User's Manual

PEDRA-1417M Detector (Wired & Wireless)

Before using this equipment, be sure to read this user's manual thoroughly.
Keep this user manual where it is easily accessible.

To customers

Thank you for purchasing a PEDRA detector. This User Manual explains how to use the detector, X-ray interface unit, and other peripheral equipment. Before using this product, be sure to read this manual thoroughly in order to utilize it more effectively.

Important information on usage and management of the equipment

1 Only a physician or a legally certified operator should use this product.

2 The equipment should be maintained in a safe and operable condition by maintenance personnel.

3 Use only computers and image display monitors complying with IEC 60601-1 or IEC 60950-1. For details, consult your sales representative or a distributor.

4 Use only the dedicated cables. Do not use any cables other than those supplied with this product.

5. professional health care environment.

Disclaimer

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

Note on installation

Request your sales representative or distributor to install this product.

Notes on disposal of this product

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

European Union (and EEA*) only

This symbol indicates that this product is not to be disposed with your household waste, according to the WEEE Directive (2002/96/EC) and your national law. This product should be handed over to a designated collection point, e.g., on an authorized one-for-one basis when you buy a new similar product or to an authorized collection site for recycling electrical and electronic equipment (EEE). Improper handling of this type of waste could have a negative impact on the environment and human heath due to potentially hazardous substances that are generally associated with EEE. At the same time, your cooperation in the correct disposal of this product will contribute to the effective usage of natural resources. For more information on where you can drop off your waste equipment for recycling, please contact your local city office, waste authority, approved WEEE scheme, or your household waste disposal service.

*EEA: Norway, Iceland, and Liechtenstein

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Safety and Regulatory

Safety Notices

The following safety notices are used to emphasize certain safety instructions. Follow the safety instructions in this manual along with warnings and cautions symbols. Ignoring such warnings or cautions while handling the product may results in serious injury or accident. It is important for you to read and understand the contents of this manual before attempting to use the product.

Warning

This notice is used to indicate a potentially hazardous situation which may cause death, severe personal injury or substantial property damage if the instructions are ignored.

Caution

This notice is used to indicate a potentially hazardous situation which may cause minor personal injury or substantial property damage if the instructions are ignored.

Regulatory

Caution

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

1 Safety Information

1.1 Safety precautions

This product is designed and manufactured to ensure maximum safety of operation and to meet all the safety requirements applicable to electronic medical equipment. Follow these safeguards and properly use the equipment to prevent injury or damage to any equipment or data.

Warning

Installation and environment of use

- Do not use or store the device near flammable chemicals such as alcohol, thinner, benzene, etc. If chemicals are spilled or evaporate, it may result in a fire or electric shock through contact with electric parts inside the device. Also, some disinfectants are flammable. Be sure to take care when using them.
- Do not connect the device with anything other than specified.

  Doing so may result in fire or electric shock.
- Always be alert when operating this device. If a malfunction occurs, do not use this device until qualified personnel correct the problems.
- The product should be installed, maintained, and serviced according to manufacturer maintenance procedures and by manufacturer personnel or other qualified maintenance personnel approved in writing by manufacturer. Operation and maintenance should be done in strict compliance with the operation instructions contained in the manual.
- The system, in whole or in part, cannot be modified in any way without written approval from manufacturer.

Adapter

- Do not operate the device using any type of adapter other than the one indicated on the rating label. Otherwise, it may result in a fire or electric shock.
- Do not handle the product with wet hands. You may experience an electric shock that could result in death or serious injury.
- Do not place a heavy object such as medical device on cables and cords, and do not pull, bend, bundle, or step on them. Doing so may damage their sheath. If you alter them, it may damage the cords which could result in a fire or electric shock.

- Do not connect a multiple portable socket-outlet or extension cord to the system.
  Doing so may result in a fire or electric shock.

Warning

Handling

- Never disassemble or modify the device. Doing so may result in a fire or electric shock. Also, since the device incorporates parts that may cause an electric shock as well as other hazardous parts, touching them may cause death or serious injury.
- Do not place anything on top of the device. The object may fall and cause an injury. Also, if metal objects such as needles or clips fall into the device, or if liquid is spilled, it may result in a fire or electric shock.
- Do not hit or drop the device. The device may be damaged if it receives a strong jolt. if the device is used without being repaired this may result in a fire or electric shock.
- Have the patient take a fixed posture and do not let him or her touch parts unnecessarily. If the patient touches connectors or switches, it may result in electric shock or malfunction of the device.

When a problem occurs

Should any of the following occur, immediately turn OFF the power to each piece of device, unplug the power cord from the AC outlet, and contact our sales representative or distributor.

- When there is smoke, an odd smell or abnormal sound.
- When liquid has been spilled into the device or a metal object has entered through an opening
- When the device has been dropped and is damaged

Maintenance and inspection

- When the device is going to be cleaned, be sure to turn OFF the power of each equipment and unplug the power cord from the AC outlet. Never use alcohol, benzene, thinner, or any other

  flammable cleaning agent. Otherwise, it may result in a fire or electric shock.
- Clean the plug of the power cord periodically by unplugging it from the AC outlet and removing dust or dirt from the plug, its periphery, and AC outlet with a dry cloth.

  If the cord is kept plugged in for a long time in a dusty, humid or sooty place, dust around the plug will attract moisture, and this could cause insulation failure that could result in a fire.
- For safety reasons, be sure to turn OFF the power to each piece of device when the inspections indicated in this manual are going to be performed. Otherwise, electric shocks may occur.

Warning

Installation and environment of use

- Before authorizing any person to operate the system, verify that the person has read and fully understood the User Manual. The owner should make certain that only properly trained and fully qualified personnel are authorized to operate the equipment. An authorized operators list should be maintained.
- It is important that this User Manual be kept at hand, studied carefully, and reviewed periodically by the authorized operators.
- Do not install the equipment in any of the locations listed below. Doing so may result in failure or malfunction, device falling, fire, or injury.
  - Close to facilities where water is used
  - Where it will be exposed to direct sunlight
  - Close to the air outlet of an air-conditioner or ventilation device
  - Close to a heat source such as a heater
  - Where the power supply is unstable
  - In a dusty environment
  - In a saline or sulfurous environment
  - Where temperature or humidity is higher than the operating temperature
  - Where there is freezing or condensation
  - In areas prone to vibration
  - On an incline or in an unstable area

Because the device cable is long, take care that cables do not become tangled during use. Also, be careful not to get your feet caught in the cable.

Otherwise, it may cause a malfunction of the device or injury to the user from tripping over the cable.

- Non-medical equipment such as the Power supply cannot be used in patient's vicinity.

Warning

Handling

- Do not spill liquid or chemicals onto the detector. In cases where the patient is injured, do not allow it to come in contact with blood or other body fluids.

  Doing so may result in a fire or electric shock. In such a situation, protect the device with a disposable covering as necessary.
- Turn OFF the power to each piece of equipment for safety when not being used.
- Do not submerge the device in water.
- The internal image sensor may be damaged if the equipment is hit, dropped, or receives a strong jolt. Also, do not place excessive weight on the detector.

<Load Limit>

Uniform load: 150kg over the whole area of the detector surface

Local load: 100kg on an area 40 ㎜ in diameter

- Be sure to use the detector on a flat surface so it will not bend. Otherwise, the internal image sensor may be damaged. Be sure to securely hold the detector while using it in upright positions.

1.2 Symbols and detail of marking

Symbol	Description
	Direct Current
	Alternating Current
	This mark indicates that this equipment must be handled with care.
	Do not jolt or apply excessive load to the equipment.
	General warning sign
	Attention, consult accompanying documents
	Read and understand all instructions and warning labels in the product documentation before using the equipment. Keep manual for future reference.
	This mark indicates that this is a Type B Applied Part according to UL 60601-1 and EN 60601-1.
	Indicates the temperature limits to which the medical device can be safely exposed.
	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)
	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC,93/42/EEC and98/79/EC.
	Indicates the date when the medical device was manufactured.
EC REP	Indicates the Authorized representative in the European Community.
CE 2195	This mark shows compliance of the essential requirement and other relevant provisions of Directive 93/42/EEC.

1.3 Notes for using the equipment

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

Image Backup

To avoid missing images which might result in the patient being exposed to additional doses of radiation, it is important to backup images by filming or using a CD or DVD option. This should be done as a routine operation for every patient.

If the hard disk of your workstation is about to be full, the operator should backup images and delete them to make storage (memory) space on the hard disk for new information (patient).

User Limitations

The PEDRA-DMS (Detector Managing Software) has the technician mode and this mode should be operated by the personnel who are qualified by the manufacturer

Disposal

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

Before exposure

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

During exposure

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

Cleaning and Disinfection

- After using the detector and its peripheral device for examination, wipe the patient contact surfaces of the detector and peripheral device (attached handle included), by disinfectants such as IPA and ethanol to prevent infection. For details on how to sterilize, consult a specialist.
- Use a dry cloth slightly damped with such disinfectants to wipe the surface of the detector and its peripheral equipment.
- Do not spray the detector directly with disinfectants or detergents.
- Do not clean the detector with substances containing organic solvents such as alcohol, benzene, thinner, or other chemicals. Otherwise, it may result in an unwanted fire or electrical shock or structural weakening of the detector.
- Do not use an abrasive brush, scraper, or acid/alkaline cleaner when cleaning the detector and other equipment.
- Do not clean the detector with its power on.

Pediatric Application

- Every request should be reviewed by a pediatric radiologist prior to beginning the examination to ensure that an appropriate study is being performed.
- If the technologist notices an unusual request, he or she must contact a pediatric radiologist. Examples, include orders- a Full Cervical, Thoracic, and Lumbar Spine series. The pediatric radiologist should contact the ordering physician and decide which study is best for the pediatric patient.
- The technologist should use a proper technique considering the patient's size to decrease the radiation dose when he or she acquires diagnostic images.
  - ALL pediatric patients shall be shielded for their X-ray examinations, except for when the shield will

  obscure the region of interest, as in a pelvic or SI joint X-ray for trauma or arthritis, or when it is physically or clinically unreasonable to shield the patient. For routine Hip X-Rays, ALL male children shall have their scrotum shielded using the small gonadal shield while females may not be shielded because doing so would obscure the hips.
- To minimize motion in infants and young children, swaddle the infant. Use distraction tools to improve cooperation and projectors with child-friendly themes, music, toys with flashing lights or music, child- friendly images on the ceiling or walls, singing, counting, and a parent reading and talking to the child through the console all can help reduce anxiety and comfort the child.
- A scoliosis series will consist of a single frontal standing view of the spine. No lateral view or supine view is needed, unless specifically asked for by the Orthopedist or Radiologist. If the female's breasts can be shielded without obscuring the spine, breast shields should be used.

Operating/storage environment

- The device is mainly for use in X-ray exposure rooms and hospital wards. To use it in other places, consult our sales representative or a distributor.

- Be sure to use and store this equipment under the conditions described below:

Parameter	Factor		Value	Units
AC/DC Adapter setting (when supplying from the output source of Adapter)	Voltage		+/-10% of rated voltage	Vac
	Frequency		50/60	Hz
Environmental	Pressure	Operation	700 to 1060	hPa
		Storage/Ship	500 to 1060	hPa
	Humidity	Operation	20 to 75	% RH
		Storage/Ship	10 to 95	% RH
	Temperature	Operation	10 to 40	℃
		Storage/Ship	-15 to 55	℃
Contact duration by operator	10 s ≤ t < 1 min			
Operator Accessible Part	Enclosure of Power Supply and X-ray Detector			
Contact duration by Patient	1 min ≤ t < 10 min			
Patient Accessible Part	Enclosure of X-ray Detector (PC Film)			
Material Group	IIb			
Pollution Degree	2			
Overvoltage Category	II(When supplying from Power Supply)			
Max. working condition (Digital X-ray Flat Panel Detector & Power Supply for wired communication)	Continuous operated with fully charged battery and cycles for image capture and transmission from Detector to PC			
Max. working condition (Digital X-ray Flat Panel	Continuous cycles for image capture and transmission from Detector to PC			

Detector & Power Supply for wireless communication)	

- Do not expose this device to high temperatures and/or high humidity. Malfunctions may occur.
- When not in use, keep the detector, handle unit, and grid in a designated location or in a location where they are safe and cannot fall down.

Others

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

Patient Population

- Age: Infant to geriatric.

  For purposes of this user manual, we are defining pediatric subpopulations as shown below.

Pediatric Subpopulation	Approximate Age Range
newborn	birth to 1 month of age
infant	1 month to 2 years of age
child	2 to 12 years of age
adolescent	12-21 years of age

- Adult patient, Body type (age 22 or above)

  Body type is divided considering the patient height and weight which are shown as below BMI (body mass index) table.

BMI	Weight Status
Below 18.5	Underweight
18.5 – 24.9	Normal
25.0 – 29.9	Overweight
30.0 and Above	Obese

- Health: Patients requiring an X-ray may have conditions ranging from mild trauma to chronic, life threatening illnesses.

2 Introduction

PEDRA 1417M detector is a digital X-ray flat panel detector which has 35 ㎝ x 43 ㎝ imaging area and communicates with wired and wifi communication feature, Giga-bit Ethernet communication method through connecting a tether cable and wifi router. The device intercepts x-ray photons and the scintillator emits visible spectrum photons that illuminate an array of photo (a-SI)-detector that creates electrical signals. After the electrical signals are generated, it is converted to digital values, and the images will be displayed on the monitor. This device should be integrated with an operating PC and an X-Ray generator. It can digitalize x-ray images and transfer them for radiography diagnostics. Advanced digital image processing allows considerably efficient diagnosis, all kinds of information management, and sharing of image information on network.

2.1 Features

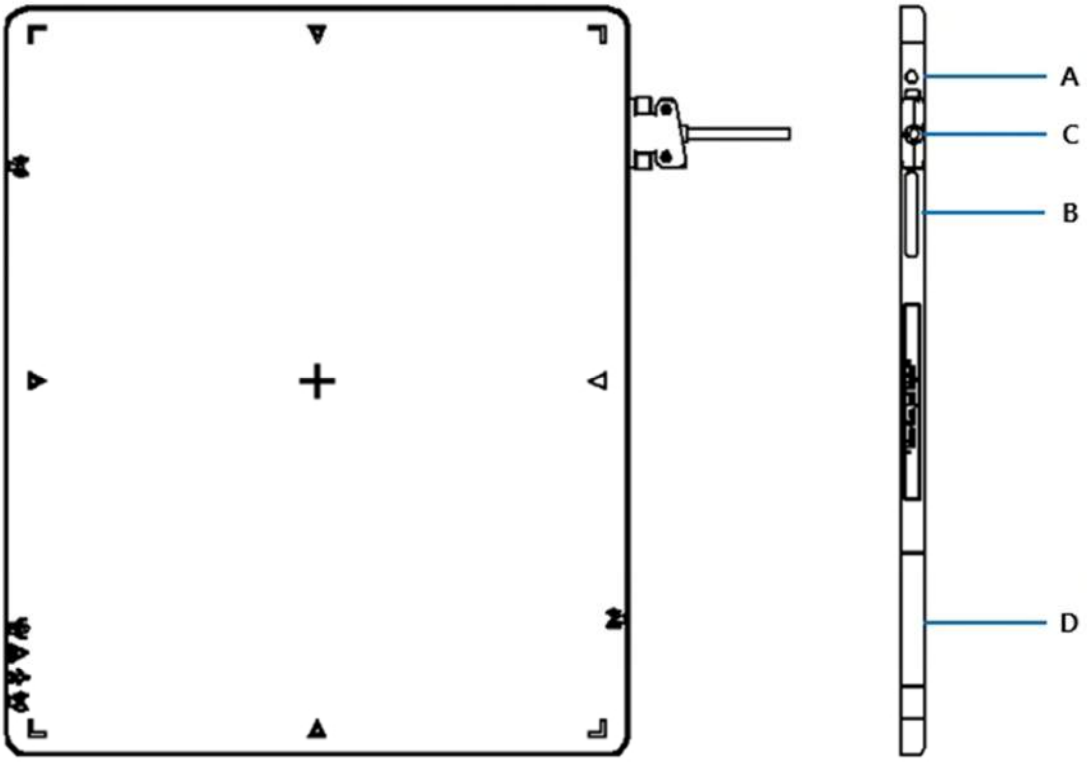
- The shape of the detector, which is identical to that of a conventional film cassette complying with ISO4090, enables digital radiography in the existing analog radiography configuration.
- The new sensor with 143 μm of pixel pitch and CsI (Cesium Iodide) / GdOS (Gadolinium Oxysulfide)used for the scintillator produces high-resolution digital images within the effective imaging area (CsI: 350 x 430 ㎜) with low doses of X-rays.
- Depending on the operating conditions at each site, the wiring unit (optional) enables the equipment to be used through expansion to a wired connection.
- Wireless LAN communication (IEEE 802.11 a/b/g/n) includes thin detector that is easy to handle.
- At the time of installation, set a specific channel in the double frequency band of 2.4 ㎓/5 ㎓ before using the LAN. Note that the available frequency band for this standard varies depending on the local radio laws, regulations, and system requirements.

2.2 Intended use

The PEDRA 1417M detector is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic system in all general-purpose diagnostic procedures. It is not to be used for mammography.

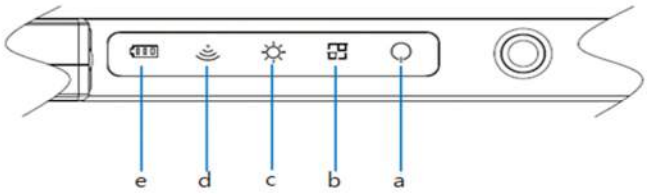
2.3 Detector Description

The detector is designed to capture radiographic images.
Captured images are transmitted to the viewer computer through a wired and wireless connection.



A. POWER button: Controls the detector power on/off

B. Status indicators



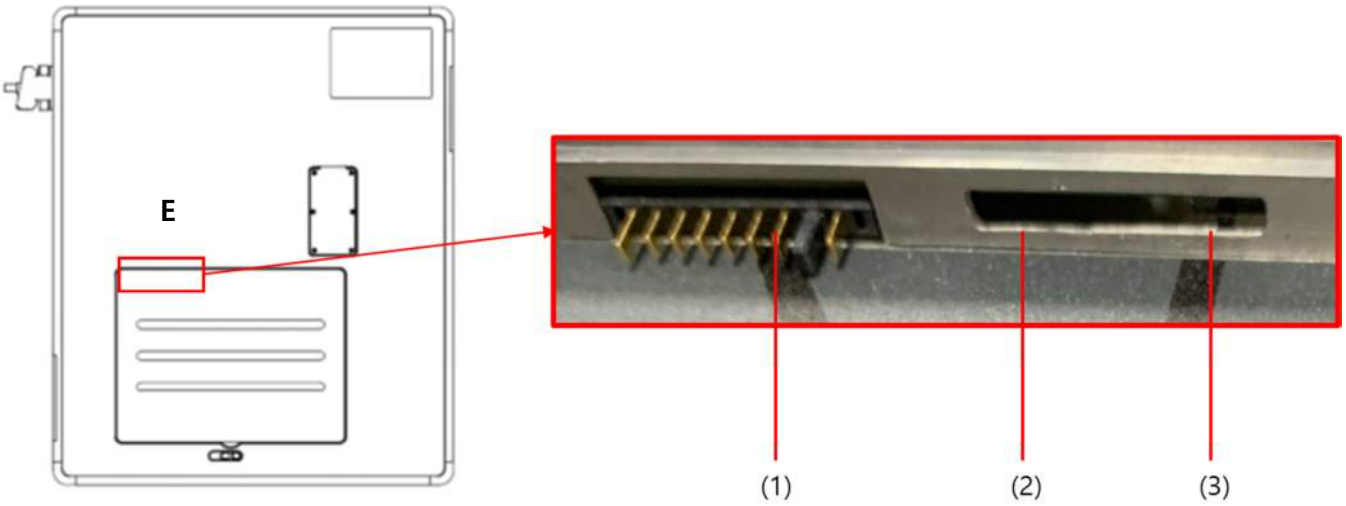
a. Power LED: Indicates power on/off status (Blue).
b. Network LED: Network Connection status of wired mode (Green)
c. Exposure status : Shooting signal of dark and X-ray (Yellow)
d. Wifi LED: Wireless status of AP mode (Green)
e. Battery LED: Battery power (Green)

C. Tether port: Allows the detector to communicate with the Power Supply via tether cabling (Gigabit Ethernet)1000 BASE-T).

D. Wifi Antenna

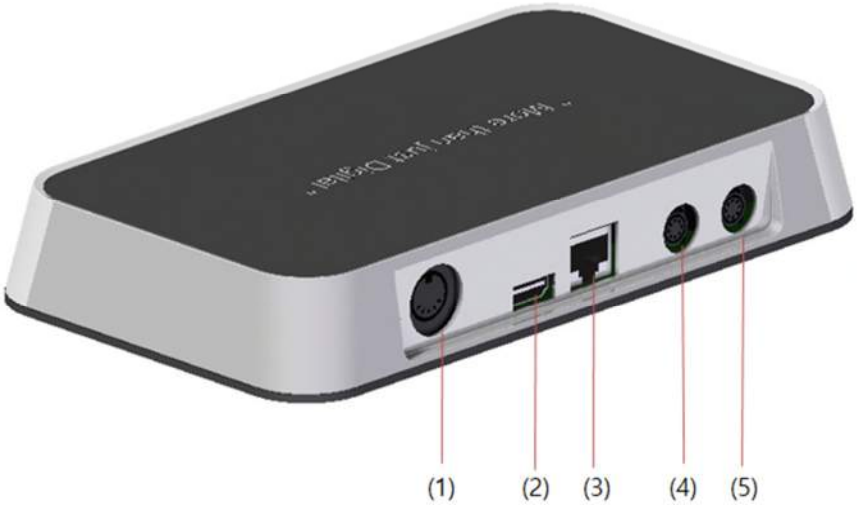
E. Battery Connector

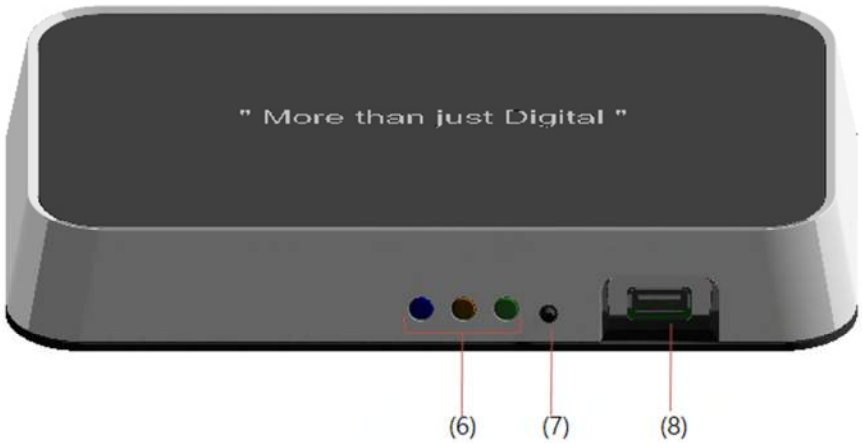
(1) Battery connection parts
(2) AP mode On/Off button: User can select AP mode or Wifi (or tether) mode.
(3) SD card Slot : saved images storage



2.4 Power & Control Box (PEDRA-PCON) Description

PEDRA-PCON is connected in between PEDRA detector and work station computer. This device supplies DC power to PEDRA detector, and receives orders from the computer. And it transmits digital images from PEDRA detector to the station.





(1) External power socket: AC/DC Adopter [MPU-64], DC +15V / 4.2A INPUT

(2) Tether cable port:

Operation: a. Detector power supply

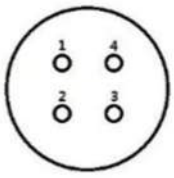
b. Control signal input section

c. Network signal communication

(3) LAN port: 10/100/1000 BASED-T Data communication port

(4) Hand switch SYNC port: READY/EXPOSURE in port

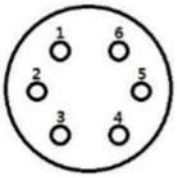
Operation: When the EXP_IN / RDY_IN of initial state for 5V is connected Pin No.2(GND), signals of RDY_IN, EXP_IN is transmitted to the detector.



PIN	DESCRIPTION
1	EXP_IN
2	GND
3	
4	RDY_IN

(5) X-ray SYNC port: READY/EXPOSURE out port

Operation: When an event occurs in normal open condition, RDY_OUT/EXP_OUT and RDY_COM/EXP_COM are closed.



PIN	DESCRIPTION
1	RDY_OUT
2	RDY_COM
3	
4	
5	EXP_OUT
6	EXP_COM

(6) Status lamps:

a. PCON Power LED: Power on LED (Blue)
b. Exposure LED: Generator X-ray exposure LED (Orange) / at DMS and Manual Mode activated
c. Detector Power LED: Power on LED (Green)

(7) Detector Power On/Off switch

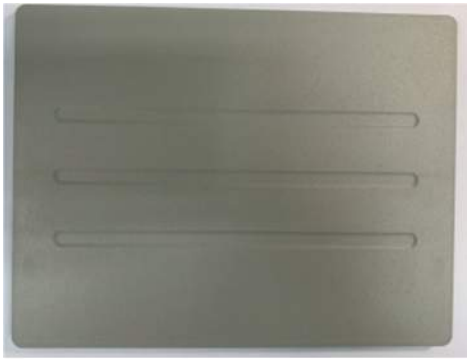
(8) USB connector:

Operation: a. Supply power to N-GENSYNC
b. Data Communication with PC

2.5 Battery Charger (PEDRA-BC001) Description

(1) Power input port: Supplies electric power by connecting a power adapter to the battery charger.
(2) Power LED: Indicates the power status On / Off
(3) Charging Status LED: Indicates charging status of a battery pack.
(4) Battery insertion: Insertion part for battery charging

2.6 Battery (PEDRA-BT001) Description



(1) Model: PEDRA-BT001
(2) Type: Lithium-ion
(3) Rating: DC 11.1V. 4.0Ah
(4) Operation time: 4hr.
(5) Cycle time: max 250 times (Fully charged/Discharged completely, 1cycle)

2.7 Components

PEDRA consists of Detector, PEDRA-PCON, Generator SYNC, Tether Cables and some accessories.

PEDRA-17F	PEDRA-PCON
AC/DC Adapter	Tether Cable
AC Power Cable (230V & 120V)	LAN Cable
Generator SYNC Cable (Option)	

Battery Charger	Battery Adapter
Battery	**AC Power Cable (230V & 120V)**

1) Standard Part:

Item	Product Name
Detector	PEDRA-1417M (scintillator: CsI (Tl)): 3.0kg (GdOS): 3.20kg
Power & Control Box	PEDRA-PCON: 0.50kg
Battery Charger	PEDRA-BACH001: 0.39kg
Battery	PEDRA-BT001: 0.25kg
PEDRA CD	PEDRA-DMS (Detector Manager Software) User Manual
Accessories	AC/DC Adapter (2m) AC/DC Adapter for Battery Charger (2m) Generator SYNC Cable (15m) Tether Cable (7.5~10m) LAN Cable (15m, Direct, 1000BASE-T, CAT 5E)

2) Optional Part

Item	Product Name
Hand Switch SYNC cable	Hand Switch
Handle	Portable used Handle
Manual Mode use	USB Cable

Caution

The use of accessories and cables other than those specified, with the exception of **PEDRA** accessories and cables sold by Manufacturer. as replacement parts for internal components, may result in increased radiation emissions or decreased stability of the equipment. Accessory device connected to the analog and digital interfaces must be certified according to the respective IEC standards. All combinations of device must be compliance with IEC 60601-1 system requirements. Any person who connects additional device to the signal input or signal output ports configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 60601-1. If in doubt, consultmanufacturer technical support representative.

2.8 Workstation (Recommended)

Item	Specification
Operating System	Windows 8, 10, 64 bit SP1 (Professional Edition or higher)
CPU	Intel Core i5 2600 or higher (or compatible CPU)
Memory	4GB or higher
Hard Disk	1TB or higher
LAN Card	Gigabit (Detector only) Intel? PRO 1000 Series (Gigabit LAN Card for network interface) Min. Requirements: 1Gbps, Jumbo Frames: 9K Receive Descriptors: 2K (higher than 1024) This is not dedicated to DICOM
Monitor	1024 X 768 or higher
Optical Disc Drive	CD or DVD R/W

2.9 Grid (Recommended not included)

Item	Description
SID	100 /130/150/180 cm
Size	384mm x 460mm x 1.5mm
Ratio	10 : 1
Frequency	200 Line/inch
Inter spacer	AL

3 Detector Installation

PEDRA_1417M detector is properly adjusted at installation by a service engineer. If you encounter any problems during normal operation or daily inspections, consult your sales representative or distributor.

3.1 Preparations

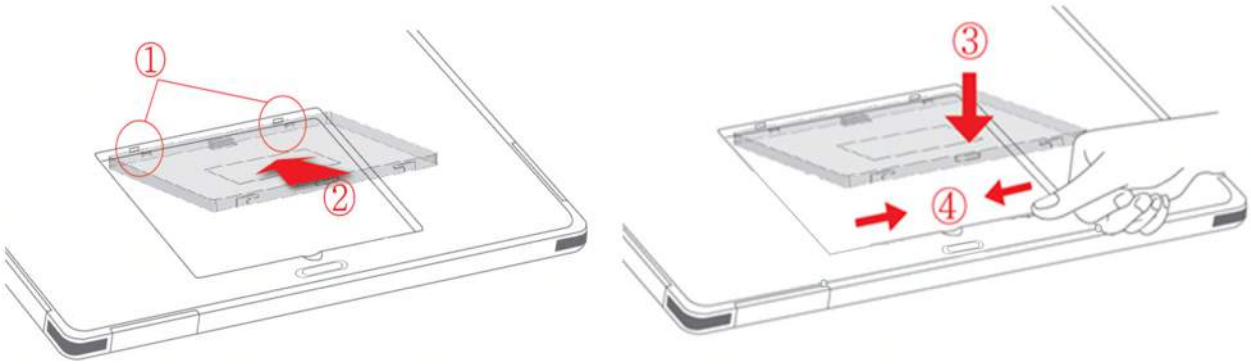
1. Charge /Attach the battery pack

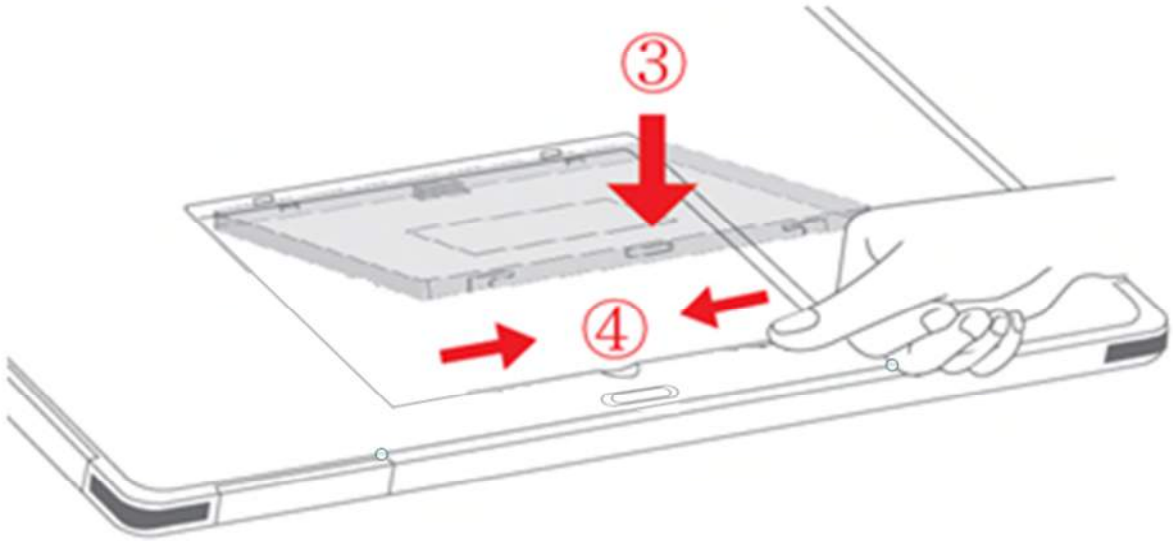
Charge the battery on the day of examination or on the previous day. Be sure to use only the dedicated battery pack for PEDRA Detector.

- How to attach the battery pack

Align the claw on the battery pack and the groove on the battery bay .Make sure that the claws on the battery pack are aligned with the groove on the battery compartment.

Slide the battery pack into the battery compartment of the detector. Push down the battery pack. Slide the battery lock lever until it clicks into place.





Caution

Make sure that the battery pack is securely attached.

The remaining battery charge can be checked on the monitor of viewer.

- You can use the detector while charging the battery by connecting tether interface.

Charging Source	Charging (quantity)	Charging Time
Charger	1 battery pack	4hrs
Tether Interface	1 battery pack	10hrs

- How to detach the battery pack

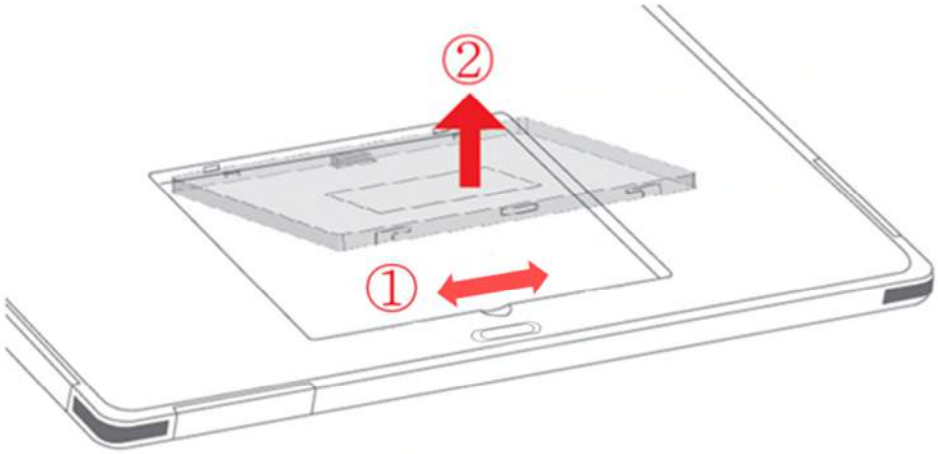
Caution

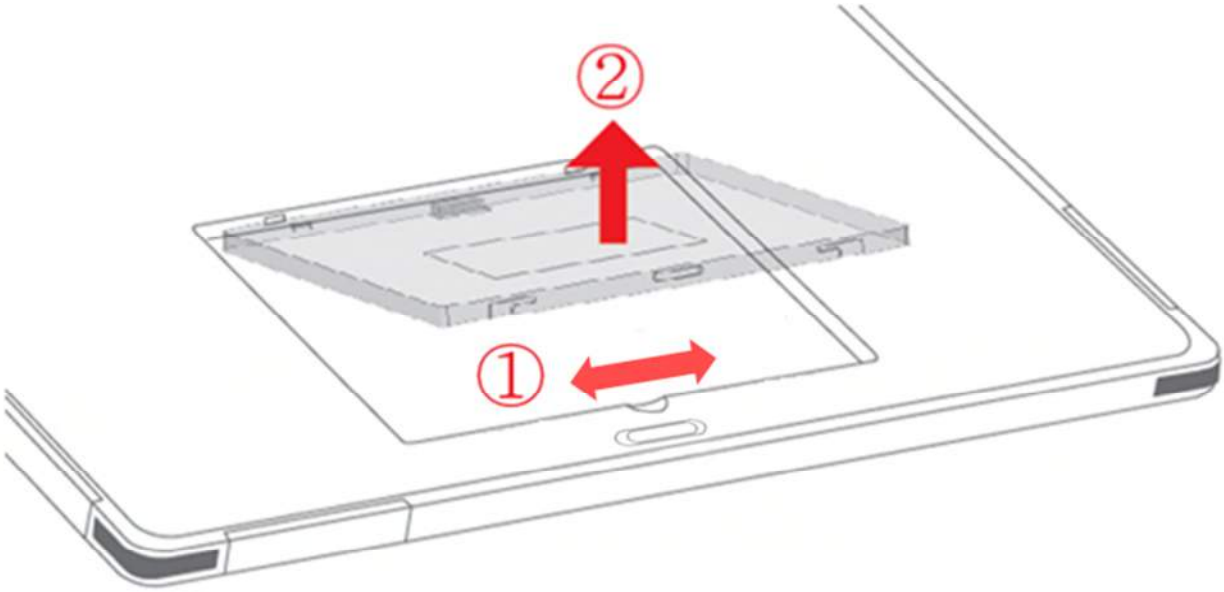
Turn off the detector

Press and hold the POWER button. (approx. 1.0 seconds) All the LED lamps are off.

- Remove the battery pack

While holding down the battery pack, slide the lock levers as shown below (unlock) (1), put your fingers on the battery pack edge that lifts up, and then pull the edge to remove the battery pack (2).





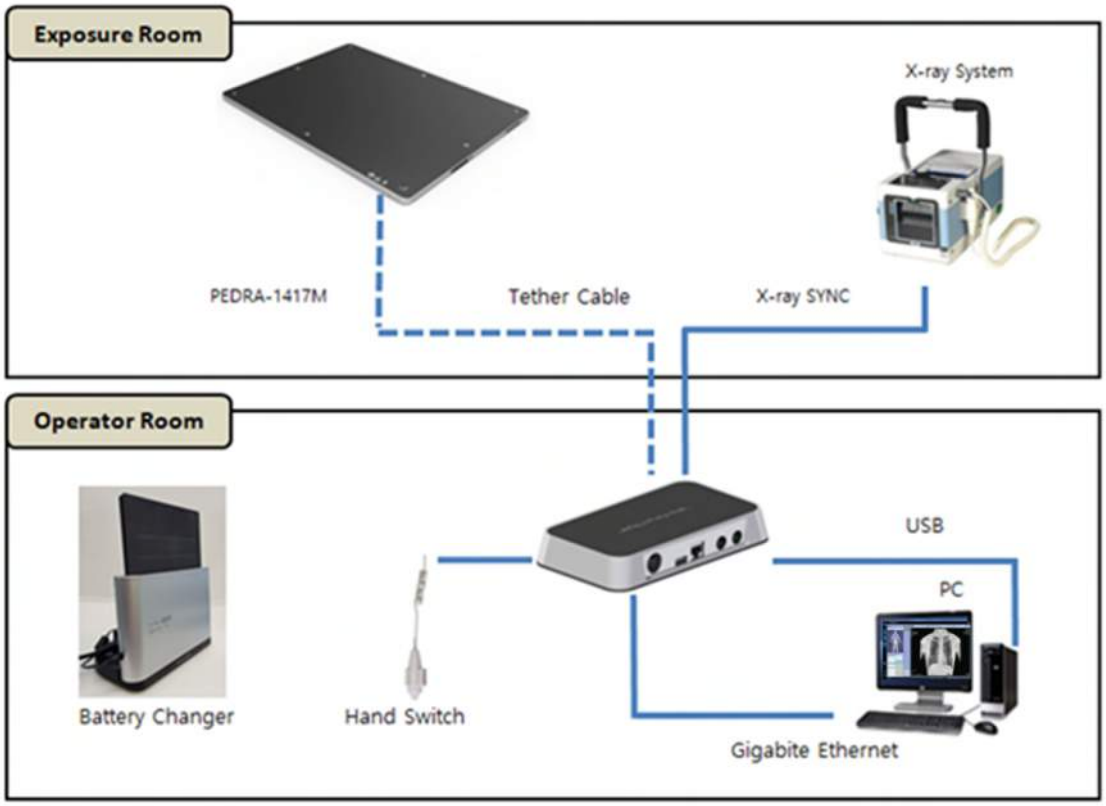
Caution

When the detector is not to be used for some time, remove the battery pack. Otherwise, over discharge may occur resulting in the shortened battery life. You can purchase an optional battery pack to replace an exhausted one.

3.2 Connection

3.2.1 Tether Connection

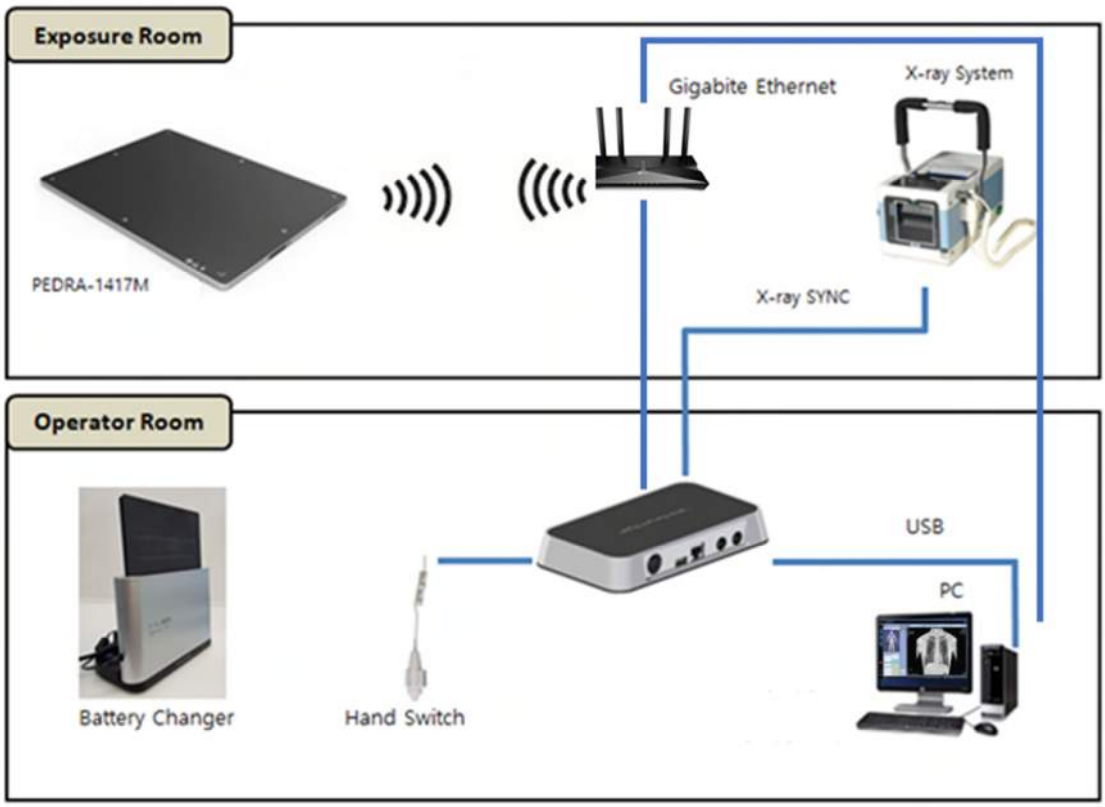
The PEDRA 1417M detector and Power box are connected with the tether cable.



Caution

PEDRA 1417M detector has a tether interface cable. With the wiring connector, it is possible to switch from a wireless configuration to a wired configuration (see the figure). Wired configuration is suitable when the detector is set in a bucky stand and table in place of a film cassette. In this configuration, for the reason that data communication and power supply are made via a cable, users do not have to be concerned about the remaining battery power and wireless communication failure. This reduces the time and labor involved in charging and replacing the battery.

3.2.2 Wireless Connection



Wireless Connection mode is the wireless connection method that connecting the detector with wifi router as the center wirelessly.

The PEDRA 1417M detector and Router are connected wirelessly. In this case, Router and Detector operate as AP (Access Point) and Station respectively.

Router, Power box, and PC are connected with the LAN cable.

The PEDRA-1417M Wireless detector is compliant with IEEE 802.11a/b/g/n (2.4 ㎓ / 5 ㎓). The available frequency band may vary depending on local radio laws and system requirements. Consult your local dealer for the frequency available in your area.

Caution	- Use of multiple WLAN devices within the same frequency band may interfere with each wireless communication and cause a decline in transmission speed. -. Do not cover or block the wireless module of the detector. Otherwise, the transmission speed or operable distance may be reduced.

3.2.3 Detector AP Connection

Detector AP mode is the wireless connection method that connecting the PC (Workstation) with the detector as the center wirelessly.

The PEDRA 1417M detector and PC are connected wirelessly. In this case, the detector and the PC operate as AP (Access Point) and STATION respectively.

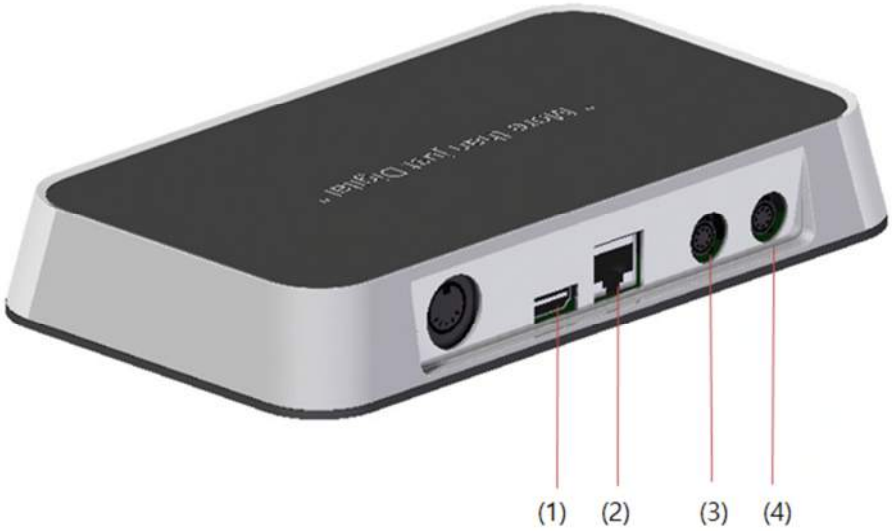
Since Powera box is not used for configuring the detector AP mode, you can only use the AED mode without a wired connection. (Cannot use the Line Trigger mode.)

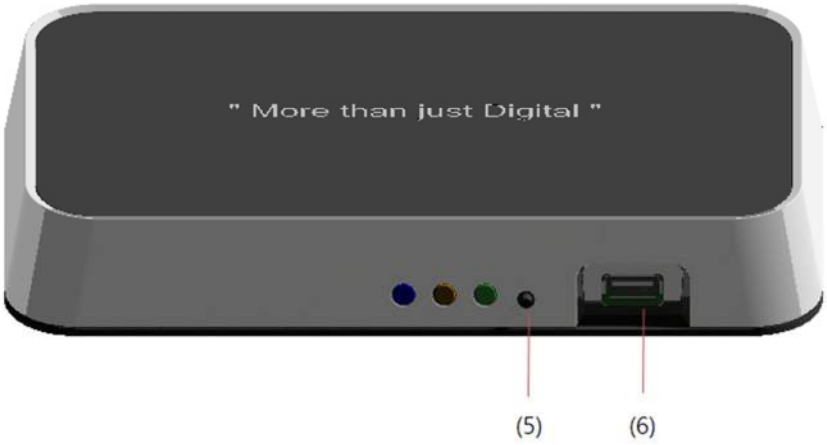
This mode can be used when mobility and portability are needed.

When configuring the detector AP mode, be sure to check the specifications of wireless module installed in the PC. The wireless communication performance can be different depending on the specifications of the wireless module.

3.3 PEDRA-PCON Connection

1) To transmit image data and generator signal using a tether cable, connect the one end of the tether cable to the PEDRA-PCON and the other to the detector.
2) Connect the one end of the LAN cable to the PEDRA-PCON, and the other to the LAN Card Connector of workstation assigned for the Data Transfer.
3) 4pin SYNC cable connects hand switch and the PEDRA-PCON. It transmits signals to control the signal from generator. It is particularly designed for manual mode.
4) Connect the one end of the generator SYNC cable, 6pin to the PEDRA-PCON, and the other to the port of the X-ray generator.
5) Detector Power On/Off switch
6) USB 2.0 cable connects work station computer and the PEDRA-PCON, transmits signals to control the signal from generator. It is particularly designed for manual mode.





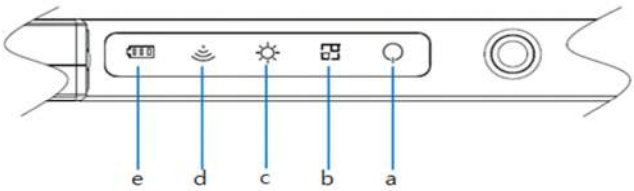
Lamp type [only for wired connection]	PCON Power	X-ray Exposure	Detector Power
Color	**Blue**	**Orange**	**Green**
a. PCON Power ON	O	X	X
b. X-ray ready & Shot	O	O	O
c. Detector Power ON	O	X	O
PCON Power OFF	X	X	X

O: Lights on X: Lights off

3.4 Turn on the detector

1. Detector status list

: Press the power button of the detector for 1.0 second, then the green LED is activated. And detector of



Green LED is activated after 40 seconds of blinking every 0.5 seconds.

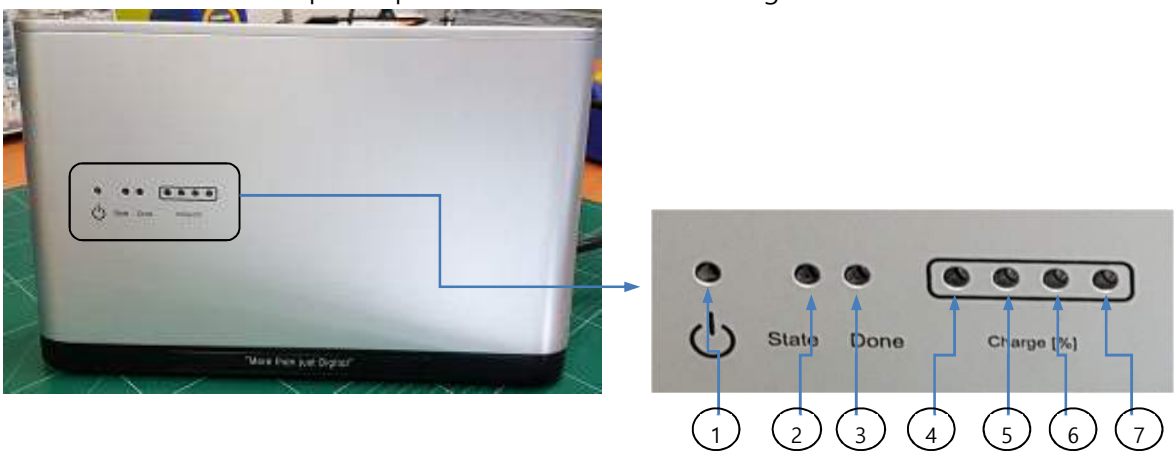
Lamp type [Wired Connection]	Lamp		Active
Color	Blue	Green	Orange
a. Power ON	O	X	X
b. Network Connection [Wired mode]	X	O	O [blinking]
c. Shooting signal of X-ray	X	O	O
d. Wifi Connection [Wireless mode]	X	X	X
e. Battery Power status	X	X	X
Power OFF	X	X	X

O: Lights on X: Lights off

Lamp type [Wireless Connection]	Lamp		Active
Color	Blue	Green	Orange
a. Power ON	O	X	X
b. Network Connection [Wired mode]	X	X	X
c. Shooting singal of X-ray	X	X	O [blinking]
d. Wifi Connection [Wireless mode]	X	O	X
e. Battery Power status	X	O	X
Power OFF	X	X	X

3.5 Turn on the Battery Charger

1) Connector for Power adapter is positioned on left side of charger.



No.	Description	Power lamp	Function
1	DC Input power (Blue)	O	15Vdc 4A(Max)
2	Status LED (Green)	O	Charging is on going
3	Done LED (Orange) 100%	O	Charging done
4	LED1 (Green) 20%	O	When charging, LED On
5	LED2 (Green) 40%	O	When charging, LED On
6	LED3 (Green) 60%	O	When charging, LED On
7	LED4 (Green) 80%	O	When charging, LED On

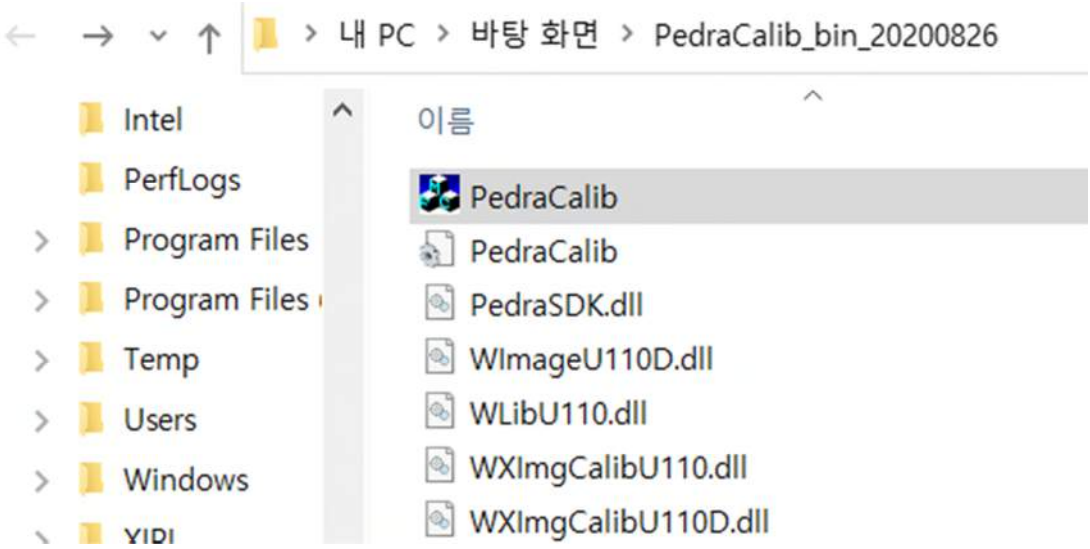
4 Detector Operation S/W Setting (PEDRA-DMS)

Caution	Allow the detector for at least 30 minutes to warm up before use for maximum performance. Otherwise, it may result in faulty images until warm up has occurred.

4.1 Installation

It needs to Copy 'PedraCalib' folder from the 'PEDRA CD' to the workstation computer.

1. "PedraCalib.ZIP" file in the PEDRA CD needs to copy in the directory of PEDRA, and release the ZIP file.
2. "PEDRA.exe", PEDRA_MODULE.DLL" file is activated in the PEDRA folder.

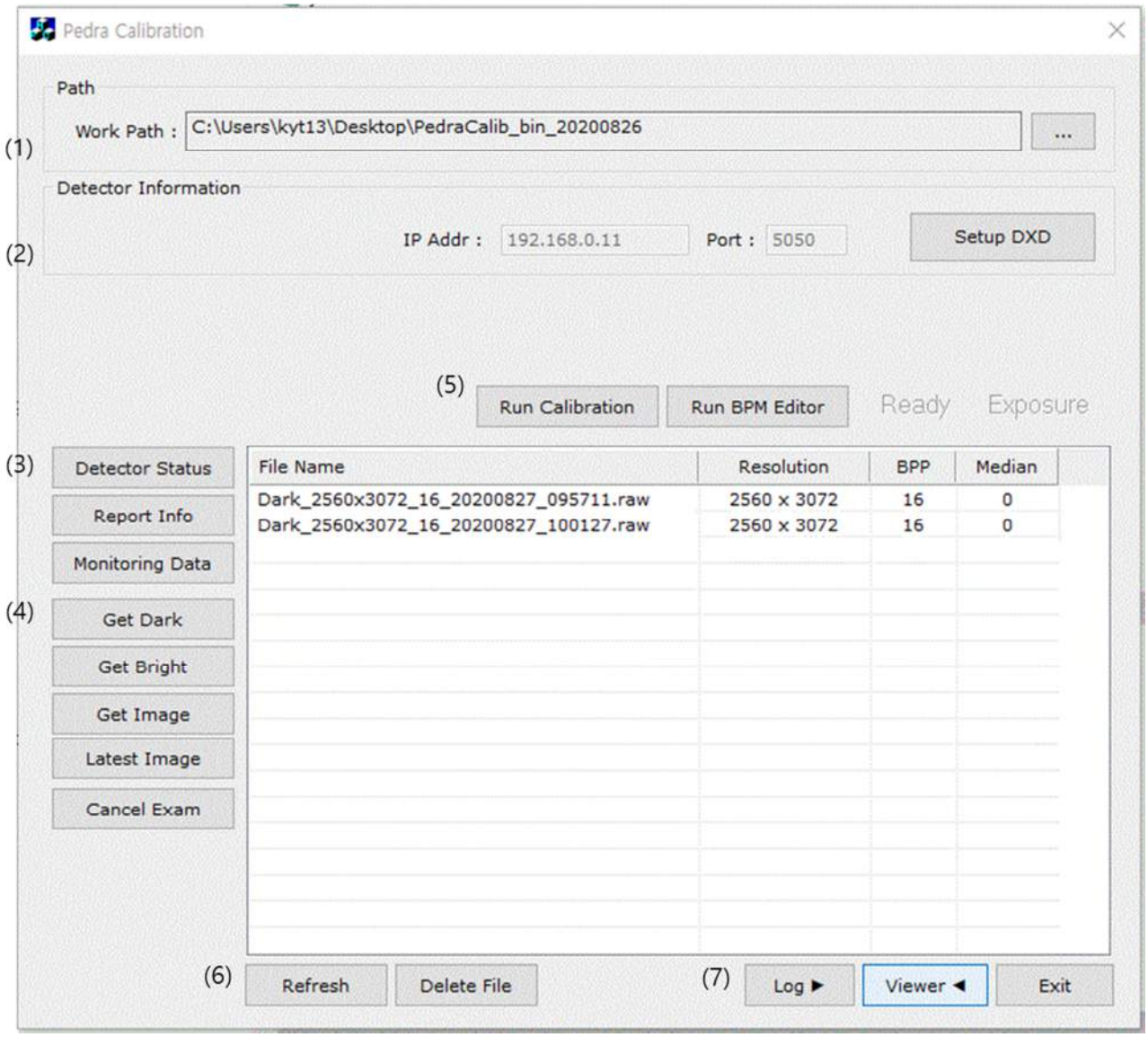


3. After installation the acquired clinical image files are stored as "PEDRA__date_number of frame.raw" at the same folder, as well as bellow files.

   - Dark.raw, bright.raw, bpm.raw files are also activated for image calibration.
   - The log file of PEDRA detector for operating is stored at the "log.ini" file.

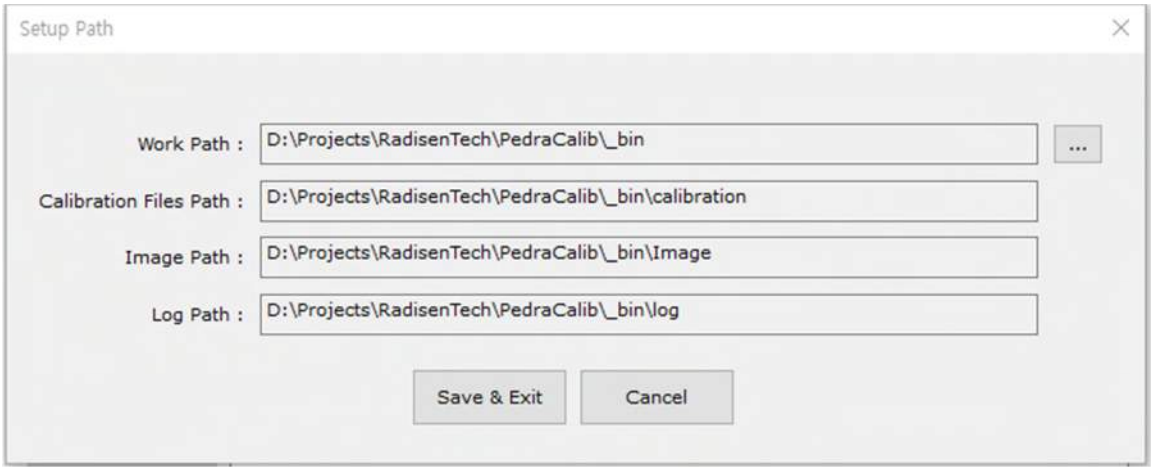
4.2 PEDRA Detector Manager

The set-up of PEDRA Detector Manager Software (hereinafter "PedraCalib") Manager is necessary for the operation of PEDRA Series.



(1) Path setting

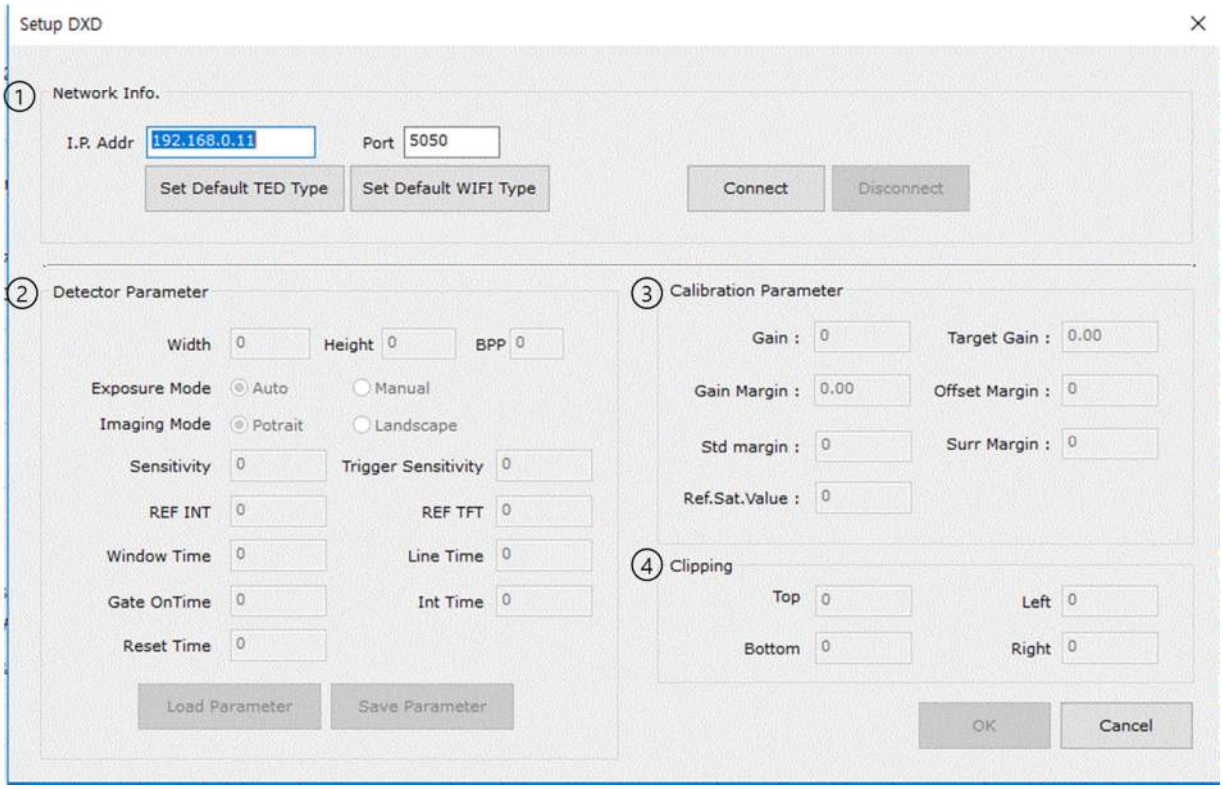
User can set work folder.



Calibration, image, log folders are automatically created in the set work folder. Calibration files are saved in the calibration folder. (dark, bright, BPM) The exposured image is saved in the image folder. Logs are saved in the log folder.

(2) Detector information

IP address & Port are displayed. User can detector set when you click



①Network Info

- IP Addr : input detector IP address
- Port : input detector Port
-

: If user use a wired detector, user can automatically call up the default IP and Port settings.
-

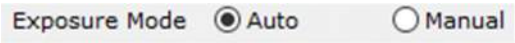
: If user use a wifi detector, user can automatically call up the default IP and port settings.
-

: User can Connect detector.
-

: If the detector is connected, it can be disconnected.

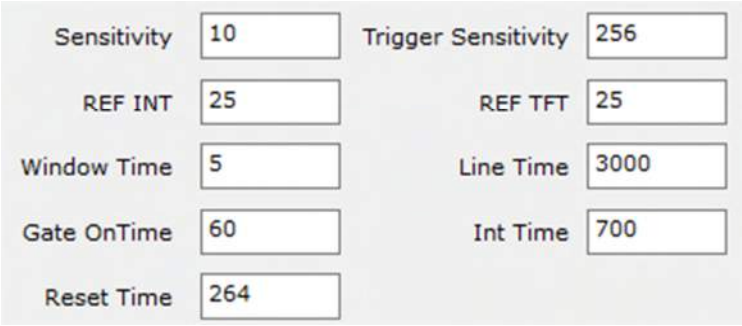
②Detector Parameter

- Detector resolution & bit



- Use AED or Manual mde (image can be acquired to Hand Switch connection with PEDRA-PCON)

- image rotate by CW +90



- Detector advanced setting (do not set in normal user)

-

: Get Detector parameter from Detector
-

: Send Detector parameter to detector

③Calibration Prameter

- Calibration advanced setting (do not set in normal user)

④Clipping

- Sets effective area of an image.

(3) Detector status check

User can check dectector status (detector temp., wifi strength, battery level)

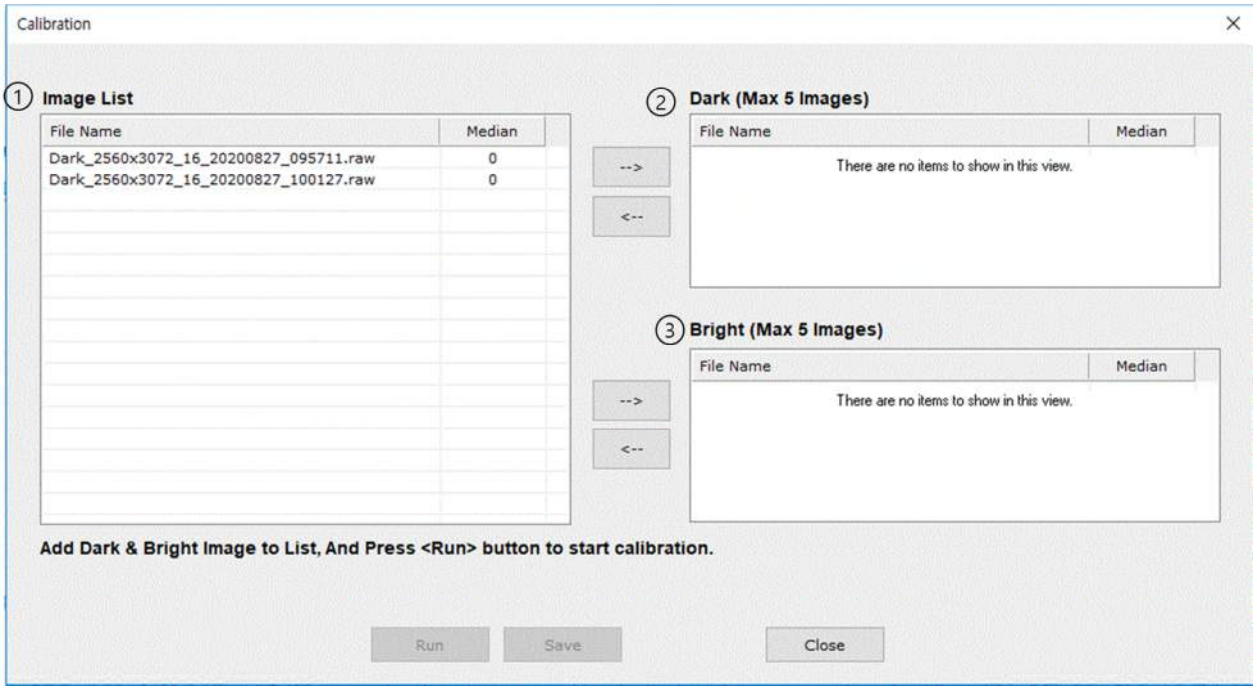
- Detector Status : User can check Detector status
- Report Info : User can check Detector log
- Monitoring Data : User can check Detector status check data

(4) Get image for calibration

- Get Dark : Get a dark image for offset calibration.
- Get Bright : Get a Bright image for gain calibration. When you click the button detector ready for get X-ray image Ready Exposure → Ready Exposure
- Get Image : Get a raw image for image check.
- Latest Image : Call the last raw image.
- Cancel Exam : Cancel calibration.

(5) RUN Calibration

- A calibration file (BPM) is created using the saved dark and bright files.
- if user need to add bad pixel or line, user can clear.
- Run Calibration : user can make calibration.

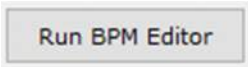


① Image list
- saved image list from dark & bright files

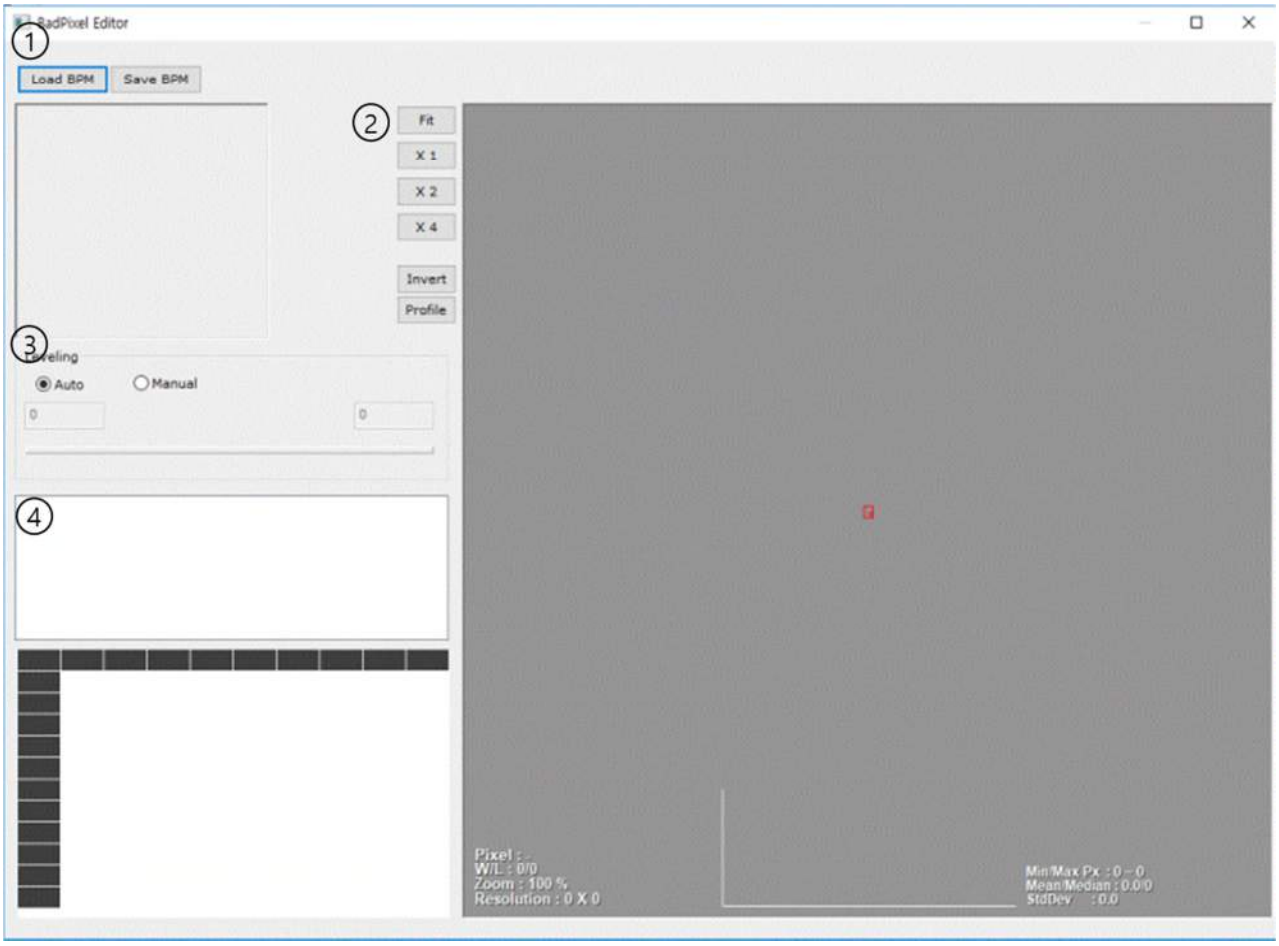
② Selected Dark files
- Dark files, selected from the dark files acquired by the user for calibration. User can select up to five for calibration.

③ Selected Bright files
- Bright files, selected from the bright files acquired by the user for calibration. User can select up to five for calibration.

After select dark & bright files, user can make BPM file when click Run.

- 

: User can delete bad pixel or line.



① Load BPM & Save BPM

- Load the BPM file that needs to be modified, or save the modified file.

② image tools

- User can adjust zoom

③ clear bad pixel

- User can add or delete defect pixel Auto or manually for calibration.

④ bad pixel location

- User can check bad pixel location.

(6) Refresh & Delete file

- Refresh : Refresh the list
- Delete File : Delete the selected dark or bright files

(7) Log & Image view

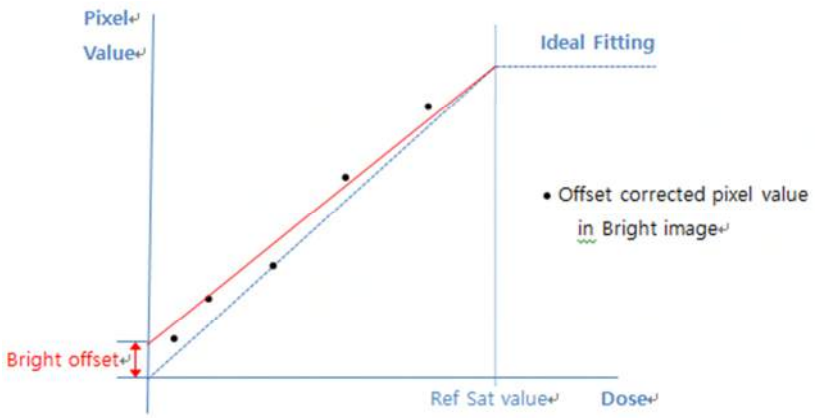
- Log ▶ User can check the PEDRACalib's log. (Click once more to disappear.)
- Viewer ◀ : User can check the dark or bright image. (Click once more to disappear.)
- Exit : Exit the PEDRACalib.

4.3 Calibration Procedure

For calibration implementing, Manual or AED mode needs to be selected to acquire the secure image, dark and bright.

To calibrate image, the five bright images are needed at five different levels of median values to be adjusted the KVP.

The values of bright image is as below for the five images.

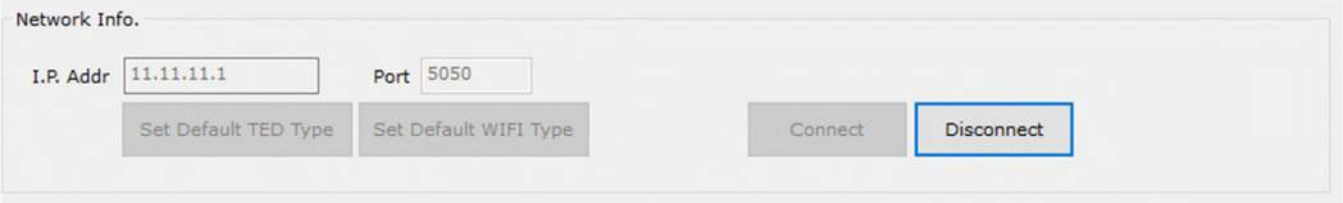


Point	Offset	1	2	3	4	5
Bright Value[LSB]	Offset Pixel value	Offset + (14000~16000)	Offset + (24000~26000)	Offset + (34000~36000)	Offset + (44000~46000)	Offset + (54000~56000)

Table 1: Bright value

Step 0.

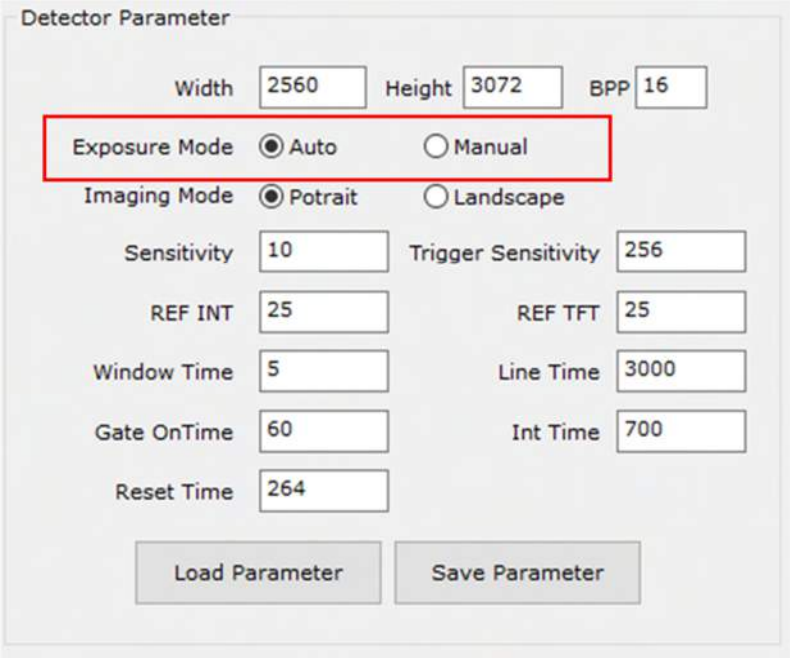
Connect detector



Input detector IP & port then Connect.

Step 1.

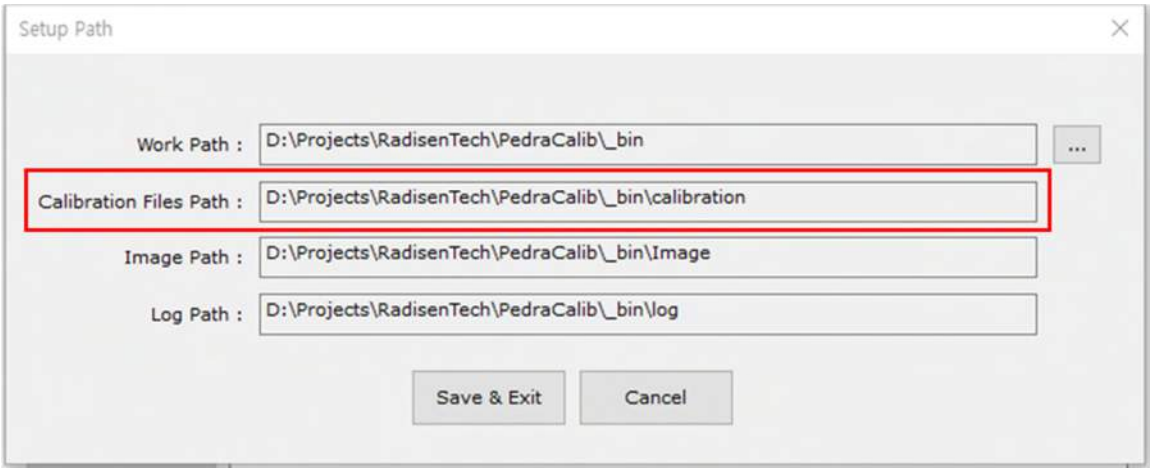
Selection of AED mode: For more detail information, refer to AED mode configuration, chapter, 5.2.



Step 2.

Click the "

" button to start acquire Dark Image from the detector. The Dark Image will save as Dark_image resolution_bit_YYYYMMDD_HHMMSS.raw (The acquired dark frame will be generated in the selected folder.) Dark image will be acquired 5 images.



Step 3.

After Step3, Click the "Get Bright" button

The X-ray condition should be set or tested beforehand, Click the "Get Bright" (The acquired Bright frame "Bright_ image resolution_bit_bright value.raw" will be generated in the selected folder.)

Bright value [LSB] is descrived on the "table 1" and then it will be acquired 5 different level of bright images.

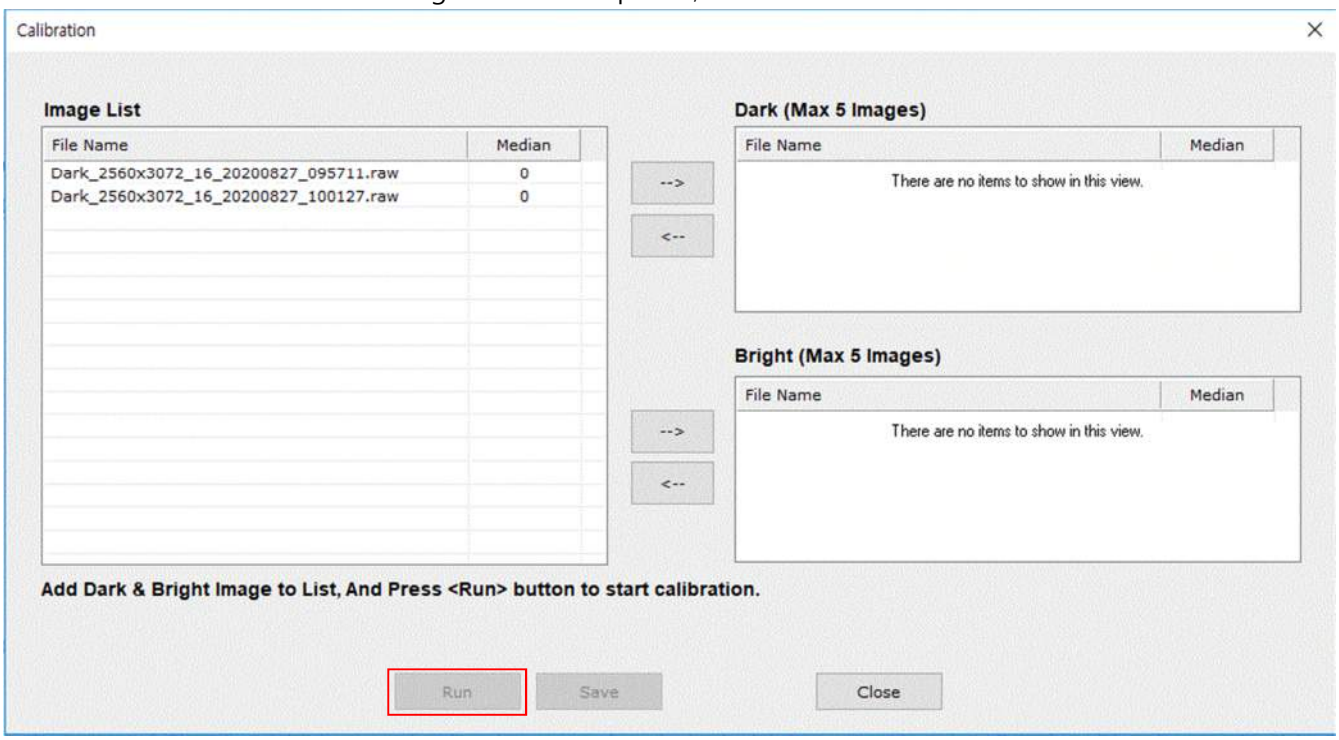
Step 4.

After Step3, Click the "Run Calibration" button

Select the desired Dark file and 5 Bright files each, and click →.

If you want to cancel the selection, select the file and click ←.

When the selection of dark and bright files is completed, click "RUN" to create the BPM file.



Step 5.

Getting raw image: Select the AED or Manual mode and shoot the X-ray using the "Hand switch or shoot button on the X-ray Generator.

The way of the image acquiring is referenced to AED or Manual mode operating, chapter 5.2 and 5.3.

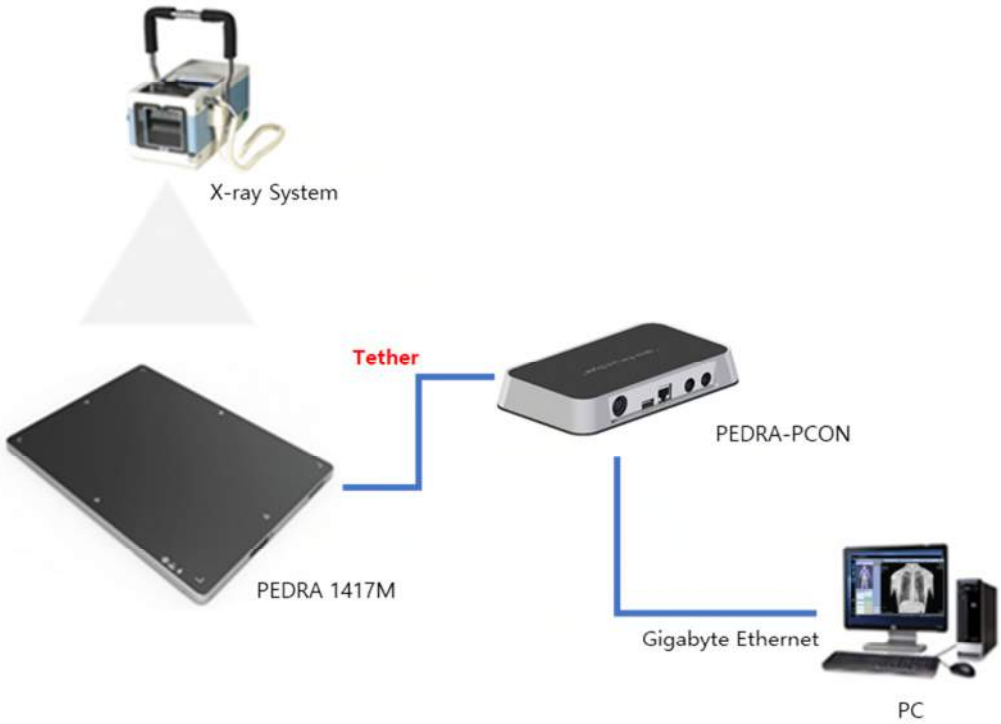
5 Operation

5.1 Wireless Standard Configuration and Operation

Generally, the PEDRA detector is used in a wireless configuration as illustrated below:

Wireless communication is established between the PEDRA detector and Router. The PEDRA detector is compliant with IEEE 802.11 a/b/g/n (2.4 GHz / 5 GHz). The available frequency band may vary depending on local radio laws and system requirements. Consult your distributor for the frequency available in your area. Appendix.2 is showing the method how to set up the default IP address.

5.2 AED Mode Configuration and Operation in wired mode



AED mode is available for acquiring images without any connection to the X-ray generator with an X-ray SYNC cable

The way of image acquiring is as follows;

1) Selection of AED mode
2) Shoot the X-ray using hand switch of X-ray generator.

Caution	• Make sure to follow operating environmental requirements (Temp: 10℃ ~ +40℃) • If you use AED Mode out of operating environmental requirements, unwanted image can be acquired without X-ray image acquiring. • Do not hit or drop the equipment. Unwanted images may be acquired in the AED Mode if it receives strong jolt. • If you use a Grid under general imaging condition (Dose) or image a thick object in the AED Mode, the efficiency of X-ray transformation may be reduced about 0% ~ 2% compared to the Manual Mode according to the thickness of the target. • If you image a thick object in the AED Mode with low X-ray tube voltage, an image may not be acquired or horizontal line noise may occur.

5.3 Manual Mode Configuration and Operation in wired mode

Hand switch is connected with the PEDRA-PCON to communicate with the PC via USB cable. Manual Mode is option to shoot the X-ray with Hand switch.

Manual mode is a wired connection with tether cable and USB cable to communicate with PC via LAN cable. The way of image acquiring is follows,

1) Selection of Manual mode
2) Shoot the X-ray using hand switch (Option part) of PEDRA-PCON.

5.4 Detector AP Configuration and Operation

Generally, the detector AP mode is used in a wireless configuration as illustrated below:

Wireless communication is established between the PEDRA detector and PC. The PEDRA detector is compliant with IEEE 802.11 a/b/g/n (2.4 ㎓ / 5 ㎓). The available frequency band may vary depending on local radio laws and system requirements. Consult your distributor for the frequency available in your area. Appendix.2 is showing the method how to set up the default IP address.

6 Troubleshooting

6.1 General

When you encounter problems or error messages while using this equipment, search 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 problem or error messages.

Caution	Troubleshooting must be performed by a technician who is trained by Radisen or an organization certified by Radisen. If an unqualified person performs troubleshooting on the system resulting in damaging the detector, software or hardware, then Radisen or its representatives are not responsible for the detector repair regardless of remaining warranty. For more detailed information, refer to "Warranty". (p.58)

6.2 Detector

Symptom	Cause	Remedy
Power (Blue) LED does not light up	The communication circuit is not secured.	Check if tether cable is securely plugged and power switch of detector is turned on. If it still does not work, replace the detector.
Network (Green) LED does not light up	The network communication is not secured	Check if LAN cable is securely plugged

6.3 Power& Control Box (PEDRA-PCON)

Symptom	Cause	Remedy
Power (Blue) LED does not light up	The communication circuit is not secured.	Check if Adapter is securely plugged in. If it still does not work, replace the PCON

6.4 Battery Charger

Symptom	Cause	Remedy
Power (Blue) LED does not light up	The communication circuit is not secured.	Check if Adapter is securely plugged in. If it still does not work, replace the Charger or check its Adapter.

7 Maintenance

In order to ensure that the device is used safely and normally, be sure to inspect the device before use. If any problem is found during the inspection and cannot be corrected, please contact your sales representative or a distributor.

■ Daily inspection

Caution	For safety reasons, be sure to turn OFF the power to each piece of device before attempting the following. Otherwise, an electric shock may result.

- Cable
  1) Ensure that cables are not damaged and cable jackets are not torn.
  2) Ensure that the power cord plugs are securely connected to both the device AC inlet and the AC outlet.
- Detector
  1) Ensure that there are no loose screws or breaks.
  2) Ensure that there is no dust or foreign matter on the detector surface and connectors.

Caution	Federal law restricts this device to be dealt or operated by a physician or medical assistant.

■ Cleaning

Use a dry cloth to clean surfaces of the device. Do not use detergents or organic solvents to clean the device.

Caution	Do not use abrasive brush, scraper, or acid/alkaline cleaner when cleaning your product.

■ Function test

Item	Period	Description
Power consumption	Daily	Confirm that the power operation of detector is normal.
Temperature	Daily	Check the monitoring in order to minimize the characteristic changes of Flat panel caused by external temperature changes.
Hard disk space	Daily	Check if the hard disk is enough to save images and allow the consecutive shootings.
Resolution	Monthly	Confirm the resolution of the detector.
Image Acquisition Time	Monthly	Confirm the acquisition of time required to get image designed with optimal specifications.
Linearity	Quarterly	Evaluate the distinct characteristics of detector through the amount of radiation coming into Flat Panel Detector, resolution and contrast of images/projections, and the unification of noises of projection.
DQE	Quarterly	Evaluate the distinct characteristics of detector through the amount of radiation coming into Flat Panel Detector, resolution and contrast of images/projections, and the unification of noises of projection.
MTF	Quarterly	Evaluate the distinct characteristics of detector through the amount of radiation coming into Flat Panel Detector, resolution and contrast of images/projections, and the unification of noises of projection.
Calibration	Annually	Compensates defect pixels and calibrates pixel gain using the installed X-ray generator and X-ray tube.

8 Information

8.1 Service information

Product lifetime

The estimated product lifetime may be up to five (3) years under appropriate regular inspection and maintenance.

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.

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:

Product name:	PEDRA Wireless Detector
Serial number:	11-digit number indicated on the name label
Description of problem:	In as much detail as possible

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.

8.2 Warranty

Radisen warrants that this product will be free from defects in materials and workmanship for a period of two (2) years from the date of delivery. If any such product proves defective during this warranty period, Radisen 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 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 Radisen with shipping charges prepaid.

This warranty shall not apply to any defect, failure, or damage caused by improper or inadequate maintenance and care. Radisen shall not be obligated to furnish service under this warranty to repair damage resulting from attempts by personnel other than Radisen 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.

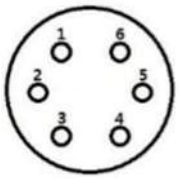
9 Revision History

Revision	Date	Descriptions
0.0	2020.07.25	Initial Release

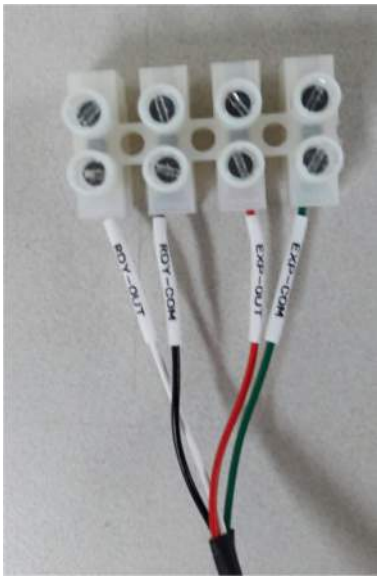
Annex.1 Generator Interface

1. X-ray SYNC

Connect the X-ray SYNC cable to the PEDRA-PCON, 6pin SYNC and the X-ray generator.



PIN	DESCRIPTION
1	RDY_OUT
2	RDY_COM
3	
4	
5	EXP_OUT
6	EXP_COM



2. Tether Cable Pin assignment

Tether Cable is female connector to connect between Detector and PEDRA-PCON.

Pin Number	Description	Pin Number	Description
1	MX4+	2	GND
3	MX4-	4	MX3+
5	GND	6	MX3-
7	MX2+	8	GND
9	MX2-	10	MX1+
11	DC_15V	12	MX1-
13	DC_15V	14	DC_15V
15	READ_OUT	16	EXPOSURE_OUT
17	GND	18	DC_15V
19	GND		

Appendix.2 Detector IP setting

1. Default IP address wired or wireless configuration if the connection is unstable or setting value information is not clear when you intend to change it.

	Wire Mode	Wireless HUB Mode	Wireless Access point Mode
PC	192.168.0.55	-	-
Subnet Mask	255.255.255.0	255.255.255.0	-
PEDRA	192.168.0.11	192.168.0.11	11.11.11.1

2. Change of network setting

: Network information can be changed using USB memory stick as follow.

1) Change Network information of the "network.ini" Text file.

2) Store changed network information to the USB memory stick.

3) Insert USB memory stick to the PEDRA detector.

4) Network information changed automatically.

If there is # in front of the text, it will be deactivated

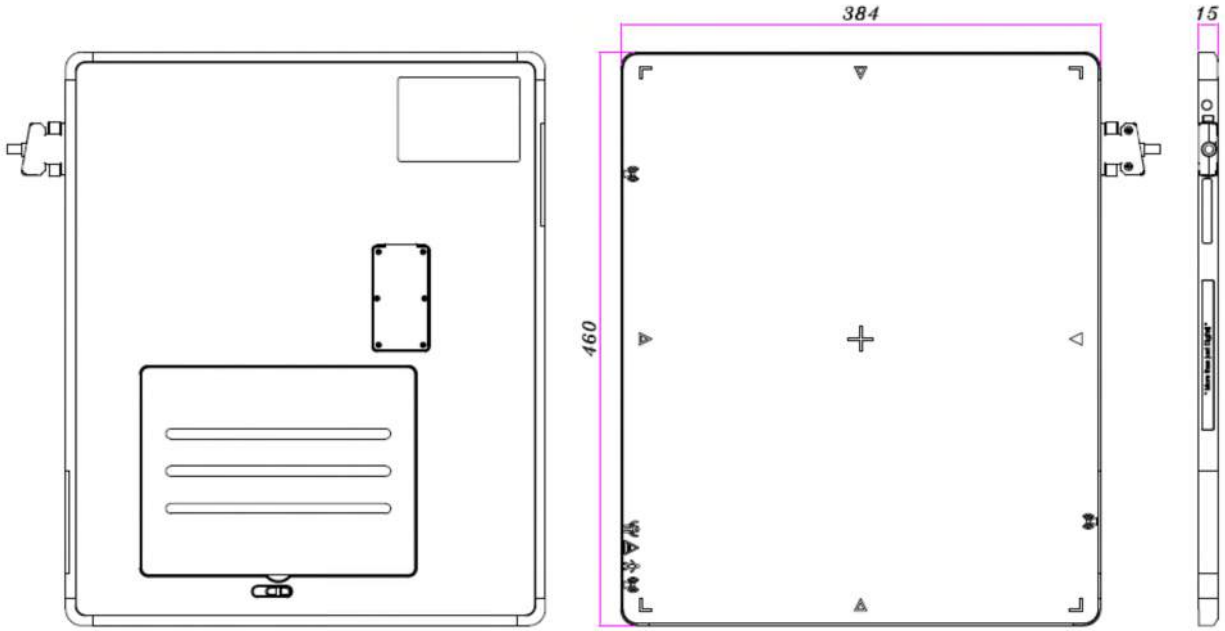
Appendix.3 Specifications

1. PEDRA-1417M Specifications

Model & Parameters		PEDRA-1417MG	PEDRA-1417MC
Scintillator		GD_2O_2S:Tb	CsI:Tl (Direct)
Sensor	Pixel size	140um, a-Si TFT active matrix with PIN diode	
	Pixel Matrix	2500 x 3052	
	Effective Area	350.0 x 427.0 mm	
Image performance	Spatial Resolution	3.4 lp/mm	
	ADC Resolution	16 bits	
	Grayscale	65536 grayscales	
	x-ray voltage Range	40 ~ 150 Kvp	
	X-ray Generator Interface	Line Trigger(Manual)/ Auto Trigger(AED Mode)	
	Shot Mode	Single / Multi	
	MTF	>70% at 0.5lp/mm (GdOS)	>77% at 0.5lp/mm (CsI)
	DQE	>20% at 1lp/mm (GdOS)	>57% at 1lp/mm (CsI)
	Image Acquisition Time	2.5 sec	
Mechanical	Weight	GD_2O_2S:Tb / 3.10 Kg	CsI / 3.20 kg
	Dimensions	Meet ISO4090 for 35x43 (14x17") cassette size (384x460x15mm)	
Communications	Wired	Giga Ethernet (1000BaseT)	
	Wireless	IEEE802.11n/2.4 or 5Gbps	
	Sync. Out Port	2 port / TTL(0~5.0V)	
	Operation Software (Console S/W)	Window 7,8,10 Support for 32/64bits Windows	
Power/ Environment	Wired	DC +15V	
	Wireless	Max. 1 Pack(Battery/12.6V/ 3.5 hour)	
	Environment	T(10~+40)/H(20 ~ 75%)/P(70~106KPa)	

* Specifications are subject to change without prior notification

2. PEDRA-17F Dimensional diagram

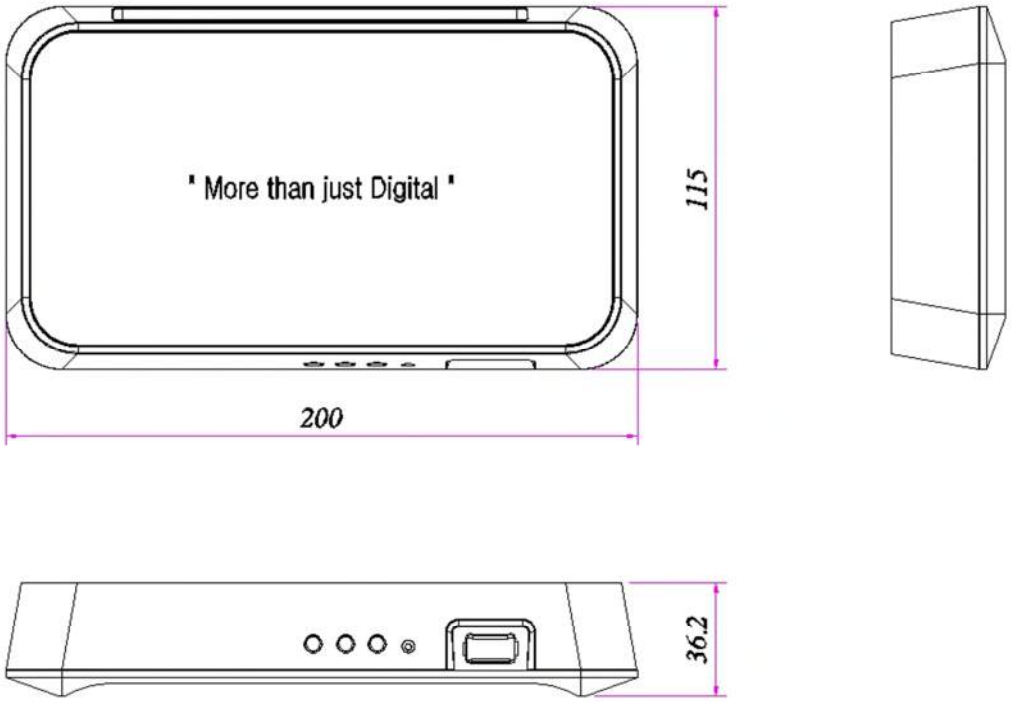


Unit: mm

3. PEDRA-PCON

Item	Description
AC/DC Adapter	Input: 100-240VAC~, 47~63Hz, 1.62-0.72 A Output: DC+15V /4.2A (max)
Cabling Ports	Gigabit Ethernet Ports –1EA USB port - 1EA X-ray SYNC - 1EA HAND switch – 1EA
Dimensions (W ×H ×D)	200 ㎜×115 ㎜×36.2 ㎜
Weight	0.50kg

Dimensional diagram

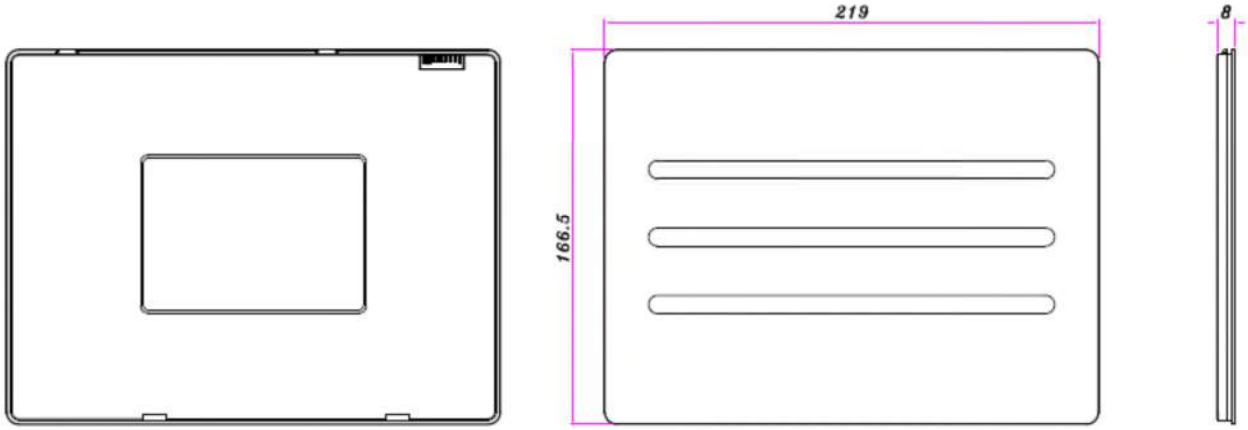


Unit: mm

4. Battery Pack

This dedicated battery pack is necessary for PEDRA wireless detector.

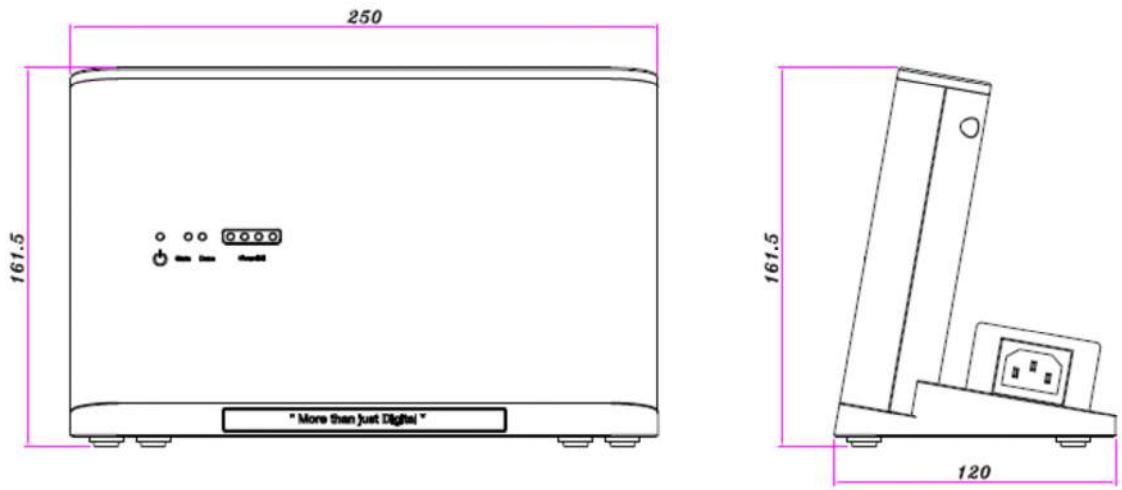
Item	Description
Model	PEDRA-BT001
Type	Lithium Polymer
Rated Power Supply	Output: DC +7.58V
Capacity	4000mAh
Number of Cell	3S1P (3 Series 1 Parallel)
Life	Approx. 500 times (charge/discharge 1cycle)
Dimension (W ×H ×D)	219 mm×166.5 mm×8.0 mm
Weight	0.30kg



5. Battery Charger

Item	Description
Model	PEDRA-BACH001
Charging	1 battery packs
Charging Time	2.5 hours
Rated Power Supply	Input: 100-240V~, 50/60Hz, 1.5 A Output: DC 15V, 4.0A
Dimension (W ×H ×D)	250.0 ㎜×120.0 ㎜×161.5 ㎜
Weight	0.6 kg

Dimensional diagram (Battery Charger)

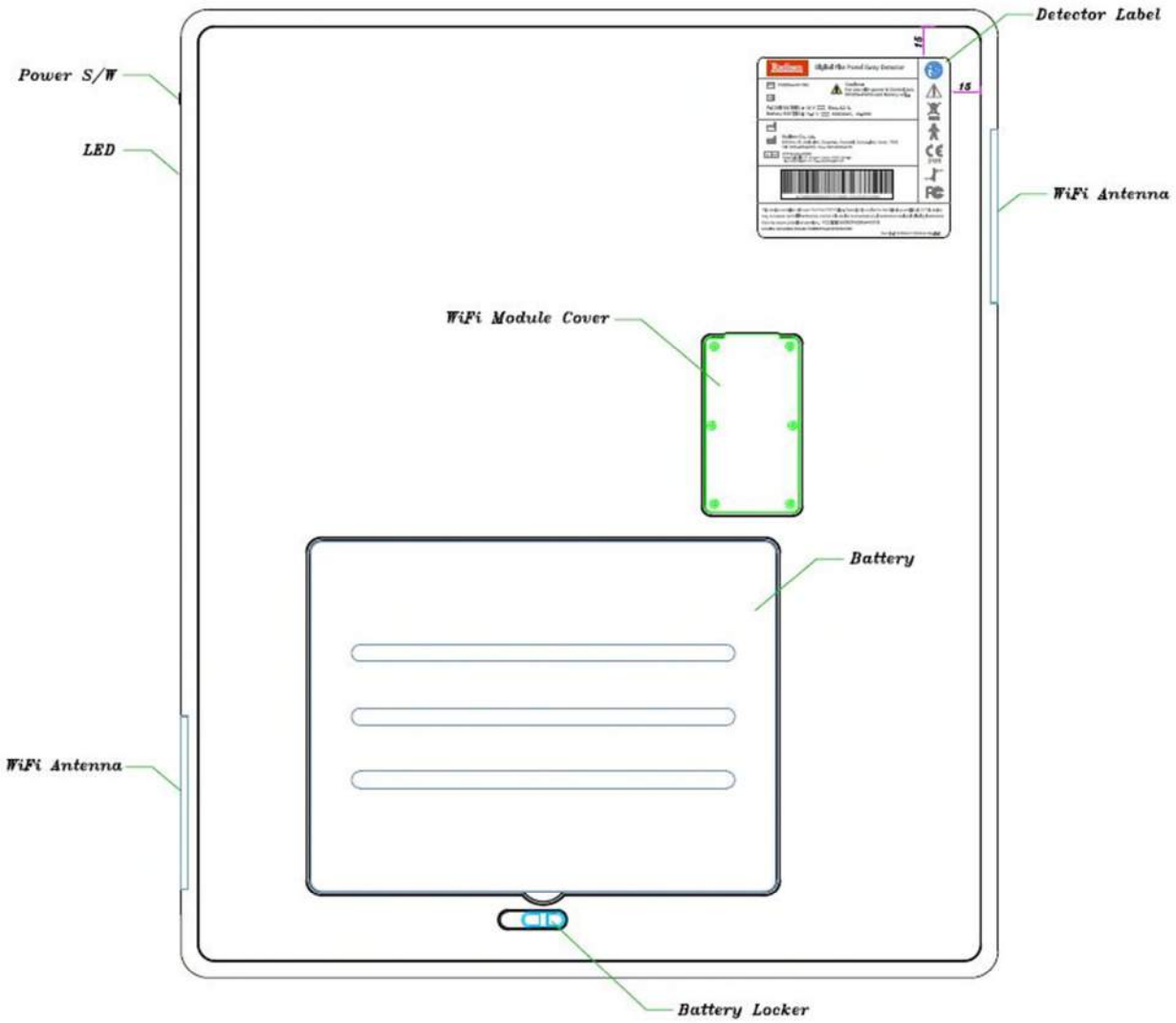


Appendix.4 Label and Symbols

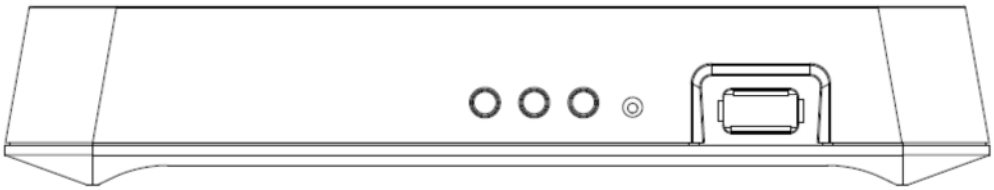
PEDRA detector and other components have labels and markings on them.

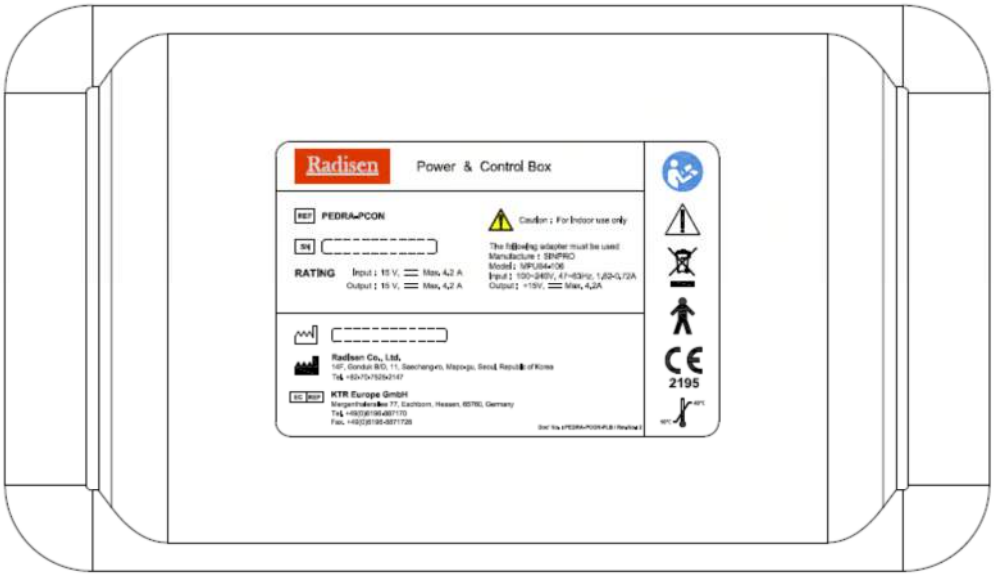
Their contents and locations are indicated below.

1. Detector



2. Power & Control Box (PEDRA-PCON)





3. Battery Charger

4. Battery Pack

5. Shipment Label

• **Out box**

Radisen

PEDRA Detector (Wireless) Digital Flat Panel X-ray Detector

Part Name	Model	Q'ty	S/N
1. Flat Panel Detector	PEDRA-1417MG [V]	1 PC	C0GFDDG1002
	PEDRA-1417MC [ ]		
2. Power Supply	PEDRA-PCON	1 PC	PC1M0DF002
3. Battery Charger	PEDRA-BACH001	1 PC	PC1M0DF002
4. Battery	PEDRA-BT001	2 PC	PC1M0DF002, PC1M0DF002

Date of Manufacture : JUN, 2019
Weight kg

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

Radisen Co., Ltd.
B/602-ho, 66, Beolmai-ro, Dongan-gu, Anyang-si, Gyeonggi-do, Korea, 14058
Tel. +8231-8084-9762 / Fax. +8231-8084-9763
Website : www.radisentech.com

Annex . 5 Regulatory Information

1. Medical equipment safety standards

■ Medical Equipment Classification

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	IPXO
Mode of operation	Continuous operation
Flammable anesthetics	NOT suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide

■ Product Safety Standards

- **U.S.A and Canada**

IEC 60601-1(ed.2 am1+am2+ co1)	Medical electrical equipment-Part1: General requirements for safety
UL 60601-1(ed.1)	
CSA-C22.2 No. 601-1-M90(R2006)	(R2006) Medical electrical equipment –Part1: General requirements for safety (adopted amendment 2:1995 to IEC 601-1:1990)
IEC 60601-1-2: 2007(ed.3)	Medical electrical equipment-Part 1-2: Collateral standard: Electromagnetic compatibility
IEC 62304:2006-Ed.1.0	Medical device software-software life cycle processes
EN ISO 14971:2012	Medical Device-Application of risk management to medical devices

- **European Union**

MDD (93/42/EEC)	Medical Device Directive
EN ISO 13485:2012+AC:2012	Medical devices –Quality Management systems –Requirements for regulatory purposes
EN 60601-1: 2006	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 62304:2006	Medical device software-Software life cycle processes
EN ISO 14971: 2012	Medical device –Application of risk management to medical devices

Annex .6 Serial Number (S/N) composition

The serial numbers for each product and accessory are composed as follows;

Product

M	0	G	F	A	A	H	1	0	0	1
Model Code (Fixed)	Rev	Sensor Type	Type Code	Secret Code	Year	Month	Place Code	Serial number		

Accessory

PC/CH/BT	1	M	0	A	H	0	0	1
Model Code	Series	Components	Rev	Year	Month	Serial number		

1. Range of serial number

- 001 to 999.

2. How to apply revision number

: Apply from'1.0' according to a change of design sequentially.

3. Initials per year

2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
A	B	C	D	E	F	G	H	I	J	K	L

4. Secret code

2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
A	B	C	D	E	F	G	H	I	J	K	L

5. Initial per month

1	2	3	4	5	6	7	8	9	10	11	12
A	B	C	D	E	F	G	H	I	J	K	L

6. Sensor type : "C" →CsI "G" →GdOS

7. Type code : "M" → Mobile "F" → Fixed

8. Place code : "1" → Republic of Korea "2" →Outside the Republic of Korea

9. Composition of serial number for each item

Item	Serial No.
PEDRA-1417FG (GdOS, Fixed Type Detector)	M0GFAAH1001
PEDRA-1417FC (CsI, Fixed Type Detector)	M0CFAAH1001
PEDRA-1417MC (CsI, Mobile Type Detector)	M0CMAAH1001
PEDRA-1417MG (GdOS, Mobile Type Detector)	M0GMAAH1001
PEDRA-PCON (Power Supply & Control Box)	PC1M0AH001
PEDRA-BACH001 (Battery Charger)	CH1M0AH001
PEDRA-BT001 (Battery Pack)	BT1M0AH001

Annex .7 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.

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 –Guidance
RF Emissions CISPR 11	Group 1	The EUT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

"WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the PEDRA-1417M, including cables specified by the manufacturer.
Otherwise, degradation of the performance of this equipment could result."
"WARNING: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals
(CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to
take mitigation measures, such as relocating or re-orienting the equipment."

Electromagnetic Immunity

The PEDRA is intended for use in the electromagnetic environment specified below. The customer or user of this device should assure that it is used in such an environment.

Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Test level/requirement
Mains terminal disturbance voltage	CISPR11:2015	Operating	AC Mains	120 V, 60 Hz 220 V, 60 Hz 230 V,50 Hz	Group1, Class A
Radiated disturbance	CISPR11:2015	Operating	Enclosure	120 V, 60 Hz 220 V, 60 Hz 230 V,50 Hz	Group1, Class A
Harmonic Current Emission	EN 61000-3-2:2014 IEC 61000-3-2:2014	Operating	AC Mains	230 V,50 Hz	Class A
Voltage change, Voltage fluctuations and Flicker Emission	EN 61000-3-3:2013 IEC 61000-3-3:2013	Operating Stand by	AC Mains	230 V,50 Hz	Pst: 1 Plt: 0.65 Tmax:0.5 dmax: 4% dc: 3.3%
Electrostatic Discharge Immunity	EN 61000-4-2:2009 IEC 61000-4-2:2008	Operating Stand by	Enclosure	120 V, 60 Hz 220 V, 60 Hz 230 V,50 Hz	± 8 kV/Contact ± 2, ± 4, ± 8, ± 15 kV/Air
Radiated RF Electromagnetic Field Immunity	EN 61000-4-3:2006+A2:2010 IEC 61000-4-3:2006+A2:2010	Operating Stand by	Enclosure	120 V, 60 Hz 220 V, 60 Hz 230 V,50 Hz	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz
Immunity to Proximity Fields from RF wireless Communications Equipment	EN 61000-4-3:2006+A2:2010 IEC 61000-4-3:2006+A2:2010	Operating Stand by	Enclosure	120 V, 60 Hz 220 V, 60 Hz 230 V,50 Hz	Table 9 in IEC 60601-1-2:2014
Electrical Fast Transient/Burst Immunity	EN 61000-4-4:2012 IEC 61000-4-4:2012	Operating Stand by	AC Mains	120 V, 60 Hz 220 V, 60 Hz 230 V,50 Hz	± 2 kV, 100 kHz repetition frequency
			SIP/SOP		± 1 kV, 100 kHz repetition frequency
Surge Immunity	EN 61000-4-5:2014 IEC 61000-4-5:2014	Operating Stand by	AC Mains	120 V, 60 Hz 220 V, 60 Hz 230 V,50 Hz	Line to Line ± 0.5 kV, ± 1 kV Line to Ground ± 0.5 kV, ± 1 kV, ± 2 kV
Immunity to Conducted Dis-	EN 61000-4-6:2014 IEC 61000-4-6:2013	Operating	AC Mains	100 V, 50 Hz 100 V, 60 Hz	3 V 0.15-80 MHz

turbances Induced by RF fields		Stand by	SIP/SOP	240 V,50 Hz 240 V, 60 Hz	6 V in ISM bands Between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Power Frequency Magnetic Field Immunity	EN 61000-4-8:2010 IEC 61000-4-8:2009	Operating Stand by	Enclosure	120 V, 60 Hz 220 V, 60 Hz 230 V,50 Hz	30 A/m 50 Hz & 60 Hz
Voltage dips	EN 61000-4-11:2004 IEC 61000-4-11: 2004	Operating Stand by	AC Mains	100 V, 50 Hz 100 V, 60 Hz 240 V,50 Hz 240 V, 60 Hz	0 % U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°
Voltage interruptions	EN 61000-4-11:2004 IEC 61000-4-11: 2004	Operating Stand by	AC Mains	100 V, 50 Hz 100 V, 60 Hz 240 V,50 Hz 240 V, 60 Hz	0 % U_T; 250/300 cycle

Annex. 8 X-ray condition (Referenced)

X-ray Energy Range: 40kVp ~ 150kVp

Below exposure conditions were set by CPI generator, CMP200 DR for customer to reference.

No.	Large group	Middle group	Small group	SID(Cm)	kVp	mAs	mA
1	Head	Skull	Skull PA	100	70	20	200
2			Skull Lat	100	70	20	200
3			SkullTown's	100	74	25	200
4		Nasal Bone	Nasal bone Lat	100	48	4	100
5	Chest	Chest	Chest PA	180	125	3	320
6		Rib	Rib AP	100	66	20	320
7		Sternum	Sternum Lat	100	80	32	200
8	Pelvic	Pelvis	Pelvis AP	100	75	20	200
9		Hip	Hip AP	100	75	25	200
10	Upper limb1	Hand	Hand PA	100	45	3	100
11			Hand Oblique	100	45	3	100
12			Hand Lat	100	50	3	100
13		Finger	Finger AP	100	45	3	100
14			Finger Lat	100	45	3	100
15		Wrist	Wrist PA	100	48	3	100
16			Wrist Lat	100	50	3	100
17		Forearm	Forearm AP	100	50	3	100
18			Forearm Lat	100	50	4	100
19	Upper limb2	Elbow	Elbow AP	100	50	4	100
20			Elbow Lat	100	50	4	100
21		Humerus	Humerus AP	100	55	4	100
22			HumerusLat	100	55	4	100
23		Shoulder	Shoulder AP	100	55	5	100
24		Clavicle	Clavicle AP	100	55	5	100
25			Clavicle Tangen-	100	58	5	100
26	Lower imb2	Foot	Foot AP	100	48	3	100
27			Foot Lat	100	52	4	100
28		Ankle	Ankle AP	100	55	4	100
29			Ankle Lat	100	55	4	100
30	Lower	Knee	Knee Lat	100	55	4	100

Annex. 9 Wireless Communication Specification

Wireless LAN Specification

Item	Description
Wireless Standard	IEEE802.11ac/a/b/g/n
Frequency Range	2.412GHz~2.484GHz, 5.150MHz~5.850MHz
Data Rate	802.11b: 11Mbps / 802.11a/g: 54Mbps / 802.11n: MCS0~7/ 802.11ac: MCS0~9 Bluetooth: 1Mbps, 2Mbps and up to 3Mbps EDR
Modulation	WiFi : 802.11b: DSSS (DBPSK, DQPSK, CCK) 802.11a/g: OFDM (BPSK, QPSK, 16 QAM, 64-QAM) 802.11n: OFDM (BPSK, QPSK, 16-QAM, 64-QAM) 802.11ac: OFDM (BPSK, QPSK, 16-QAM, 64-QAM, 256-QAM) Bluetooth: GFSK, Π/4 DQPSK, 8DPSK
Transmission Power	Max. 16dBm
Security	WEP, WPA, WPA2
Antenna	Triple Band Antennas (Detector: internal)

Setting Parameters

Wireless LAN Setting Parameter

Item	Description
AP ON/OFF	ON: Turns on Access Point function. The detector can use Detector AP Mode. OFF: Turns off the Access Point function. Only a wired communication is available to operate for power supply.
Frequency	2.4GHz: Uses 2.4GHzfrequency band 5 GHz: Uses 5 GHz frequency band
Country	KR, US, EU Serviceable channels are limited according to the countries you set.

Annex. 10 Default value of detector initialization

Network

IP Address : 192.168.0.11

Port : 5050

WNetwork

SSID : PEDRADXD-5G

Key : 12345678

AP

AP On/Off : Off

Frequency : 5GHz

SSID : PEDRA-AP-5G

Key : 12345678

Security : WPA2-PSK

Detector Parameter

Exposure mode : Auto

Imaging mode : Portrait

Image windows time : 500ms

Sleep mode : off

Annex. 11 FCC-Related information and explanation

Installation Procedure

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

- RF Exposure SAR statement

RF exposure compliance
The available scientific evidence does not show that any health problems are associated with using low power wireless devices. There is no proof, however, that these low power wireless devices are absolutely safe. Low power wireless devices emit low levels radio frequency energy (RF) in the microwave range while being used. Whereas high levels of RF can produce health effects (by heating tissue), exposure of low-level RF that does not produce heating effects causes no known adverse health effects. Many studies of low-level RF exposures have not found any biological effects. Some studies have suggested that some biological effects might occur, but such findings have not been confirmed by additional research. This device has been tested and found to comply with FCC/IC radiation exposure limits set forth for an uncontrolled equipment and meets the FCC radio frequency (RF) Exposure Guidelines in Supplement

FCC Statement
Federal Communication Commission Interference Statement
This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.
FCC Caution: Any changes or modifications not expressly approved by the party responsible for
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
For product available in the USA/Canada market, only channel 1~11 can be operated. Selection of other channels is not possible.
This device is going to be operated in 5.15~5.25GHz frequency range, it is restricted in indoor environment only.

IMPORTANT NOTE:
FCC Radiation Exposure Statement:
This device meets FCC limits for exposure to radio waves. It is designed not to exceed the limits for exposure to radio waves (radio frequency electromagnetic field) adopted by the Federal Communications Commission.
This equipment should be installed and operated with minimum distance 0mm between the radiator & your body.
This device and its antenna(s) must not be co-located or operation in conjunction with any other antenna or transmitter.

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