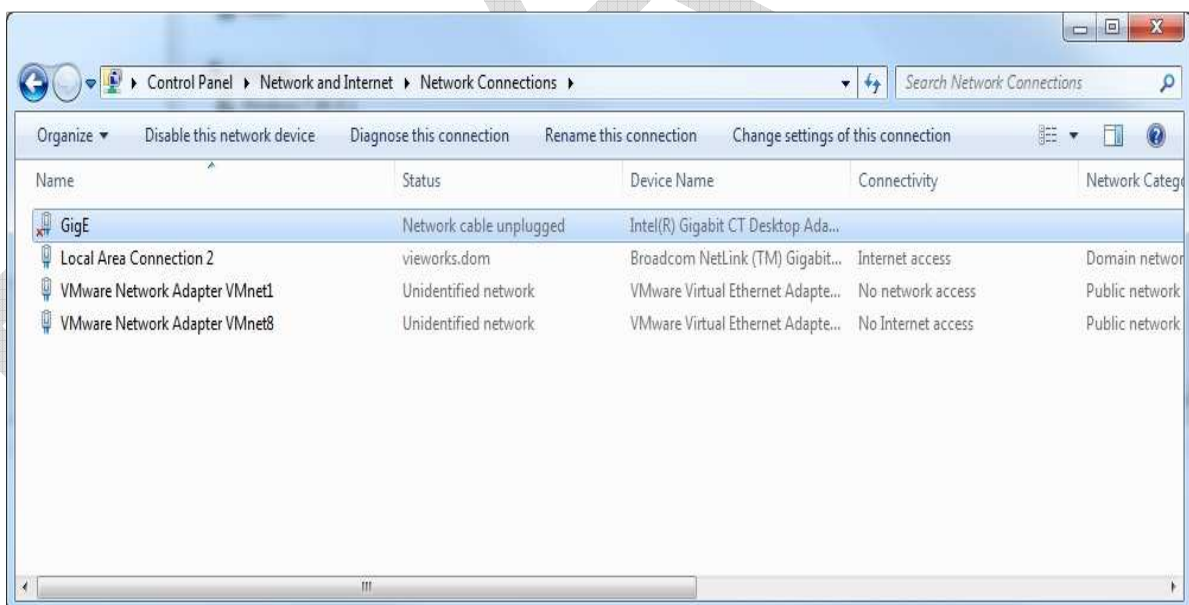
4.4.1 Network Configuration [TBD]



- Communication disruption between the detector (Or SCU) and workstation occurs unless the network adaptor is proper is set properly, it may cause serious repercussion to the product and image quality.

Selecting Network Adaptor

- 1 Click **Start** → **Control Panel** → **Network and Internet** → **Network and Sharing Center** → **Change Adapter Setting**.
- 2 Choose the networks adaptor for communicating with the detector and SCU, and then rename it.

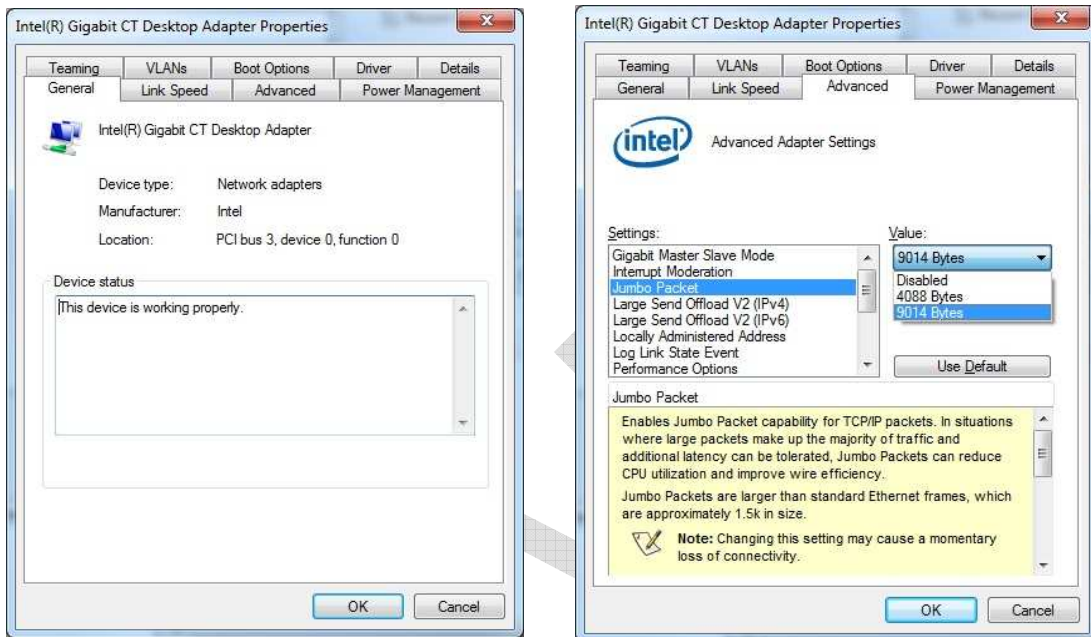


- It is recommended to change the name of network adaptor to distinguish it from other connection names.
- Even though the name is changed, it will not affect to the operation and communication performance of the equipment.

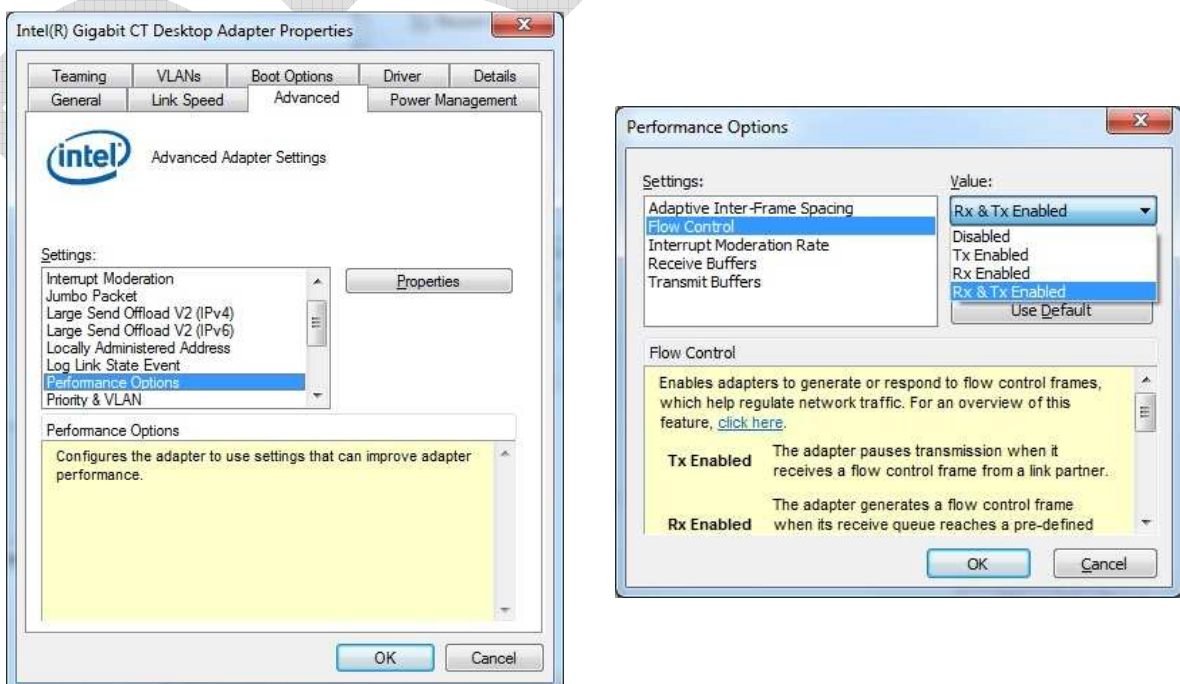
- Click the chosen network adaptor with the right mouse button and click **Properties** to display the **Properties** window.

Setting Network Adaptor

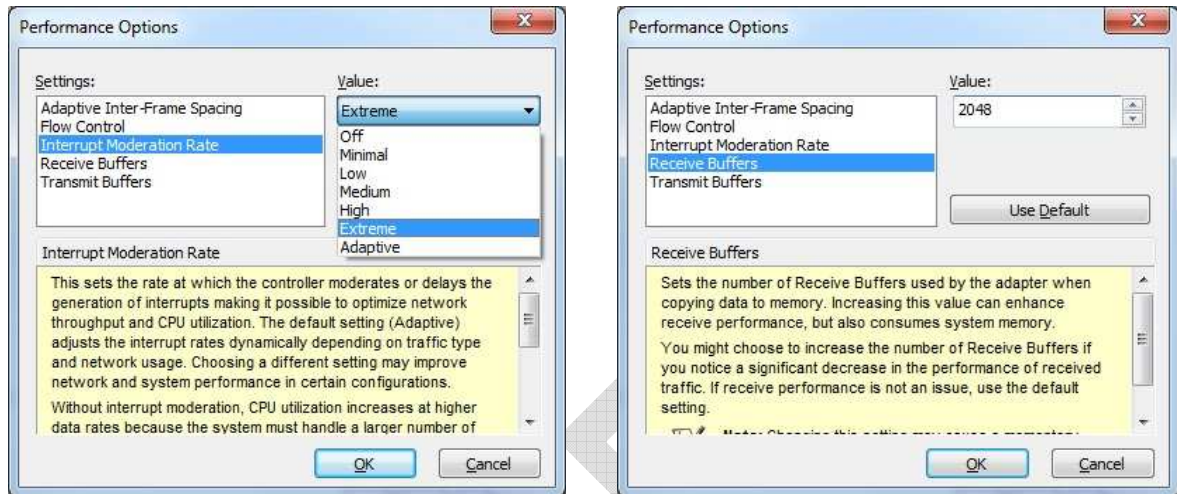
- Click **Configure** button to open the following dialog box, and then go to the **Advanced** tab.
- Set **Jumbo Packet** to the maximum value. (Recommended value: 9014 Bytes)



- Choose **Performance Options** in the list of **Settings** and click **Properties** button on the right.
- Choose **Flow Control** in the list of **Settings** and select **Rx & Tx Enabled** on the **Value** list as shown below.

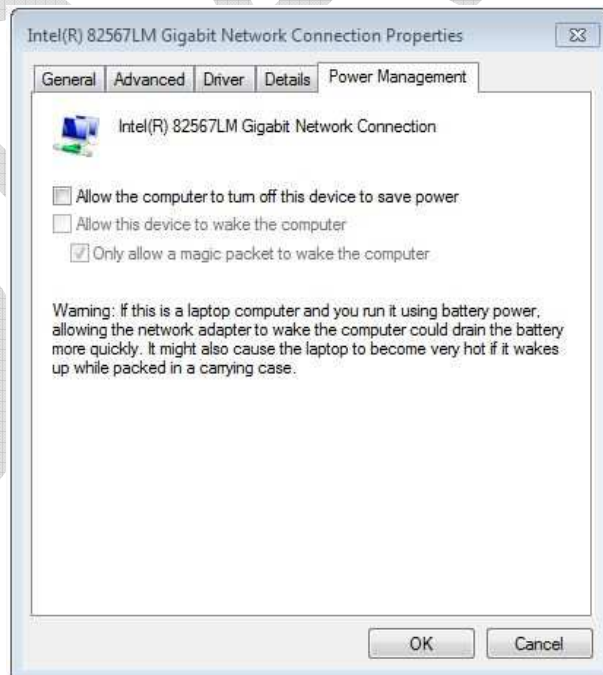


- 5 Choose **Interrupt Moderation Rate** in the list of **Settings** and select **Extreme** on the **Value** list as shown below.
- 6 Choose **Receive Buffers** and set it to the maximum value.
- 7 Click **OK** button.



Deactivate Power-Saving Mode on Network Adaptor

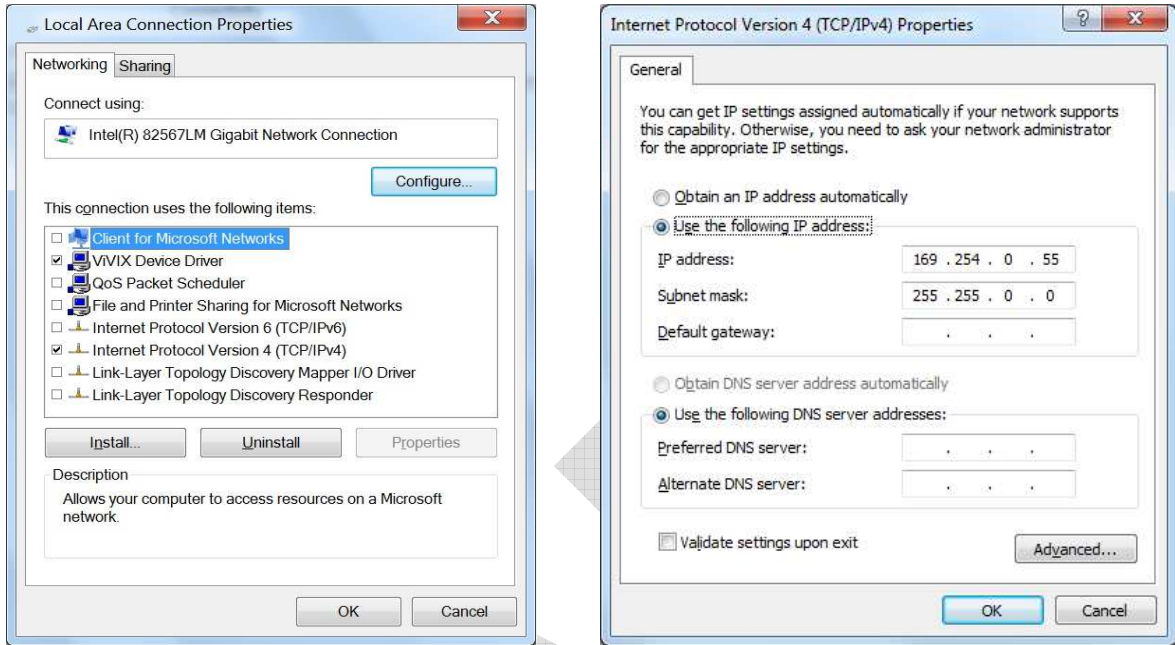
- 1 Click the **Power Management** tab and uncheck **Allow the computer to turn off this device to save power**.
- 2 Click **OK** button.



- Viewer may not work normally if the power save mode is activated.
- Deactivate the power save mode of all the installed network adaptors.

Protocol Selection and IP Address Setting

- 1 Choose **Internet Protocol Version 4 (TCP/IPv4)** and click **Properties** button.
- 2 Input the IP address and subnet mask as shown below, and then click **OK** button.



- **ViVIX Device Driver** is the image filter driver for acquiring images from a detector.
- It is recommended to uncheck the other items on the list except for **ViVIX Device Driver** and **Internet Protocol Version 4(TCP/IPv4)**, since they are not related with the detector communication.

Summary of Network Configuration

Item	Value
Jumbo Packet	Maximum or 9014 Bytes
Flow Control	Rx & Tx Enabled
Interrupt Moderation Rate	Extreme
Receive Buffers	Maximum
Allow the computer to turn off this device to save power	Unchecked
IP Address	169.254.0.(50 ~ 254)
Subnet Mask	255.255.0.0

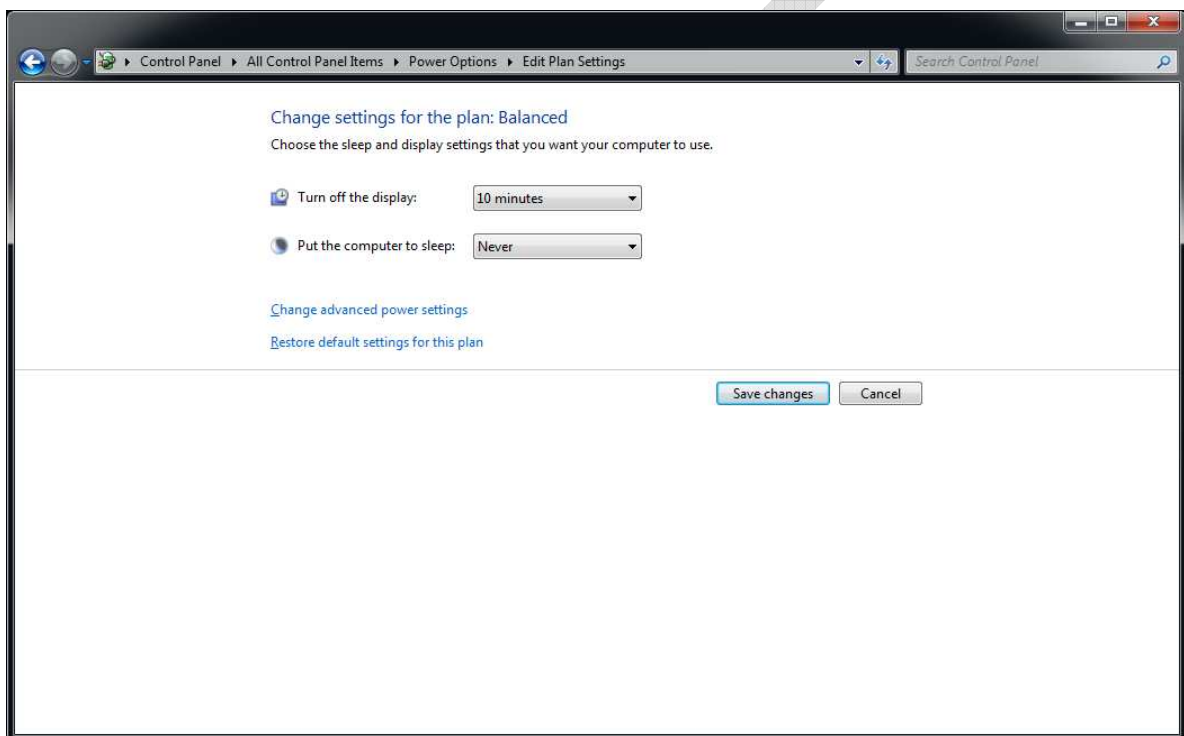
- It is recommended to set the IP address and subnet mask within the range presented in this document.
- If you use IP address and subnet mask out of the suggested range, it could be difficult to identify and resolve the cause of communication disorder.

4.4.2 Disabling Sleep Mode of Monitor



- If you use the sleep mode, viewer may not work normally.

- 1 Click **Start** → **Control Panel** → **Power Options** and then move to the **Choose when to turn off the display** tab.
- 2 Set **Put the computer to sleep** to **Never** to disable the sleep mode.
- 3 Click **Save changes** button.



5. Setting [TBD]

This section gives information about the product setting with using the Setup program.

Start Setting
VIVIX SCU Setting
Detector Setting

5.1 Start Setting

5.1.1 Setup Program

The **Setup** program provides functions for setting and managing the internal data to make **VIVIX-S 1012N** wireless detector and SCU work normally. In addition, The **Setup** program has diagnostic function for checking performance and abnormality of the devices as well as the image calibration function for improving the image quality.

5.1.2 Checking Devices

5.1.3 Getting into the Devices

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5.2 SCU Setting

DRAFT

5.3 Detector Setting

5.3.1 Detector Configuration

5.3.2 Detector Power Save Function

DRAFT

6. Calibration [TBD]

This chapter gives information about the calibration methods after installing a detector.

Calibration Dialogue
Detector Configuration
Calibration Guide
Calibrating by Loading the Calibration Data
Direct Calibration

6.1 Calibration Dialogue

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6.2 Detector Configuration

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6.3 Calibration Guide

The different installation environment of each detector and unique features of the X-ray generator device can affect the acquired images. Therefore, the certified engineer from Vieworks should do the detector calibration after installing it. Otherwise, the image quality can be affected seriously.

Vieworks provides two types of calibration for performing calibration.

- Performing calibration by loading the calibration data CD provided by Vieworks.
- The service engineer proceeds calibration and generate calibration data.



- We strongly recommend the service engineer to carry out the calibration by oneself as the detector condition and image quality can be different by the operation method or use environment.

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6.4 Calibrating by Loading the Calibration Data



- Vieworks provides the offset calibration data as a CD with the detector. However, we recommend the service engineer to carry out the calibration by oneself as the detector condition can be different by the operating method or use environment.

6.4.1 Preparing Calibration Data

- 1 Prepare the calibration data CD provided with the detector.
- 2 Copy the calibration data files and save them to a safe route such as local HDD.

- The calibration data CD is consisted of 4 data files as below.

File	Description
Pre-Offset	Detector Offset data 1
Post-Offset	Detector Offset data 2
Gain Offset	Image sensitivity Offset data
Defect Map	Defect calibration map data



- Each name of a data file is made with the combination of rules as follows.

□ [Serial number]_[Calibration data name].dat

	V3DABF019_Defect_Map-2012-08-27....	2012-08-27 ...	53KB	DAT
	V3DABF019_GainOffset-2012-08-27.dat	2012-08-27 ...	30,721KB	DAT
	V3DABF019_PostOffset-2012-08-27.dat	2012-08-27 ...	15,369KB	DAT
	V3DABF019_PreOffset-2012-08-27.dat	2012-08-27 ...	15,369KB	DAT

6.5 Direct Calibration

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7. Diagnosis, Inspection and Maintenance [TBD]

This section gives information about diagnosis, inspection & maintenance of the product.

Diagnosis

Product Inspection

Cleaning and Disinfection

Product Initialization

Replacing the Fuse of VIVIX SCU

7.1 Diagnosis

7.1.1 Image Diagnosis



- Check the image quality through Diagnosis tools after installing the detector or before usage. If the problems with regard to products or image occur during diagnosis, try to do a calibration again. If the problems are not solved, consult the sales representative in Vieworks or a service engineer.

You can acquire and review an image from the **Diagnosis** window in **Setup** program.

- You can review images by acquiring them through real exposure or getting Dark image by clicking **Get Normal Image** button.
- The number of images, pixel value and ROI value will be displayed.
- The effective area or whole area of an image can be checked.
- It is also available to check the image by changing its direction.
- Save the reviewed image as a raw one to analyze.
- You can acquire an image either applying Offset / Gain data or not.

7.1.2 Battery Pack Diagnosis



- Install the battery pack to the detector and check the voltage and remaining amount of the battery pack. Furthermore, always check the remaining amount of the battery pack during use of the detector. If performance of the battery pack has some problems, consult the sales representative in Vieworks or a relevant engineer.



- The battery pack belongs to consumables which performance will be decreased as time passed. Make sure to check the battery life during usage.

Check Voltage of Battery Pack

[TBD]

Check remaining amount of battery pack

7.1.3 Wireless Communication Diagnosis



- In case of using the detector with wireless communication way, make sure to check the status of wireless communication before starting to use. If the status of wireless communication is bad, the speed of acquiring images will be very slow or failed to acquire images. Try to check the surrounding wireless communication status not to occur communication interference. If wireless communication module in the detector has problems, consult the sales representative in Vieworks or a relevant engineer.

Check the Connection Status

User can check the connection status of wired or wireless detector through **VXvue** or **VIVIX SDK**.

Check the Strength of Wireless Communication Signal

The signal strength of wireless communication is provided as 5 stages or percentage (%), user can check it through **VXvue** (Vieworks Viewer) and **VIVIX SDK**.



- Since the signal strength of wireless communication at the 1st stage is not good, it is required to check the surrounding wireless communication status.

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7.2 Product Inspection



- To use products safely, make sure to check the products before use. If problems occur during inspection or the product is impossible to repair, consult the sales representative in Vieworks or a relevant engineer.

7.2.1 Daily Inspection

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

Item	Description
Detector	<ul style="list-style-type: none"> • Ensure that there are no loose screws or breaks. • Ensure that there is no dust or foreign matter on the battery bay connector. • Ensure that there are no breaks or short-circuits in the battery bay connector.
Cable	<ul style="list-style-type: none"> • 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.

7.2.2 Performance Inspection

Check the detector and other devices periodically as follows.

Item	Period	Description
Self-Diagnosis	Half-yearly	<ul style="list-style-type: none"> • Conduct Self-Diagnosis of the Setup program for the internal devices of the detector and check the status.
Resolution	Half-yearly	<ul style="list-style-type: none"> • Check the resolution of the detector through resolution chart or using a phantom.
Sensitivity	Half-yearly	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Updating calibration data. (Offset → Gain → Defect) • Proceed to calibrate when X-ray Generator, Tube, Collimator or exposure environment are changed.



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

7.3 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.

Recommended Detergent Foam

- Recommended disinfectant wipe
 - **Wip' anios** manufactured by **Anios**
 - **Sani-cloth Active Wipes** by **PDI**
- Recommended disinfectant product
 - **Sulfa'safe**
 - Storage temperature: **5°C ~ 35°C**

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 After it has been cleaned, leave the equipment un-used for 15 minutes.
- 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 battery bay and the connector on the side of products.



- 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.

7.4 Product Initialization

If the connection status of system is not stable or setting value is not correct, user can initialize the products.

7.4.1 SCU Initialization

- 1 Click Configuration button of SCU after running the **VIVIX Setup** program.
- 2 Click **Factory Reset** button in Configuration dialogue.
- 3 Wait for SCU to be initialized and rebooted automatically.
- 4 Check whether SCU initialization is completed.

Default value of SCU initialization

Item	Default Value
Network	
IP Address	
Subnet Mask	
Gateway	
AP	
AP On/Off	
Frequency	
Country	
Band	
Channel	
SSID	
Key	
Security	
GI (Guard Interval)	
Tx Power	
Test Mode	
On/Off	
Period	
Trigger	
Method	
Polarity	

7.4.2 Detector Initialization

- 1 Click Configuration button of Detector after running the **VIVIX Setup** program.
- 2 Click **Factory Reset** button in **Configuration** dialogue.
- 3 Wait for Detector to be rebooted automatically.
- 4 Check whether detector initialization is completed.

Default value of detector initialization

Item	Default Value
Network	
IP Address	
Subnet Mask	
Gateway	
WNetwork	
SSID	
Key	
AP Scan	
AP	
AP On/Off	
Frequency	
Country	
Band	
Channel	
SSID	
Key	
Security	
GI (Guard Interval)	
Tx Power	
Test Pattern Type	
Image Timeout Time	
Power Management	
Sleep	
Sleep After	
Shut Down	
Shut Down after	
Power Off	
Wireless Only	

7.4.3 Wireless Initialization of Detector

- 1 Turn off the detector.
- 2 Press and hold the power button while installing a battery into the battery compartment of the detector.
 - Keep pressing the power button.
- 3 Keep pressing the power button until the orange LED flickers three times. (It will take about 15 seconds.)
- 4 Initialization will be conducted when orange LED is flickering, after that, the detector will be turned off automatically.
- 5 Turn on the detector and check whether detector initialization is completed.

Default value of wireless initialization

Item	Default Value
IP Address	
Subnet Mask	
Gateway	
AP ON/OFF	
SSID	
Key	
Wireless Only	



- When processing the wireless initialization of a detector, only the detector's network information is initialized as a default value.

7.5 Replacing the Fuse of SCU (Basic SCU only)

There are 2 fuses attached on the standard SCU for the purpose of electrical accident precaution, in case of over current from external power input. Stop using the SCU 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	 <p>Separate the fuse from the holder located power input port on the back side of standard SCU by pulling the fuse holder.</p>
2	 <p>After checking, replace the fuse with correct specifications in case of need.</p>
3	<p>-</p> <p>Insert the fuse holder again.</p>

8. Troubleshooting [TBD]

This section gives information about troubleshooting.

Troubleshooting

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8.1 Troubleshooting

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 <Warranty>.

8.1.1 Failed to Turn the Detector On

Symptom

- Failed to turn on the power of the detector.

Expected Causes

- Not installing battery pack well
- Dead battery pack
- Battery pack or Detector is broken down

Solutions

- 1 Install battery pack
- 2 Charge battery pack
- 3 Check the result after getting rid of the battery pack and connecting the tether cable.
- 4 Replace other battery packs and check the result of it.
- 5 Replace other Detectors and check the result of it.
- 6 Replace corresponding devices.

8.1.2 The Power Switch of SCU or Status LED is not worked

Symptom

- The power switch of Basic SCU or Mini SCU is not working.
- The status LED of SCU is not responding.

Expected Causes

- Power cable is broken down.
- Errors in the fuse
- Internal circuit is broken down.

Solutions

- 1 Check the connection between AC power cable and basic SCU.
- 2 Check the connection between DC power cable and mini SCU.
- 3 Turn off the power switch and turn on again and then check the fan or status of back side.
- 4 Replace another SCU and check the result of it
- 5 Replace the fuse of standard SCU. (refer to Change fuse of SCU)
- 6 Replace corresponding devices.

8.1.3 Communication Test is failed

Symptom

- Transmission error is occurred, failure of communication test is occurred.

Expected Causes

- Network connection problem
- Network setting problem
- PC environment setting problem
- Wireless environment environment problem
- Devices failure

Solutions

- 1 Check the connection of network cable between Workstation and SCU.
- 2 Check if the accurate network cable is used or not. (CAT 5E or 6)
- 3 Set the network information of Workstation, SCU and detector again.
- 4 Check whole workstation environment again such as firewall setting and release the power save mode.
- 5 Check surrounding wireless communication environment.
- 6 Boot up detector and SCU again by processing initialization. (Refer to <오류! 참조 원본을 찾을 수 없습니다. 오류! 참조 원본을 찾을 수 없습니다.>.)
- 7 Replace other SCU and Detectors and check the result of it
- 8 Replace corresponding devices.

8.1.4 The Active LED and Data LED of the Detector are blinking

Symptom

- The active LED and data LED is blinking when power LED is ON.

Expected Causes

- Detector registration error
- Data transmission error

Solutions

- 1 Turn on SCU again
- 2 Check the network cable connection
- 3 Check the workstation environment and network information again

- 4 Check if the surrounding wireless communication is good
- 5 Check cable connection again when connected with tether interface cabel
- 6 Replace other devices and check the result of it
- 7 Replace corresponding devices.

8.1.5 Errors in Detector LED

Symptom

- All LED lamps of detector are blinking.
- 2 LED lamps of detector are blinking and remaining is blinking slowly.

Expected Causes

- Internal hardware errors of the detector.

Solutions

- 1 Boot up the detector again and check the result of it
- 2 Replace the detector.

8.1.6 Rapid Consumption of Battery

Symptom

- Consumption of fully charged battery pack is fast.

Expected Causes

- Performance decrease caused by usage of long time.
- Usage of battery pack in low temperature environment.

Solutions

- 1 Replace to new battery pack if the battery pack has been used for a long time. (Battery pack is consumables)
- 2 Use battery pack in room temperature environment. Charging capacity of battery pack in low temperature environment will be decreasing.

8.1.7 Battery Pack or Installation Part of Battery is Getting Hot

Symptom

- Battery pack or compartment for installation of battery pack is getting hot.

Expected Causes

- Battery pack failure
- Detector Failure

Solutions

- 1 Do not use battery pack

- 2 Consult with service engineers of Vieworks.

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9. Regulatory Information

This section gives explanation about the regulatory information and standard related to the products

Medical Equipment Safety Standards

Radio Frequency Compliance Information

Labels and Symbols

Guidance and Manufacturer Declaration for EMC

9.1 Medical Equipment Safety Standards

9.1.1 Medical Equipment Classification

Item	Description
Type of protection against electrical shock	Class I equipment Internally powered
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 a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

9.1.2 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	고시 2009-54호 별표 2의 36.202/36.202.4/ KN61000-4-4
서지(Surge) 시험	고시 2009-54호 별표 2의 36.202/36.202.5/KN61000-4-5
전도성 RF 전자기장 시험	식품의약품안전청 고시 2009-54호 별표 2의 36.202/36.202.6/ KN61000-4-6
전원주파수자기장 시험	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 60601-1:2007(ed.3) 10.2.2 power supply 및 식품의약품안전청 고시 2009-54호 별표 2의 36.202.14


U.S.A / Canada

Item	
IEC 60601-1(ed.2 am1+ am2+ co1)	Medical electrical equipment- Part1: General requirements for safety
UL 60601-1(ed.2)	-
CSA-C22.2 No. 601-1-M90 (R2006)	Medical electrical equipment – Part 1: General requirements for safety (adopted amendment 2:1995 to IEC60601-1)
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	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
EN ISO 13485:2012	Medical devices – Quality Management systems – Requirements for regulatory purposes
EN 60601-1: 2007(ed.3)	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.

9.2 Radio Frequency Compliance Information

Country	Item
U.S.A	<ul style="list-style-type: none"> FCC Part 15.107 Subpart (b) / 15.109(g) Subpart B FCC Part 15 Subpart E 15.407 FCC Part 15 Subpart C 15.247
European Union	<ul style="list-style-type: none">  [TBD]
South Korea	<ul style="list-style-type: none"> Clause 3, Article 58-2 of Radio Waves Act Clause 2, Article 58-2 of Radio Waves Act
Japan	<ul style="list-style-type: none"> Article 2-1-19, 2-1-19-3, 2-1-19-3-2 of the Radio law (MIC)

9.2.1 FCC Compliance

- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of **FCC Rules**. These limits are designed to provide reasonable protection against harmful interference in a residential installation.
- Operation is subject to the following two conditions.
 - This device may not cause harmful interference.
 - This device must accept any interference received, including interference that may cause undesired operation.
- This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measure.
 - Reorient or relocate the receiving antenna.
 - Increase the separation between the equipment and receiver.
 - Connect the equipment into an outlet on a circuit different from where the receiver is connected.
 - Consult the distributor or an experienced radio/TV technician for help.



- Change or modification which is not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- 5.15-5.35GHz band is restricted to indoor operations only.



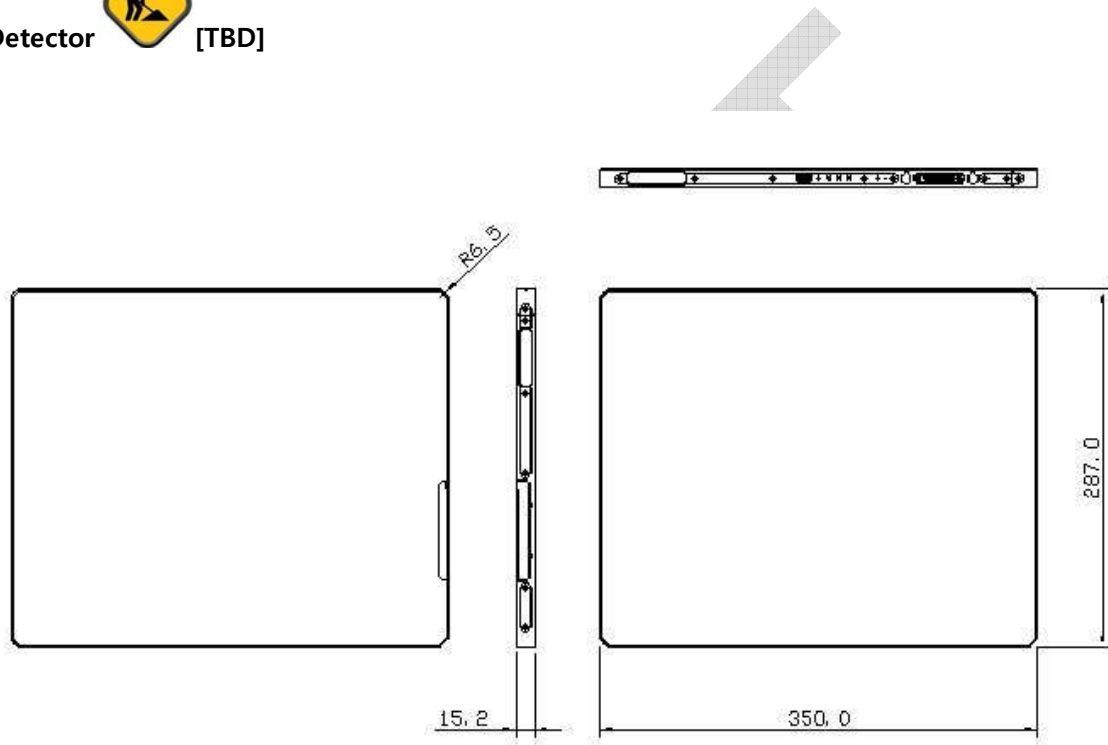
- The **SAR** limit set by the FCC is 1.6 W/kg.
 - The highest **SAR** value for this model when tested for use at the front is 0.568 W/kg.
- The front side of a detector should be used for image acquisition.

9.3 Labels and Symbols

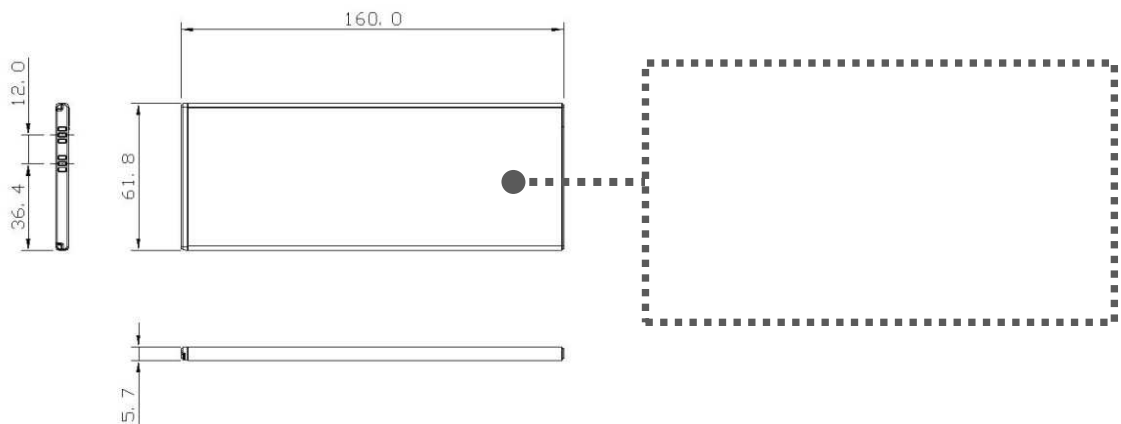
The ViVIX-S 1012N detector and relevant components have labels attached on them. The contents and locations of each label are indicated below.

9.3.1 Label

Detector  [TBD]



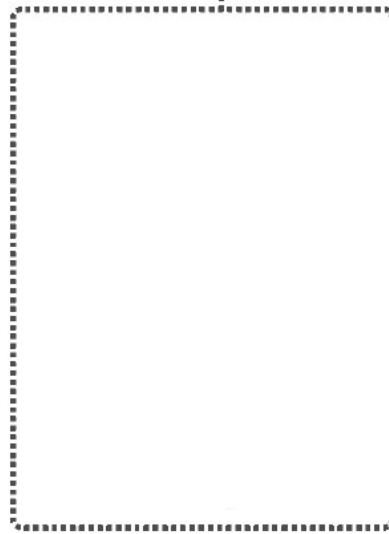
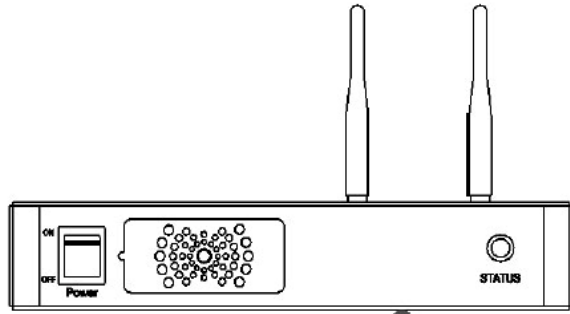
Battery  [TBD]



VIVIX SCU (VIVIX System Control Unit)



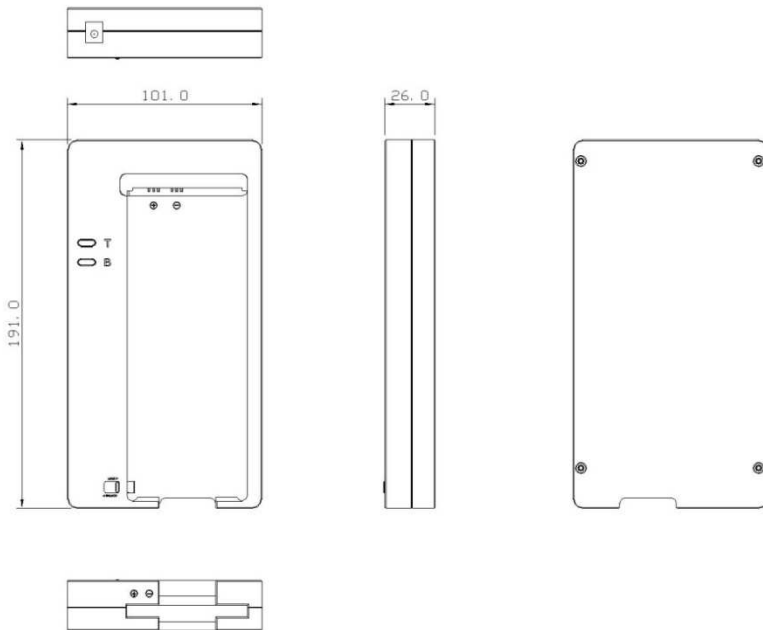
[TBD]



Battery Charger



[TBD]



Outer Box  [TBD]

9.3.2 Product Serial Number

Serial Number Composition

The serial numbers for each product or accessory are composed as follows.

1	0	-	R	1	D	A	B	J	0	0	1
Revision		-	Item	Composition	Year	Month			Serial number		




- Revision will be updated in case of follows.
 - Mass production or a large amount of order.
 - Exterior alteration.
- Item code will be produced based on internal management standard of vieworks.
- Composition code is like follows.
 - D: Detector
 - S: VIVIX SCU
 - C: Battery Charger
- Range of Serial Number is 001 ~ 999.

Initial 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 Item  [TBD]

Model	Composition	Serial Number
1012NA	Detector	10-V5D??
1012NB	Detector	10-V6D??
FXRC-02A	Battery Charger	10-V5C??
FXRS-04A	VIVIX SCU	10-V5S??

9.3.3 Product Symbols

Symbol	Description
	Direct current
	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)
	This mark indicates that the battery must be collected separately under the Directive on Waste Electrical and Electronic Equipment 2002/96/EC (WEEE) in the European Union. (For European Union)

9.4 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.

9.4.1 Electromagnetic Emissions

The Equipment Under Test (EUT) is intended for use in 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	
Harmonic emissions (IEC 61000-3-2)	Class A	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.
Voltage fluctuations/ Flicker emissions (IEC 61000-3-3)	Complies	

9.4.2 Electromagnetic Immunity

The **ViVIX-S 1012N** 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	<ul style="list-style-type: none"> Electrostatic discharge (ESD) IEC 61000-4-2
IEC 60601 test condition	<ul style="list-style-type: none"> Contact $\pm 6\text{kV}$ Air $\pm 8\text{kV}$
Compliance Level	<ul style="list-style-type: none"> Contact $\pm 6\text{kV}$ Air $\pm 8\text{kV}$
Electromagnetic Environment - Guidance	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Electrical fast transient/burst IEC 61000-4-4
IEC 60601 test condition	<ul style="list-style-type: none"> Power supply lines $\pm 2\text{kV}$ Input / output lines $\pm 1\text{kV}$
Compliance Level	<ul style="list-style-type: none"> Power supply lines $\pm 2\text{kV}$ Input / output lines $\pm 1\text{kV}$
Electromagnetic Environment - Guidance	<ul style="list-style-type: none"> Main power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5

Item	Description
Immunity test	<ul style="list-style-type: none"> Surge IEC 61000-4-5
IEC 60601 test condition	<ul style="list-style-type: none"> Differential mode $\pm 1\text{kV}$ Common mode $\pm 2\text{kV}$
Compliance Level	<ul style="list-style-type: none"> Differential mode $\pm 1\text{kV}$ Common mode $\pm 2\text{kV}$
Electromagnetic Environment - Guidance	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11
IEC 60601 test condition	<ul style="list-style-type: none"> <5% U_T (>95% dip in U_T) for 0.5 cycle. 40% U_T (60% dip in U_T) for 5 cycles. 70% U_T (30% dip in U_T) for 25 cycles. <5% U_T (<95% dip in U_T) for 5 sec.
Compliance Level	<ul style="list-style-type: none"> <5% U_T (>95% dip in U_T) for 0.5 cycle. 40% U_T (60% dip in U_T) for 5 cycles. 70% U_T (30% dip in U_T) for 25 cycles. <5% U_T (<95% dip in U_T) for 5 sec.
Electromagnetic Environment - Guidance	<ul style="list-style-type: none"> 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 or a battery.



U_T is the AC power prior to approving the test level voltage.

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

Item	Description
Immunity test	<ul style="list-style-type: none"> Power frequency (50/60 Hz) magnetic field IEC 61000-4-8
IEC 60601 test condition	<ul style="list-style-type: none"> 3 A/m
Compliance Level	<ul style="list-style-type: none"> 3 A/m
Electromagnetic Environment - Guidance	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3
IEC 60601 test condition	<ul style="list-style-type: none"> 3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz
Compliance Level	<ul style="list-style-type: none"> 3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz

• 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.

$$d = \left[\frac{3.5}{V_1} \right] \sqrt{P} \quad d = \left[\frac{3.5}{V_1} \right] \sqrt{P} \text{ 80 MHz to 800 MHz}$$

$$d = \left[\frac{7}{E_1} \right] \sqrt{P} \text{ 80 MHz to 800 MHz}$$

Electromagnetic Environment - Guidance

- 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, should be less than the compliance level in each frequency range b.
- Interference may occur in the vicinity of equipment marked with the symbol.



- 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.

10. Information

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

Service Information

Warranty

Revision History

DRAFT

10.1 Service Information

10.1.1 Product Lifetime

The estimated product lifetime may be up to five (5) years under the appropriate regular inspection and maintenance.

10.1.2 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.

10.1.3 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.

- Model name: **FXRD-1012NAW / FXRD-1012NBW**
- Serial number: 12 digit-number on the product label
- Explanation of problem: Describe as detailed as possible.

10.1.4 Replacement Parts 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.

10.1.5 Consumables

The following consumable can deteriorate because of its characteristics and structure. For purchase of consumables, contact your sales representative or distributor.

- Battery pack: FXRB-03A

10.2 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 MERCHANTABILITY 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

10.3 Revision History

Version	Date	Descriptions
1.0	2015-01-??	• Initial Release



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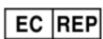
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