

• If the power LED lights up green, the DC power is permitted normally.

• If the active LED lights up orange, the detector is compeleted to boot up normally.

4.2.5 Checking Status LED of Detector

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.

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.
- The active LED is blinking when the detector turns to sleep mode.
- The active LED is blinking when the wireless communication is being initialized. (Refer to <5.3.3Wireless Initialization of Detector>.)

Data LED

- The data LED indicates status information of the data processing in blue.
- The data LED lights up when the detector is available to make data communication.
- The data LED is blinking while the detector transmits or saves data.

Detector AP LED

- The AP LED lights up in blue when the detector AP is on.
- The AP LED is blinking in blue when the detector switches the AP status.
- The AP LED is blinking in orange while the detector is synchronizing the wireless settings.
- The communication status of detector is indicated when the detector AP is off.
 - ^a Wireless communication: Green LED at the 3rd level or higher / Orange LED under 2nd level.
 - ^a Wired communication: Green LED in case of 1Gbps / Orange LED in case of 100Mbps connection.

Summary List of Detector Status LED (Side)

| Information | Power L | ED | Active L | .ED | Data LE | D |
|--|---------|-------|----------|-------|---------|----|
| In process of booting after the power permission | | Blink | OFF | | OFF | |
| Booting completed (Abnormal) | | ON | - | | - | |
| Booting completed (Normal) | | ON | | ON | OFF | |
| Ready for communication | | ON | | ON | | ON |
| Sleep Mode | | ON | | Blink | OFF | |
| In process of wireless initialization | | ON | | Blink | OFF | |

| Data Communication (Send or Store) | | ON | | ON | | Blink |
|------------------------------------|-----|----|-----|----|-----|-------|
| Power OFF | OFF | | OFF | | OFF | |

Summary list of the Detector AP LED

| Information | Detector AP LED |
|---|-----------------|
| Detector AP OFF (Communication status: Good) | |
| • Wireelss communication: 3 rd level or higher | ON |
| Wired communication: 1000Mbps | |
| Detector AP OFF (Communication status: Normal) | |
| • Wireelss communication: Under 2 nd level | ON |
| Wired communication: 100Mbps | |
| Detector AP ON | ON |
| Switching the status of detector AP | Blink |
| The wireless setting is being synchronized | Blink |
| Power OFF | OFF |



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

Summary List of Detector Status LED (Rear)

| Category | Item | Icon | Description |
|----------|---------|--------------------------------|---------------------------------|
| А | AD | | Operates under the AP mode |
| | AP | VVVVVVVVVVV 000.000.000.000 | Indicates SSID and IP address |
| | | | Operates under the station mode |
| | | ((• | • Link Quality – Level 5 |
| | | | Operates under the station mode |
| Network | | | • Link Quality – Level 4 |
| Status | | ((| Operates under the station mode |
| | Station | | • Link Quality – Level 3 |
| | Station | (((1- | Operates under the station mode |
| | | | • Link Quality – Level 2 |
| | | | Operates under the station mode |
| | | | • Link Quality – Level 1 |
| | | | Operates under the station mode |
| | | | • Link Quality – Level 0 |

| | | VVVVVVVVVVV 000.000.000.000 | Indicates SSID and IP address |
|-----------|----------------------|--------------------------------|---|
| | | | Operates under the tether interface mode |
| | | | Connected by 1Gbps |
| | Tether Interface | | Operates under the tether interface mode |
| | | | Connected by 100Mbps |
| | | VVVVVVVVVV 000.000.000.000 | Indicates SSID and IP address |
| | Initianlization | | Initializing the system |
| | | 4 | Battery remains – Level 5 |
| | Ramains (Charging) | 4 | Battery remains – Level 4 |
| Patton | | 4 | Battery remains – Level 3 |
| Battery | | 4 | Battery remains – Level 2 |
| | | 4 | Battery remains – Level 1 |
| | | | Battery remains – Level 0 |
| Image | | | Sets coordinates information to make the |
| Direction | Indicating Direction | <u> + </u> | direction of a bar locate on the top of the |
| 2.1.00001 | | | image. |

4.2.6 Connecting SCU Lite (FXRP-02A)



1 Connect one end of the tether interface cable to the detector, and connect the other end to **PoE port** of SCU Lite.

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- 2 Connect one end of the LAN cable to the **LAN port** of SCU Lite, and connect the other end to the LAN card connector of workstation assigned for data transfer.
- 3 Connect the DC power adaptor to the power input port of SCU Lite.

4.2.7 Booting Up SCU Lite and Detector



- 1 Turn on the power switch at rear side of SCU Lite.
- 2 Check if the LINK LED of SCU Lite lights up green.
- 3 Check if the power LED of the detector lights up in light green.
- 4 Check if the active LED of the detector lights up in light green.
 - When the LINK LED of SCU Lite lights up green, it means that the power is approved normally.

• The detector starts booting up when you turn on the power of SCU Lite.



- Refer to <5.3Product Initialization> for the detailed information about the default setting status of a detector.
- If the power LED of the detector does not light up, check if the tether interface cable is connected to the PoE port of SCU Lite correctly.

4.3 Device Setting

4.3.1 Software Installation

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

| 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 / SCU. |

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.

4.3.2 Setting Detector and SCU

- 1 After executing VIVIX Setup, access to the detector and SCU 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.

4.3.3 Setting NFC Tag

- To change the all detector settings by using NFC tag at once, you need to register Preset Configuration and set connection with the NFC tag to use from **VIVIX Setup** in advance.
- If you already set the NFC tag, you can change it to the Preset Configuration by contacting it on the contacting part of NFC located at the rear of the detector.
- The NFC mode is only to adjust settings and are not used simultaneously with Wi-Fi mode.



| Category | Item | Factory Reset |
|-----------------------------|---|---------------|
| Network | IP Address, Netmask, Gateway | 0 |
| WNetwork | SSID, Key, Wireless Only | 0 |
| Image | Timeout, Option | 0 |
| AP | On/Off, Frequency, Band, Channel, SSID, Key | 0 |
| Power Mode | Sleep, Shutdown, Power Control | 0 |
| Exposure Mode | DR Trigger, AED | |
| Auto Offert Defrech Cetting | Use offset refresh, Time Interval, | 0 |
| Auto Offset Refresh Setting | Temperature Interval, Number of shot | 0 |
| Direction Compensation | Auto On/Off | |

Preset Items (Changeable by using NFC tag)



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



• The device setting should be done by an engineer who understands the **VIVIX Setup**, Windows system, wired/wireless network and the related technique. If not, an error could occur while operating the detector, or the image quality could be affected.

4.4 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. |
| Battery Pack | Diagnoses the condition of a battery pack. |
| Wireless Communication | Diagnoses the status of wireless communication. |
| Wired/Wireless Communication Speed | Diagnoses the speed of wired/wireless communication. |
| Self-diagnosis | Diagnoses defects of a detector by self-diagnosis. |



• 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.

4.4.1 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.

4.4.2 Battery Pack Diagnosis

Check battery remains from the detector

- 1 Check if a battery pack is attached to the detector.
- 2 Check remains of a battery from LED display located at the rear of a detector.

Check battery remains from VIVIX Setup

- 1 Execute VIVIX Setup and go to the Information tab of the Diagnosis dialog.
- 2 Check remains and voltage of a battery.

| Battery | | |
|----------------|-------------|-----------------|
| Remain | 0 | Low(1) |
| | #1 | #2 |
| Equipped | Not Equippe | ed Not Equipped |
| Charging State | Not Chargir | ng Not Charging |
| Voltage | 0.0 V | 0.0 V |



You can also check the battery remains from VXvue or VIVIX SDK.
Refer to VIVIX Setup Operation Manual for the information about the battery diagnosis.

• Since a battery pack is consumables which performance will be decreased as time passes, make sure to check its life when you use it. If a battery pack has any problems, consult service personnel in Vieworks.

Display of Battery Remains

| Level | Value | Battery Remains | LED Display | |
|--------------|-------|-----------------|-------------|--|
| Full | 5 | 81% ~ 100% | 4 | |
| Half Quarter | 4 | 61% ~ 80% | 4 | |
| Half | 3 | 51% ~ 60% | 4 | |
| Quarter | 2 | 31% ~ 50% | 4 | |
| | 1 | 11% ~ 30% | 4 | |
| LOW | | 1% ~ 10% | | |
| Unknown | 0 | | 4 | |



• If the battery remains under 30% or is at the 1st level, the system warns low battery and the detector will be turned off automatically after the battery is consumed for a specific period of time. Therefore, it is recommended to change the battery when a warning message or an indicator displays.

4.4.3 Wireless Communication Diagnosis

- 1 Execute VIVIX Setup and go to the Information tab of the Diagnosis dialog.
- 2 Check the status of wireless communication from the Network item.

| Network | |
|-------------------|--------------|
| Connection Type | Wireless |
| Link Speed | Unknown |
| Wi-Fi Information | |
| Link Quality | 67 Very Good |
| Signal Level | -43 dBm |
| Bit rate | 240 Mbps |
| Frequency | 5180 MHz |



You can also check the communication status from VXvue or VIVIX SDK.
Refer to VIVIX Setup Operation Manual for the detailed information about the wireless communication diagnosis.

Strength of Wireless Communication Signal

| Stage | Level | Status LED | Link Quality | Meaning |
|-----------|-------|------------|--------------|--|
| Very Good | 5 | ((()- | 66 ~ 70 | The wireless communication is running smoothly, and it |
| Good | 4 | (((1- | 56 ~ 65 | ensures the image acquisition. |
| Normal 3 | 2 | | 41 ~ 55 | The wireless communication status is normal, but it does |
| | 5 | | | not ensure performace of the image acquisition. |
| Bad | 2 | | 31 ~ 40 | The wireless communication status can become unstable. |
| Very Bad | 1 | (((+ | 1 ~ 30 | Impossible to make wireless communication normally. |
| Unknown | 0 | ((| 0 | Impossible to get the wireless communication status, or |
| | U | | U | the system is not connected wirelessly. |

• The communication cannot run smoothly when the strength of wireless communication is under the level 2. Therefore, it is required to check the surrounding wireless communication status.

• In case of using the detector under wireless communication, be sure to check the communication status before starting to use the detector. If the status is bad, the speed of acquiring images will be very slow or you may fail to acquire images.



• Be sure to check the surrounding wireless communication to prevent communication interference. If wireless communication module in the detector has any problems, contact the service engineer in Vieworks.

4.4.4 Wired/Wireless Communication Speed Diagnosis

- 1 Execute VIVIX Setup and go to the Information tab of the Diagnosis dialog.
- 2 Click on the **Download** button in **Image Transmission Time** and check image transmission speed of the detector.
- 3 Click on the Start button in Throughput Measurement to check the data traffic per setting time.

| Performance Test | ٦ |
|------------------------------|---|
| Image Transmission Time | |
| Download ms | |
| Progress | |
| | |
| Throughput Measurement | |
| Time 💌 10 sec. Bit rate Mbps | |
| Start | |
| | |



• Refer to **VIVIX Setup Operation Manual** for the detailed information about the communication speed diagnosis.



• Be sure to check the communication environment if there is any problem occurs in the communication speed. Contact the person in charge of service if the problem is related to the communication module of a detector and SCU.

4.4.5 Self-Diagnosis

- 1 Execute VIVIX Setup and go to the Self Diagnosis tab in the Diagnosis dialog.
- 2 Check the desired items to diagnose from the **Test Case** list.
- 3 Click on the Execute Test button to perform self-diagnosis.
- 4 Check the status and result of diagnosis for each item in the Result dialog.





• Click **Save to File** button to save the result of a diagnosis as a file and contact the service engineer if any problem is found.

Self-diagnosis items of detector and measures

Voltage

| Item | Form | Expected problem | Measures |
|--------|----------|--|-----------------------------|
| | | Defective tether interface cable | Change a tether cable. |
| DDC | Decision | Poor power supply to the wired operation mode. | Contact a service engineer. |
| MAIN | Decision | Poor power supply to the processor. | Contact a service engineer. |
| SIGNAL | Decision | Poor power supply to FPGA. | Contact a service engineer. |

Battery

| Item | Form | Expected problem | Measures |
|-----------|-------------|--------------------------------------|--|
| | Decision | The battery is not attached. | Check if a battery is attached or not. |
| Detection | | A defective ciruit is connected to a | Contact a convice angineer |
| | | battery pack. | Contact a service engineer. |
| Voltage | Information | N/A | N/A |
| Remain | Information | N/A | N/A |

Wireless

| Item | Form | Expected problem | Measures |
|------------|----------|---------------------------------|--------------------------------------|
| Detection | Decision | Defective wireless module | Contact a service engineer. |
| | | Inconsistent environment of the | Check obstacles and distance between |
| Connection | Decision | wireless communication. | a detector and SCU. |
| | | Defective wireless module | Contact a service engineer. |

Sensor

| Item | Form | Expected problem | Measures |
|---------------|----------|------------------------------|-----------------------------|
| Impact Sensor | Decision | Defective shock sensor | Contact a service engineer. |
| Temperature | Decision | Defective temperature sensor | Contact a service engineer. |
| AED | Decision | Defective AED sensor | Contact a service engineer. |

Memory

| Item | Form | Expected problem | Measures |
|--------------|-------------|---------------------------------------|-----------------------------|
| | Decision | Impossible to save backup images. | Contact a service engineer. |
| Detection | | Impossible to save logs. | Contact a service engineer. |
| | | The calibration data is inapplicable. | Contact a service engineer. |
| File evetere | Decision | Impossible to save backup images. | Contact a service engineer. |
| rile system | | Impossible to save logs. | Contact a service engineer. |
| Status | Informatior | n N/A | N/A |

| Item | Form | Expected problem | Measures |
|------------|-------------|--------------------------------|-------------------------------|
| EDGA | Decision | Impossible to take images from | a Contact a service engineer. |
| | | detector. | |
| Fuel Cauge | ge Decision | Impossible to check the | Contact a convice angineer |
| ruei Gauge | | remaining of a battery pack. | contact a service engineer. |

Self-diagnosis items of SCU and measures

Wireless

| Item | Form | Expected problem | Measures |
|-----------|----------|---------------------------|------------------------------|
| Detection | Decision | Defective wireless module | Contact a service eingineer. |

Memory

| Item | Form | Expected problem | Measures |
|-------------|-------------|--------------------------|------------------------------|
| Detection | Decision | Impossible to save logs. | Contact a service eingineer. |
| File system | Decision | Impossible to save logs. | Contact a service eingineer. |
| Status | Information | N/A | N/A |

IC

| Item | Form | Expected problem | Measures |
|--------------|----------|--|------------------------------|
| Switching IC | Decision | Impossible to connect the detector and | |
| Switching IC | | PC. | contact a service emgineer. |
| Current | Decision | Impossible to block overcurrent when | Contact a convice singinger |
| Controller | | using the wired mode. | Contact a service eingineer. |

5. Inspection and Maintenance

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

Product Inspection Cleaning and Disinfection Product Initialization Detector Power Save Function (Sleep) Replacing the Fuse of SCU

5.1 **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.

5.1.1 Daily Inspection

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

| Item | Description | |
|----------|--|--|
| | • Ensure that there are no loose screws or breaks. | |
| Detector | • 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. | |
| SCU | Check if the antenna is damaged. | |
| | • Ensure that cables are not damaged and cable jackets are not torn. | |
| Cable | • 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 |
|----------------|-------------|---|
| | | • Conduct Self-Diagnosis of the VIVIX Setup program for the internal |
| Self-Diagnosis | Hall-yearly | devices of the detector and check the status. |
| Decelution | | • Check the resolution of the detector through resolution chart or using a |
| Resolution | Half-yearly | phantom. |
| | | • Evaluate the characteristic of the detector through checking gray value |
| Sensitivity | Half-yearly | of the images made by X-ray dose amount reaching to the surface of |
| | | the detector. |
| | | • Updating calibration data. (Offset \rightarrow Gain \rightarrow Defect) |
| Calibration | Half-yearly | • 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.

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

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.
- Do not make liquid soak when cleaning battery bay and a connector on 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.

5.3 **Product Initialization**

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

5.3.1 SCU Initialization

- 1 Click on the **Configuration** button of SCU after running the **VIVIX Setup** program.
- 2 Click on the Factory Reset button in the 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 | 169.254.2.100 |
| | Subnet Mask | 255.255.0.0 |
| | Gateway | 169.254.2.100 |
| AP | | |
| | AP On/Off | ON |
| | Frequency | 5GHz |
| | Country | KR |
| | Band | 40MHz |
| | Channel | +36 |
| | SSID | vivix |
| | Кеу | 1234567890 |
| Trigger | | |
| | Method | Packet |
| | Polarity | Auto |

5.3.2 Detector Initialization

- 1 Click Configuration button of Detector after running the **VIVIX Setup** program.
- 2 Click on the Factory Reset button in the 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 | 169.254.1.10 |
| Subnet Mask | 255.255.0.0 |
| Gateway | 169.254.2.100 |
| WNetwork | |
| SSID | vivix |
| Кеу | 1234567890 |
| AP Scan | OFF |
| AP | |
| AP On/Off | OFF |
| Frequency | 5 GHz |
| Country | KR |
| Band | 40MHz |
| Channel | +36 |
| SSID | vivix_ap |
| Кеу | 1234567890 |
| Test Pattern Type | 20 sec. |
| Image Timeout Time | Disable |
| Power Management | |
| Sleep | OFF |
| Sleep After | 10 min. |
| Shut Down | OFF |
| Shut Down after | 30 min. |
| Power Control | By Detector |

5.3.3 Wireless Initialization of Detector

- 1 Turn off the detector.
- 2 Press and hold both the power button and AP button over 3 seconds.
- 3 Initialization will be conducted when orange LED is flickering, after that, the detector will be turned off automatically.
- 4 Turn on the detector and check whether detector initialization is completed.

Default value of wireless initialization

| Item | | Default Value |
|---------|---------------|---------------|
| Network | | |
| I | P Address | 169.254.1.10 |
| 9 | Subnet Mask | 255.255.0.0 |
| (| Gateway | 169.254.2.100 |
| WNetwo | rk | |
| 9 | SSID | vivix |
| I | Кеу | 1234567890 |
| ١ | Wireless Only | OFF |
| AP | | |
| | AP On/Off | OFF |
| I | Frequency | 5 GHz |
| (| Country | KR |
| I | Band | 40MHz |
| (| Channel | +36 |
| 9 | SSID | vivix_ap |
| | Кеу | 1234567890 |



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

5.4 Detector Power Save Function (Sleep)

The battery pack can be comsumed slowly by using the power save function.

• The power save function is operated only when the battery supplies power to the detector. In other words, the power save function cannot be operated if a tether interface cable supplies power to the detector.

Types of Power Save Mode

| Item | Description |
|-----------|--|
| Normal | The detector can be operated and take images at any time. |
| Sleep | The detector cannot be operated. User can take an image by disabling the Sleep mode. |
| Shut Down | The detector has been turned off. User can take an image after the detector is rebooted. |

Setting Items of Power Save Function

| Item | Description | |
|-----------------|--|--|
| Sleep | Sets whether you use the sleep mode function of the detector or not. (On / Off) | |
| Sloop offer | If the detector is not used for the specific setting time, it is turned to the sleep mode. | |
| Sleep alter | This mode activates only when the sleep mode is set. (10 / 15 / 20 / 25 / 30 min.) | |
| Shut Down | Sets whether you use the shut down function in the detector or not. (On / Off) | |
| Shut Down offer | The power of detector is off if it is not used within the setting time. This menu is | |
| Shut Down after | activated while the Shut Down function is being used. (30 / 60 / 90 / 120 min.) | |

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• Refer to **VIVIX Setup Operation Manaul** for the detailed information about the power save mode functions.

Entry Condition of Power Save Mode (Sleep)

| Item | Description | |
|-----------|---|--|
| Normal | - | |
| Sleep | The detector turns to sleep mode if not used for the setting time (Sleep after). | |
| | The detector is turned off if not used for the setting time (Shutdown after) under the | |
| Shut Down | sleep mode. However, if the detector is not operated during the setting time when it is | |
| | not in the sleep mode, the detector will be turned off. | |

Checking Power Save Condition

| Item | Description | |
|-----------|---|--|
| Normal | All status LEDs are turned on. | |
| | The Status LED (Green) is blinking. | |
| Sleep | You can check the Sleep status from VIVIX Setup or VXvue. | |
| | • VIVIX SDK notices the status of Sleep. | |
| Shut Down | All LEDs are turned off. | |

Disabling Power Save Function

| Item | Description | |
|-----------|--|--|
| Normal | - | |
| Class | 1 Turns off sleep mode from VIVIX Setup or VXvue | |
| Sleep | 2 Calls the function from VIVIX SDK to turn off sleep mode. | |
| Shut Down | Reboots the detector by pressing a power button on the detector. | |

Other Information

| Mode | Default value | Turnaround time | Power consumption |
|-----------|---------------|-----------------|-----------------------------------|
| Nermal | | | 24V, 360mA (Standby) |
| Normai | - | - | 24 V, 950mA (While taking images) |
| Sleep | OFF / 10min. | Approx. 10 sec. | 24V, Max. 180mA |
| Shut Down | OFF / 30min. | Approx. 15 sec. | - |

5.5 Changing the Wireless Setting

5.5.1 Switching to the Detector AP Mode

You can change the detector mode as AP by the two ways as follows.

Convert to the Detector AP mode by using the Detector AP button

- Press the **AP** button on the detector for 5 seconds to set the **Detector AP** mode.
- The LED of detector AP blinks in a blue color while the mode is being switched, and turns on blue after the mode is compeleted to be converted.



• This method can be used only when the detector is under the wireless communication status without connecting a tether interface cable.

Convert to the Detector AP mode from VIVIX Setup

• Choose AP as On or Off from the Detector Configuration dialog in VIVIX Setup program.

| AP | |
|-----------|---------------------|
| AP | 🔘 On 💿 Off |
| Frequency | 🔘 2.4 GHz 🛛 💿 5 GHz |
| Country | KR |
| Band | 40 MHz 🔹 |
| Channel | + • 36 • |
| SSID | vivix_ap |
| Key | 1234567890 |
| | |

5.5.2 Synchronizing the Wireless Setting

Synchronize the wireless setting with a tether interface cable as follows.

- 1 Connect the detector and SCU with a tether interface cable.
- 2 Press the detector AP button for 5 seconds after the detector is turned on.
- 3 The LED of detector AP blinks while processing synchronization.
- 4 The sync information is saved automatically after it is transmitted to the detector where SSID and KEY of SCU are connected.
- 5 The detector is switched to the wireless communication mode.



• Refer to **VIVIX Setup Operation Manaul** for the detailed information about the synchronization of wireless setting.

5.6 Replacing the Fuse of SCU



• The description in the section is applicable to the SCU Basic model only.

There are 2 fuses attached on the SCU Basic 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.

| Item | Specifications |
|----------------|--------------------------|
| Model | Littelfuse® 218002 (2EA) |
| Туре | Time Lag Cartridge Fuse |
| Amp Rating | 2A |
| Voltage Rating | 250V |

Fuse Information

- 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.
- This product has lower breaking capacity type. So do not install the product at the building power system which prospective short-circuit current is exceeding 35 A.

How to Replace the Fuse

| No. | Description |
|-----|---|
| 1 | Separate the fuse from the holder located power input port on the back side of standard SCU 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

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>.

6.1.2 Fail to Turn the Detector On

| Category | Description | | | | |
|-----------------|---|--|--|--|--|
| Symptom | • Failed to turn the power of the detector. | | | | |
| Expected Causes | The battery pack is attached wrongly. | | | | |
| | The battery pack is discharged. | | | | |
| | The battery pack or detector is broken down. | | | | |
| Solutions | 1 Attach a battery pack | | | | |
| | 2 Charge a battery pack | | | | |
| | 3 Check the result after getting rid of a battery and connect the tether cable. | | | | |
| | 4 Replace other battery packs and check the result. | | | | |
| | 5 Replace other Detectors and check the result. | | | | |
| | 6 Replace the corresponding devices. | | | | |

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

| Category | Description | | | | |
|-----------------|---|--|--|--|--|
| Symptom | The power switch of Basic SCU or SCU mini is not working. | | | | |
| Symptom | The status LED of SCU is not responding. | | | | |
| | Power cable is broken down. | | | | |
| Expected Causes | • Errors in the fuse | | | | |
| | Internal circuit is broken down. | | | | |
| | 1 Check the connection between AC power cable and SCU Basic / DC power cable | | | | |
| | and SCU mini. | | | | |
| Solutions | 2 Turn off the power switch and turn it on again. Check a fan or the back side. | | | | |
| Solutions | 3 Replace the fuse of Basic SCU. (refer to <5.6 Replacing the Fuse of SCU>) | | | | |
| | 4 Replace another SCU and check the result of it. | | | | |
| | 5 Replace corresponding devices. | | | | |

| Category | Description | | | | |
|-----------------|---|--|--|--|--|
| Symptom | • The LINK LED of SCU Lite is not working even though its power switch is turned | | | | |
| Symptom | on. | | | | |
| Expected Causes | The power cable is broken down. | | | | |
| | • The internal circuit is broken down. | | | | |
| | 1 Check the connection between DC power cable and SCU Lite. | | | | |
| Solutions | 2 Turn off the power switch and turn it on again. Check if the LINK LED of SCU Lite | | | | |
| | is working properly. | | | | |
| | 3 Replace SCU Lite to another one and check the result. | | | | |

6.1.4 The Power Switch of SCU Lite is not Working

6.1.5 Communication Test is failed

| Category | Description | | | | |
|-----------------|--|--|--|--|--|
| Symptom | • Transmission error occurred, and the communication test is failed. | | | | |
| | Network connection problem | | | | |
| | Network setting problem | | | | |
| Expected Causes | PC environment setting problem | | | | |
| | Wireless environment environment problem | | | | |
| | Errors in devices | | | | |
| | 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 | | | | |
| Solutions | the power save mode. | | | | |
| 5010110115 | 5 Check surrounding wireless communication environment. | | | | |
| | 6 Reboot the detector and SCU again by processing initialization. (Refer to | | | | |
| | <5.3Product Initialization>) | | | | |
| | 7 Replace the detector and SCU Basic to another ones and check the result of it. | | | | |
| | 8 Replace corresponding devices. | | | | |

| Category | Description | | | | |
|-----------------|---|--|--|--|--|
| Symptom | • The active LED and data LED are blinking while power LED is turned ON. | | | | |
| Expected Causes | Detector registeration error | | | | |
| expected Causes | Data transmission error | | | | |
| | 1 Turn on SCU again. | | | | |
| | 2 Check the network cable connection. | | | | |
| | 3 Check the workstation environment and network information again. | | | | |
| Solutions | 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. | | | | |

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

6.1.7 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. | | | |
| Expected Causes | Internal hardware errors of a detector. | | | |
| Solutions | 1 Reboot the detector and check the result. | | | |
| | 2 Replace the detector to another one. | | | |

6.1.8 Rapid Consumption of Battery

| Category | Description | | | | |
|-----------------|--|--|--|--|--|
| Symptom | • The fully-charged battery is consumed rapidly. | | | | |
| Expected Causes | • The performance of a detector is decreased by its length of use. | | | | |
| | In case of using a battery under in low temperature. | | | | |
| Solutions | 1 Replace a battery pack if it is used for a long time. (Battery pack is consumables.) | | | | |
| | 2 Use a battery pack at room temperature. Charging capacity of a battery pack is | | | | |
| | decreased in low temperature. | | | | |

6.1.9 Battery Pack or Installation Part of Battery is Getting Hot

| Category | Description | | | |
|-----------------|---|--|--|--|
| Symptom | • A compartment for installing a battery pack is getting hot. | | | |
| Expected Causes | A battery malfunction | | | |
| | Detector failure | | | |
| Solutions | 1 Stop using a battery pack. | | | |
| | 2 Contact the service engineer in Vieworks. | | | |

7. 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

7.1 Medical Equipment Safety Standards

7.1.1 Medical Equipment Classification

| Item | Description | | | |
|---|---|--|--|--|
| Type of protection against electrical shock | Class I or Internally Powered | | | |
| Degree of protection against electrical shock | Type B applied parts | | | |
| Degree of protection against ingress of water | IP56 (Degrees of protection againt ingress of water | | | |
| | provided by enclosure.) | | | |
| Operation mode | Continuous operation | | | |
| | NOT suitable for use in the presence of a flammable | | | |
| Flammable anesthetics | anesthetic mixture with air or with oxygen or 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) | |
|--------------|---|
| 저지피 저드 | 식품의약품안전청 고시 2009-54호 1종 A급 기기로서 별표 1의 5.1 |
| 신사파 신도 | 식품의약품안전청 고시 2009-54호 별표 1의 전자파장해 (간섭) |
| 저지희 바니 | 식품의약품안전청 고시 2009-54호 1종 A급 기기로서 별표 1의 5.2 |
| 신자파 경자 | 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 | 36.202/36.202.5/ KN61000-4-5 |
| 전도성 RF 전자기장 시험 | 식품의약품안전청 | 고시 | 2009-54호 | 별표 | 2의 | 36.202/36.202.6/ KN61000-4-6 |
| 전원공급 입력선의 전압 강하, 순간정전 및 전압변동 시험 | 식품의약품안전청 | 고시 | 2009-54호 | 별표 | 2의 | 36.202/36.202.7/KN61000-4-11 |

U.S.A / Canada

| Item | | | | | |
|---------------------------------|---|--|--|--|--|
| ANSI/AAMI ES60601-1(2005) + | Medical electrical equipment – Part1: General requirements for | | | | |
| AMD1(2012) | basic safety and essential performance | | | | |
| | Medical electrical equipment – Part 1: General requirements for | | | | |
| CAN/CSA-C22.2 No. 60601-1(2014) | basic safety and essential performance (adopted IEC 60601-1:2005, | | | | |
| | including Amendment 1:2012, with Canadian deviations) | | | | |
| IEC 60601 1 2: 2007(ad 2) | Medical electrical equipment-Part 1-2: Collateral Standard : | | | | |
| 1ec 60601-1-2. 2007(ed.3) | Electromagnetic compatibility | | | | |
| IEC 62304:2006 | Medical device software-software life cycle processes | | | | |
| ISO 14071-2012 | Medical Device- Application of risk management to medical | | | | |
| 150 149/1.2012 | devices | | | | |

European Union

| Item | |
|--------------------------------|---|
| MDD (Medical Device Directive) | 93/42/EEC as amended by 2007/47/EC |
| EN ISO 12495-2012 | Medical devices – Quality Management systems – Requirements for |
| EN 150 15465.2012 | regulatory purposes |
| EN 60601 1: 2006 (A1:2012 | Medical electrical equipment- Part1: General requirements for basic |
| EN 60601-1. 2006/A1.2015 | safety and essential performance |
| EN 60601 1 2: 2007(ad 2) | Medical electrical equipment-Part 1-2: Collateral Standard : |
| EN 60601-1-2. 2007(ed.5) | Electromagnetic compatibility-Requirements and tests |
| EN 62304:2006 | Medical device software-Software life cycle processes |
| ISO 14971: 2012 | Medical device – Application of risk management to medical devices. |

| Country | Item |
|----------------|--|
| | • FCC Part 15.107(b) / Part 15.109(b) |
| U.S.A | FCC Part 15 Subpart E 15.407 |
| | • FCC Part 15 Subpart C 15.247 |
| | • ETSI EN 301 489-1 V1.9.2:2011 (EMC) |
| European Union | • ETSI EN 301 489-17 V2.2.1:2012 (EMC) |
| | • EN 300 328 V.1.8.1; EN 301 893 V1.7.1 (RF) |
| South Karoo | • KN 301 489-1 |
| South Korea | • KN 301 489-17 |

7.2 Radio Frequency Compliance Information

7.2.1 FCC Compliance

- This equipment has been tested and found to comply with the limits for a Class A 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.
 - ^a 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.
 - ^a Reorient or relocate the receiving antenna.
 - ^a Increase the separation between the equipment and receiver.
 - ^a Connect the equipment into an outlet on a circuit different from where the receiver is connected.
 - ^a 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.
 - This equipment complies with FCC&CE SAR regulation.
- The front side of a detector should be used for image acquisition.



- The SAR limit set by FCC is 2W/kg (for EU and Japan) and 1.6W/kg (for USA and Korea).
- The highest reported SAR for WLAN 2.4G head and WLAN 5G head exposure conditions are 0.493 W/kg, 0.966 W/kg, respectively.

- This equipment complies with FCC&CE SAR regulation.
- The front side of a detector should be used for image acquisition
- The front with touch configuration was only tested since only the front is touched to human body in normal operation condition of this device.

7.2.2 FCC SAR

• OET Bulletin 65, Supplement C (Edition 01-01)

7.2.3 CE R&TTE SAR

| Item | |
|-----------------|---|
| EN 62211-2009 | Assessment of electronic and electrical equipment related to human exposure |
| EN 62311:2008 | restrictions for electromagnetic fields. (0 Hz - 300 GHz) |
| | Human exposure to radio frequency fields from hand-held and body-mounted |
| EN 62209-1:2006 | wireless communication devices – Human models, instrumentation, and procedures. |
| | • Part 1: Procedure to determine the specific absorption rate (SAR) for hand-held |
| | devices used in close proximity to the ear (frequency range of 300 MHz to 3 GHz). |
| | Human Exposure to Radio Frequency Fields from Handheld and Body-Mounted |
| | Wireless Communication Devices – Human models, Instrumentation, and Procedures. |
| EN 62209-2:2010 | • Part 2: Procedure to determine the specific absorption rate (SAR) for mobile |
| | wireless communication devices used in close proximity to the human body |
| | (frequency range of 300 MHz to 6 GHz). |

7.2.4 NFC Specifications and Certifications

| Item | Specifications / Certifications | | | | | |
|-------------------|--|--|--|--|--|--|
| | 13.560 MHz (RFID) | | | | | |
| | 2412 MHz ~ 2472 MHz (802.11b/g/n 20 MHz BW) | | | | | |
| Frequency Dense | 2422 MHz ~ 2462 MHz (802.11n 40 MHz BW) | | | | | |
| Frequency Range | 5745 MHz ~ 5825 MHz (802.11a/n 20/ac 20 MHz BW), | | | | | |
| | 5755 MHz ~ 5795 MHz (802.11n 40/ac 40 MHz BW), | | | | | |
| | 5775 MHz (802.11ac 80 MHz BW) | | | | | |
| | ASK (RFID) | | | | | |
| Modulation System | DSSS (802.11b), OFDM (802.11a/g/n 20 MHz BW/n 40 MHz BW/ | | | | | |
| | ac 20 MHz BW/ac 40 MHz BW/ac 80 MHz BW) | | | | | |
| | A1D (RFID) | | | | | |
| Type of Emmision | G1D (802.11b), D2D (802.11 a/g/n 20 Mz BW/n 40 Mz BW/ | | | | | |
| | ac 20 MHz BW/ac 40 MHz BW/ac 80 MHz BW) | | | | | |
| Channel | 1 Ch (RFID) | | | | | |
| | • 2 400 MHz Band | | | | | |



| | ■ 13 Ch (802.11b/g/n 20 Mz BW), 9 Ch (802.11n 40 Mz BW) |
|--------|--|
| | • 5 725 MHz Band |
| | 5 CH (802.11a/n 20 Młz BW/ ac 20 Młz BW), |
| | 2 CH (802.1n 40 Mz BW/ac 40 Mz BW), |
| | ■ 1 Ch (802.11ac 80 Mz BW) |
| | Under 47.544 mV/m in 10m of distance |
| | • 2 400 MHz Band |
| | 10 mW/MHz: 802.11b/g/n 20 MHz BW (ANT 1, 2, 3, MIMO (ANT 1+2), MIMO |
| | (ANT 2+3), MIMO (ANT 1+3), MIMO (ANT 1+2+3)) |
| | 5 mW/MHz: 802.11n 40 MHz BW (ANT 1, 2, 3, MIMO (ANT 1+2), MIMO (ANT |
| | 2+3), MIMO (ANT 1+3), MIMO (ANT 1+2+3)) |
| Output | • 5 725 MHz Band |
| | 10 mW/MHz: 802.11a/n/ac 20 MHz BW (ANT 1, 2, 3, MIMO (ANT 1+2), MIMO |
| | (ANT 2+3), MIMO (ANT 1+3), MIMO (ANT 1+2+3)) |
| | 5 mW/MHz: 802.11n/ac 40 MHz BW (ANT 1, 2, 3, MIMO (ANT 1+2), MIMO |
| | (ANT 2+3), MIMO (ANT 1+3), MIMO (ANT 1+2+3)) |
| | 2.5 mW/MHz: 802.11ac 80 MHz BW (ANT 1, 2, 3, MIMO (ANT 1+2), MIMO |
| | (ANT 2+3), MIMO (ANT 1+3), MIMO (ANT 1+2+3)) |

7.2.5 KC Wireless Certification

| Item | Description |
|------------------------------------|--|
| Symbol | |
| Name of the Device | FXRD-1417NAW |
| Certification Number | MSIP-CRM-VJM-FXRD-1417NAW |
| Name of the Manufacturer | Vieworks Co., Ltd. |
| Manufacturer/ Country of Origin | Vieworks Co., Ltd. / Republic of Korea |
| Certified Module Used | MSIP-CRI-VJM-WLE900VX-VW |

7.3 Labels and Symbols

The **VIVIX-S 1417N** detector and relevant components have labels attached on them. The contents and locations of each label are indicated below.

7.3.1 Label

FXRD-1417NAW / FXRD-1417NBW



Battery (FXRB-03A)



Battery Charger (FXRC-02A)



Battery Charger (FXRC-03A)



SCU Basic (FXRS-03A)



SCU mini (FXRS-04A)



SCU Lite (FXRP-02A)



7.3.2 Product Serial Number

Composition

The product serial numbers are composed as follows.

| V | 1 | D | А | В | J | 0 | 0 | 1 |
|-----|---|-------------|------|---|-------|----------------------|---|--------|
| Ite | m | Composition | Year | | Month | Manufacturing number | | number |
| | | | | | | | | |

- The serial number will be updated in case of follows;
 - Mass production or a large amount of order.
 - Exterior alteration.



- Composition code is consisted as;
 - D: Detector
 - S (or P): SCU
 - C: Battery Charger
- Range of manufacturing 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 |
|---|---|---|---|---|---|---|---|---|----|----|----|
| Α | В | С | D | E | F | U | V | W | Х | Y | Z |

Composition of Serial Number for Each Item

| Model | Composition | Serial Number |
|--------------|---------------------------|---------------|
| FXRD-1417NAW | Detector | VUDAGA001 |
| FXRD-1417NBW | Detector | VVDAGA001 |
| FXRC-02A | Battery Charger | VACAGA001 |
| FXRC-03A | Dual-type Battery Charger | VBCAGA001 |
| FXRS-03A | SCU Basic | VCSAGA001 |
| FXRS-04A | SCU mini | VASAGA001 |
| FXRP-02A | SCU Lite | V3PAGA001 |

7.3.3 Product Symbols

| Symbol | Description |
|---------------------------|---|
| | Direct current |
| \sim | Alternating current |
| | Protective earth (Ground) |
| Å | Equipotentiality |
| | Power on |
| \odot | Power on for part of the equipment |
| \bigcirc | Power off |
| Ċ | Power off for part of the equipment |
| \bigwedge | Attention, consult accompanying documents |
| <u>/</u> | General warning sign |
| 4 | Warning sign for electricity |
| c UL us | 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 ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012), CAN/CSA-C22.2 No. 60601-1 (2014) |
| C€ ₀434 | This mark shows compliance of the essential requirement and other relevant provisions of Directive 93/42/EEC as a mended 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. |
| $\mathbf{R}_{\mathbf{X}}$ | 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 |
| Ŷ | This mark indicates that this equipment must be handled with care. |

| 100% | Do not jolt or apply excessive load to the equipment. |
|------------|---|
| Ŕ | This is a Type B Applied Part according to UL 60601-1 and EN 60601-1. |
| X | This mark indicates that the equipment must be collected separately under the |
| | Directive on Waste Electrical and Electronic Equipment 2012/19/EC (WEEE) in the |
| | |
| | This mark indicates that the battery must be collected separately under the Directive |
| X | on Waste Electrical and Electronic Equipment 2012/19/EC (WEEE) in the European |
| | Union. (For European Union) |
| \bigcirc | Shows direction of installing the detector and generator tube. |

7.4 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.

7.4.1 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 | 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 |
| (CISPR II) | | interference in nearby electronic equipment. |
| RF Emissions | | |
| (CISPR 11) | Class A | |
| Harmonic emissions | Class A | The EUT is suitable for use in all establishments other than domestic |
| (IEC 61000-3-2) | | and those directly connected to the public low-voltage power |
| Voltage fluctuations/ | | supply network that supplies buildings used for domestic purposes. |
| Flicker emissions | Complies | |
| (IEC 61000-3-3) | | |

7.4.2 Electromagnetic Immunity

The **VIVIX-S 1417N** 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.

| 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 |
| Electromognotic Environment | Floors should be wood, concrete or ceramic tile. |
| Guidanco | • If floors are covered with synthetic material, the relative humidity |
| | should be at least 30%. |

Electrostatic Discharge (ESD) IEC 61000-4-2

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 - | • Main power quality should be that of a typical commercial or hospital |
| Guidance | 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 - | • Main power quality should be that of a typical commercial or hospital |
| Guidance | environment. |

Voltage Dips, Short Interruptions/Voltage Variations on Power Supply Input Lines IEC 61000-4-11

| Item | Description |
|-------------------------------|---|
| Immunity to st | Voltage dips, short interruptions and voltage variations on power |
| | supply input lines IEC 61000-4-11 |
| | • <5% Uτ (>95% dip in Uτ) for 0.5 cycle. |
| IEC 60601 test condition | • 40% Uτ (60% dip in Uτ) for 5 cycles. |
| | • 70% Uτ (30% dip in Uτ) for 25 cycles. |
| | • <5% UT (<95% dip in UT) for 5 sec. |
| | • <5% Uτ (>95% dip in Uτ) for 0.5 cycle. |
| Compliance Level | • 40% Uτ (60% dip in Uτ) for 5 cycles. |
| | • 70% Uτ (30% dip in Uτ) for 25 cycles. |
| | • <5% UT (<95% dip in UT) for 5 sec. |
| | • Main power quality should be that of a typical commercial or hospital |
| | environment. |
| Electromagnetic Environment - | • If the user of the EUT image intensifier requires continued operation |
| Guidance | during power mains interruptions, it is recommended that the EUT |
| | image intensifier be powered from an uninterruptible power supply or |
| | a battery. |



Ut 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 | • 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 - | • Power frequency magnetic fields should be at levels characteristic of a |
| Guidance | 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 = [^{3.5}/_{V₁}]√P d = [^{3.5}/_{V₁}]√P 80 Wz to 800 Wz d = [⁷/_{E₁}]√P 80 Wz to 800 Wz 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 surveya, should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with ^{((*))}. |
| At 80 Mtz These gui | and 800 MHz, the higher frequency range applies. delines 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 Lifetime

The estimated product lifetime may be 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.

- Model name
 - ^D FXRD-1417NAW / FXRD-1417NBW
- Serial number
 - ^o 9 digit-number on the product label
- Explanation of problem
 - ^D Describe as detailed as possible.

8.1.4 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.

8.1.5 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

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 | Descriptions |
|---------|------------|------------------------------------|
| 1.1 | 2016-10-12 | • Initial Release |
| 1.3 | 2016 11 07 | • (Modified) 2 Product |
| | 2010-11-07 | (Modified) 7 Reglatory Information |
| 1.5 | 2017 02 17 | (Modified) Image of 1417N detector |
| | 2017-02-17 | • (Modified) 2 Product |

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