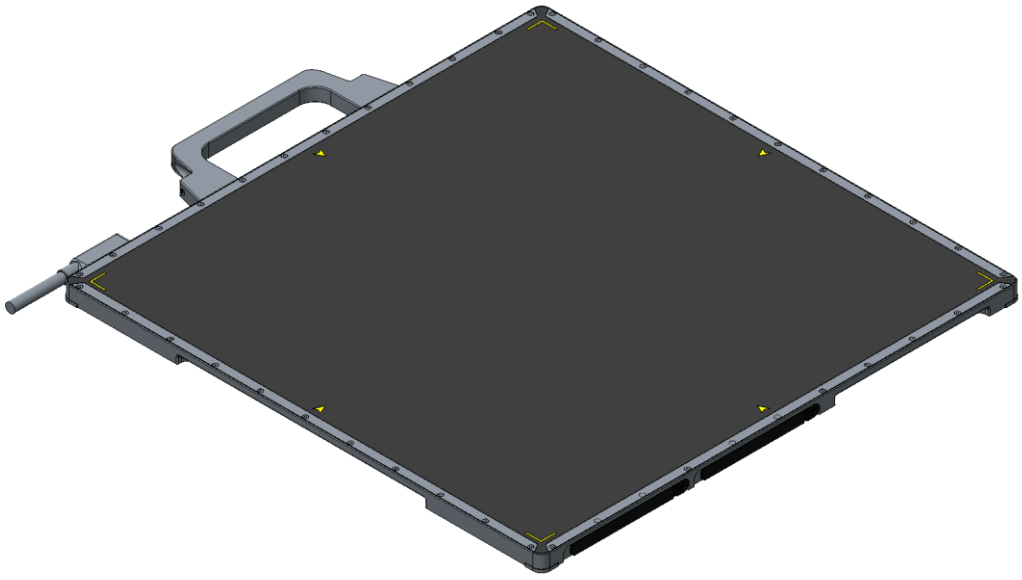
CE 1370

This product is certified to conform to the Class IIa requirements of the 93/42/EEC Medical Devices Directive.

Install & Service Manual

Prudent

Flat-panel Digital X-ray Detector



Model: Prudent1717/1417/1212

ver. 1.0.8

Be sure to read and understand this manual thoroughly before using the product, and keep this manual in an easily accessible location for quick reference when required.

INTRODUCTION

PRUDENT is a high-resolution digital X-ray imaging device commonly referred to as a flat panel detect. A built-in a-Si TFT flat panel type digital sensor receives X-ray and converts to digital image. X-ray photons are converted to digital output signals. The digital signals are then read out by TFTs. The image data file is saved at the computer for display, which can be linked with PACS and printed by DICOM printer through acquisition software. It is specifically designed to deliver x-ray imaging for medical, veterinary and industrial applications.

ATTENTION

1. This manual guides the PRUDENT user to perform all installation and set-up procedures. Be sure that the user reads this manual thoroughly.
2. This includes the instructions of NETWORK card installation.
3. The use of calibration data and the method of creating calibration data are demonstrated.
4. Guidelines for the manual mode when connecting the generator directly to the PRUDENT is included.
5. No Modifying warning statement
   Never disassemble or modify the product as it may result in fire or electric shock. Also, since the instrument incorporates parts that may cause electric shocks and other hazardous parts, touching them may cause death or serious injury
6. FCC 15C Compliance statement
   Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
7. 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

REVISION HISTORY

PRUDENT Manual Revision History

Revision	Revisions	Revised Date	Reviser
1.0.0	Initial drafting	2015.03.20	MoonKi Choi NamYeol Lee JiHong Jung
1.0.1	Add related content: Introduction, Warning, Micromagnetic ect.	2015.04.09	NamYeol Lee
1.0.2	Modified layout: 6.2 Environment, 6.4 PICB	2015.04.14	NamYeol Lee
1.0.3	Add related content: FCC and SAR test	2015.05.06	JiHong Jung
1.0.4	Add related content: Revision Hestory, DOC No.	2015.08.21	JiHong Jung
1.0.5	Revision by change of Company name	2018.03.02	JongMyung Shin
1.0.6	Modified some contents and typos : Page 1,2,9,11	2018.06.11	JongMyung Shin
1.0.7	A model(PIXX2430) with a miniaturized image sensor was added.	2020.06.30	JongMyung Shin
1.0.8	A model(Prudent) with a miniaturized image sen sor was added.	2020.07.06	JongMyung Shin

Contents

1. Safety Information

1.1. Safety Information

PRUDENT passed all legal safety requirements as an electromedical equipment to guarantee the user's safety. Do not ignore following cautions while handling the products, and read thoroughly this page before use.

CAUTION!.
◆ Do not use the instrument, if a malfunction has occurred, until the problems are solved by qualified personnel. ◆ Do not install the instrument in a location with the conditions listed below. -Otherwise, it may result in failure or malfunction, fall or cause fire or injury. -Close to facilities where water is used. -Where it will be exposed to direct sunlight. -Close to heat source such as a heater. -Prone to vibration. -Insecure place. -Dusty environment. -Saline or sulfurous environment. -High temperature or humidity. ◆ Do not use the instrument unless designated. ◆ Do not touch any screws fixed in the instrument. Otherwise, loosened screws will result in the deterioration of image quality or the damaged instrument.
◆ Only authorized engineers from PIXXGEN are qualified for installation. Be sure to follow the instructions in this manual. Any inquries related to the maintenace should be in touch with PIXXGEN Service Team at tech@pixxgen.com. ◆ Approach us if the instrument did not respond as shown in the instructions.
◆ Disclaimer - Manufacturer is not liable to accidents or breakdown caused by the use of Detector by legally unqualified personnel. - The manufacturer is not liable to any accidents or technical problems caused by modification or repair of the device by agents or unspecified engineer.

CAUTION!.

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 compliance could void the user's authority to operate this equipment.

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.

CAUTION!.

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.

WARNING!.

- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth
- Do not touch signal input, signal output or other connectors, and the patient simultaneously.
- External equipment intended for connection to signal input, signal output or other connectors, shall comply with relevant IEC Standard (e.g., IEC60950 for IT equipment and IEC60601-1 series for medical electrical equipment). In addition, all such combination-system-shall comply with the standard IEC60601-1 and/or IEC60601-1-1 harmonized national standard or the combination. If, in doubt, contact qualified technician or your local representative.
- No modification of this equipment is allowed
- Do not modify this equipment without authorization of the manufacturer.
- In the event of any serious accident with respect to the device, it shall be reported to the manufacturer and the relevant authority.
- Remove the battery if the ME EQUIPMENT is no likely to be used for some time.

ELECTROMAGNETIC!

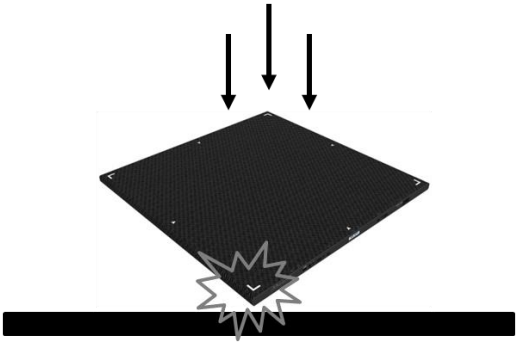
- This equipment has been tested and found to comply with the limits for medical devices in EN 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, 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 measures:
  - Reorient or relocate the receiving device.
  - Increase the separation between the equipment.
  - Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
  - Consult the manufacturer or field service technician for help.

1.2. Handling

Handle the detector carefully.

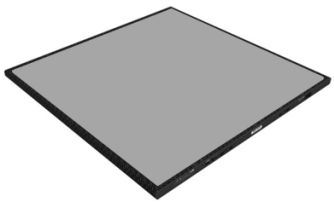
CAUTION!.

- Be sure to securely hold the detector while using it in upright positions. Otherwise, the detector may fall over, resulting in injury to the user or patient, or may flip over, resulting in damage to inner device.
- Be sure to use the detector on a flat surface so it will not bend. Otherwise, the internal image sensor may be damaged.
- Do not submerge the detector in water.
- Do not receives a strong jolt, or dropped, or if something hits against detector. Otherwise, the internal image sensor may be damaged.



- Do not place excessive weight on the detector. Otherwise, the internal image sensor may be damaged.

(Load Limit)



Uniform load: 20Kg over the whole area of the detector surface (Portable hardcase 200kg)

Local load: 10kg on an area 4cm x 4cm in diameter (Portable hardcase 100kg)

1.3. Cleaning

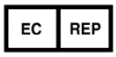
Use a dry cloth only and be sure to turn off the power when cleaning the instrument surfaces. Never use any cleaning agents. Otherwise, it may result in the damage on surfaces or the corrosion of structure.

1.4. Disposal

When disposing of this product, approach us before disposing or return all components of

PRUDENT.

1.5. Marks

	Attention, see instruction manual.
	The CE mark shows that the instrument obtained EU countries' requirements. CE number can be followed by the CE mark.
	Manufacturer's name and address.
	EU representative's name, address and contact details.
	Consult instructions for use
	Fragile, handle with care
	This symbol shall be accompanied by the manufacturer's serial number.
	Temperature limit.
	Symbol for the marking of electrical and electro-network equipment that must be recycled.
	Do not disassemble or open the instrument.
	Do not place the instrument near where liquid is present.
	Use a dry cloth only when cleaning the instrument.
	This way up
	Stacking Limited by number
	Keep away from rain
	Alternating Current
	Direct Current
	Device is switched on in order to bring it into the Stand-by condition

1.6. Condition for installation

- Do not install this equipment in any of the locations listed below.
  - Where the power supply is unstable.
  - Where temperature and humidity are high.
  - Where the room is without air-conditioner or ventilation.
  - Where it is exposed to direct sunlight.
- It is highly recommended to separate X-ray power in the distributing board of the electricity of the building.
- It is highly recommended to take internet connection nearby workstation pc in the room
- Check the distance between workstation PC in the operation room and the area which detector will be placed.
- The wall outlet or the circuit breaker shall be installed near the equipment and shall be easily accessible when problems occur.
- Turn off the detector after the operation.
  - For wired Detector: Press the stand-by button and check the power display (Green ->Red)
  - For wireless Detector: Press the Stand-by button and remove the battery pack. (Lift up the battery pack and remove it.)

1.7. Environment

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

	Temperature	Humidity
Storage	-20 to 70℃	10 to 95 % RH(Non-condensing)
Operation	10 to 35℃	20 to 75% RH(Non-condensing)

- Do not expose this equipment to high temperature and humidity since it makes detector malfunctions.

1.8. Etc.

- Type of protection against electric shock
  - Class I and/or Internally powered equipment.
- Degree of protection against electric shock
  - Not classified - No applied parts
- Classification according to the degree of protection against ingress of water
  - IPX0, ordinary equipment
- This equipment is not suitable for use in the presence of flammable anesthetics or oxygen
- Mode of operation:
  - continuous operation

2. Product Part Introduction

2.1. Product parts

2.1.1. Standard parts

NO.	Part	Description	Q'ty
1	PRUDENT (Detector)	17*17/14*17/12*12sized, Wired/Wireless Flat-panel X-ray Detector	1
2	PICB (Interface unit)	Battery Charger & Control Box - Switching Power Supply - AC/DC Adapter * It should be arranged to make it easier to cut off the power.	1
3	Battery Pack	Supplies power to the detector in wireless mode.	1
4	SensorProbe USB	- SensorProbe Program - PRUDENT Calibration data - NETWORK Driver - USER Manual	1

2.1.2. Optional parts

NO.	Part	Description	Q'ty
1	Zview USB	- Zview Acquisition Program. - User & Service Manual - USB Security Dongle Key	1
2	Router	It transmits the signal and image data to the PRUDENT. It is not provided from the package since it uses a different frequency in each country.	1
3	Network adapter	The network card is required for installation and connection of PRUDENT. Users are able to use wireless LAN card when they want to have wireless connection between router and work station computer. ☞ P.18 Chapter. 4.1. LAN Setting for installation. **Note: Using a gigabit Ethernet card is recommend.**	1

Immediately upon receipt, inspect the shipment and its contents against the PARTS LIST enclosed with the shipment for evidence missing components. Save all shipping containers in case a return. If there is any discrepancy, please contact the PIXXGEN Service Team at tech@pixxgen.com.

3. Specifications

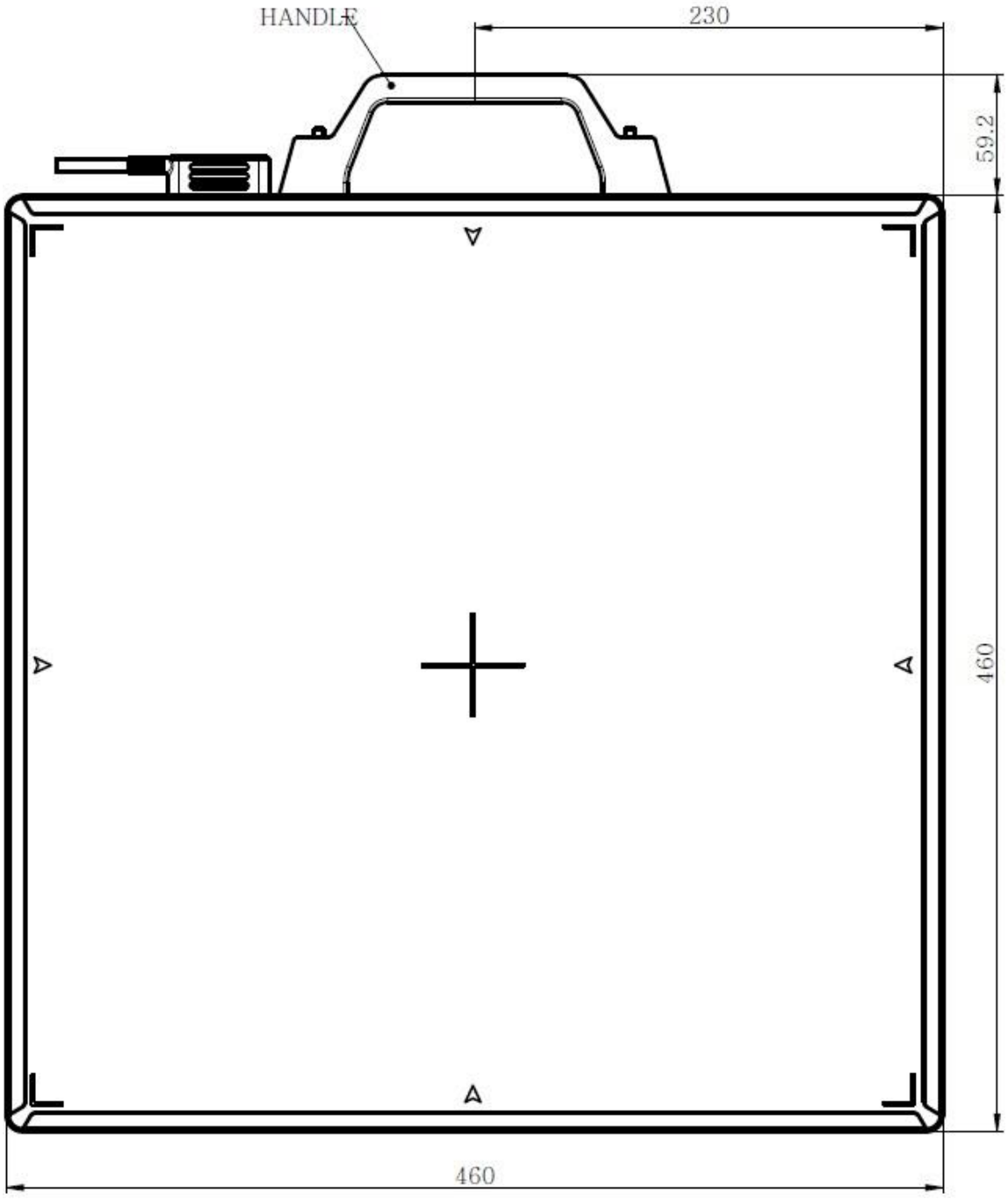
3.1. PRUDENT Specifications

Application		General or Dynamic Radiography
Sensor		IGZO or a-Si TFT array Flat Panel Detector
Conversion Screen		GOS / CsI
Active Area		Prudent1717: 17 X 17 Inch (430mm x 430mm) Prudent1417: 14 X 17 Inch (350mm x 427mm) Prudent1212: 11.3 X 11.3 Inch (287mm x 287mm)
Sensor Pixel		Prudent1717: 4302x4302 / 3072x3072 / 2560x2560 Prudent1417: 3534x4302/ 2500x3052 Prudent1212: 2867x2867/ 2048 X 2048
Image Data		16bit
Trigger Mode		AED (Automatic Exposure Detection),Manual Trigger
Calibration Mode		ACC (Automatic Calibration Control), Manual Calibration
Data Transfer Time		Less than 1 sec
Capture Cycle Time		2 ~ 5sec. (Approx.)
Wired interface		Gigabit Ethernet
Voltage	Adaptor	18 V d.c., 3.5 A (HPU63A-107)
	Battery	14.8 V d.c., 3300 mAh
Battery Performance		Approx. 8 hours of continuous operation Lithium ion Polymer Battery
Dimensions(W x L x T)		Prudent1717: 460mm(W) x 460mm(L) x 15mm(T) Prudent1417: 382mm(W) x 460mm(L) x 15mm(T) Prudent1212: 327mm(W) x 315mm(L) x 15mm(T) (Cassette-size for the standard table or wall Bucky)
Weight		Prudent1717 : 3.9Kg ±10% (with battery) Prudent1417 : 3.3Kg ±10% (with battery) Prudent1212 : 2.0 Kg ±10% (with battery)

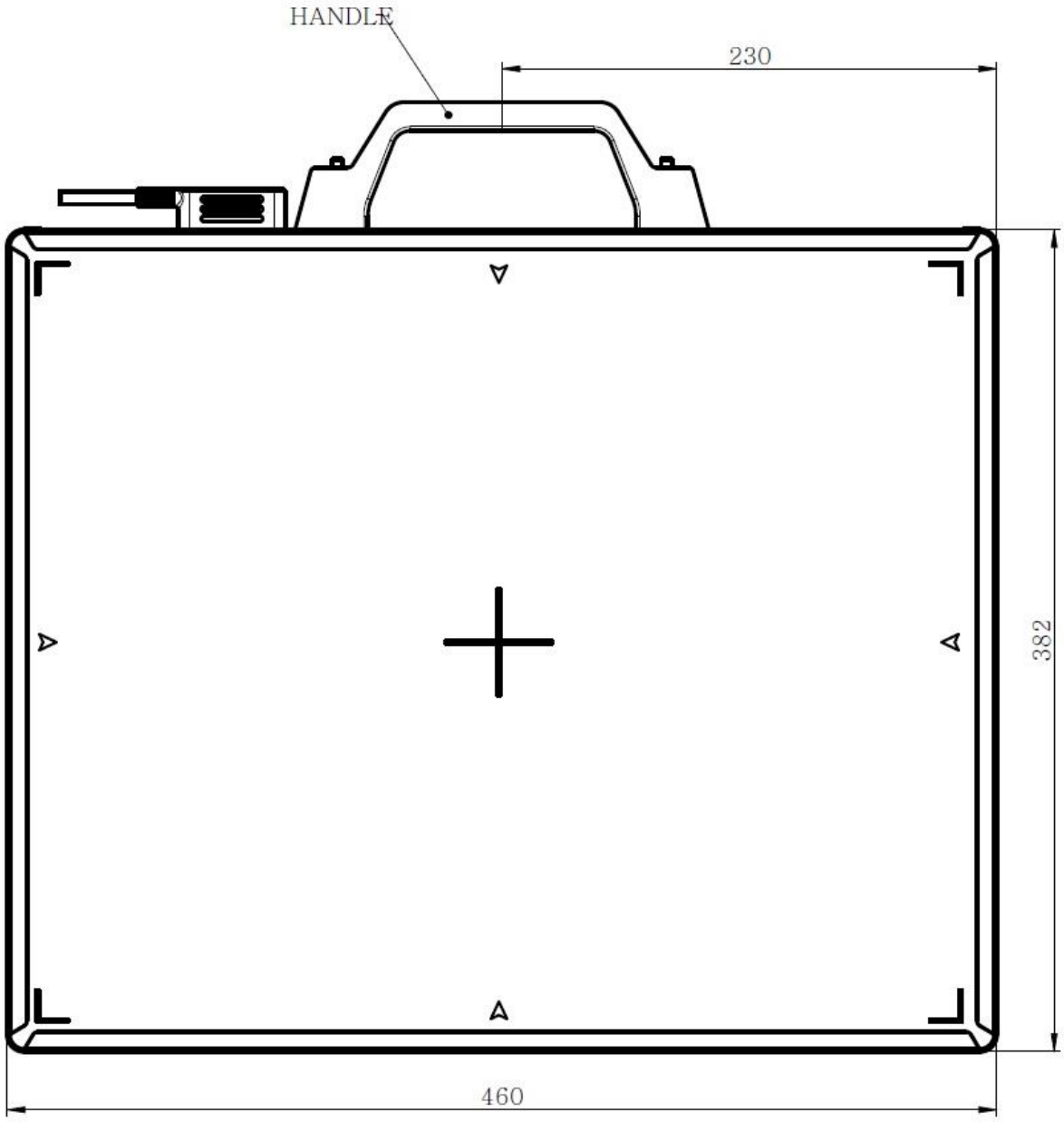
3.2. Environment

Operating condition	Temperature (°C)	10°C - 35°C
	Relative humidity (%)	20% - 75%
	Atmospheric Pressure (hPa)	700hPa - 1060hPa
Transport and storage condition	Temperature (°C)	-20°C – 70°C
	Relative humidity (%)	10% - 95%
	Atmospheric Pressure (hPa)	400hPa - 1500hPa

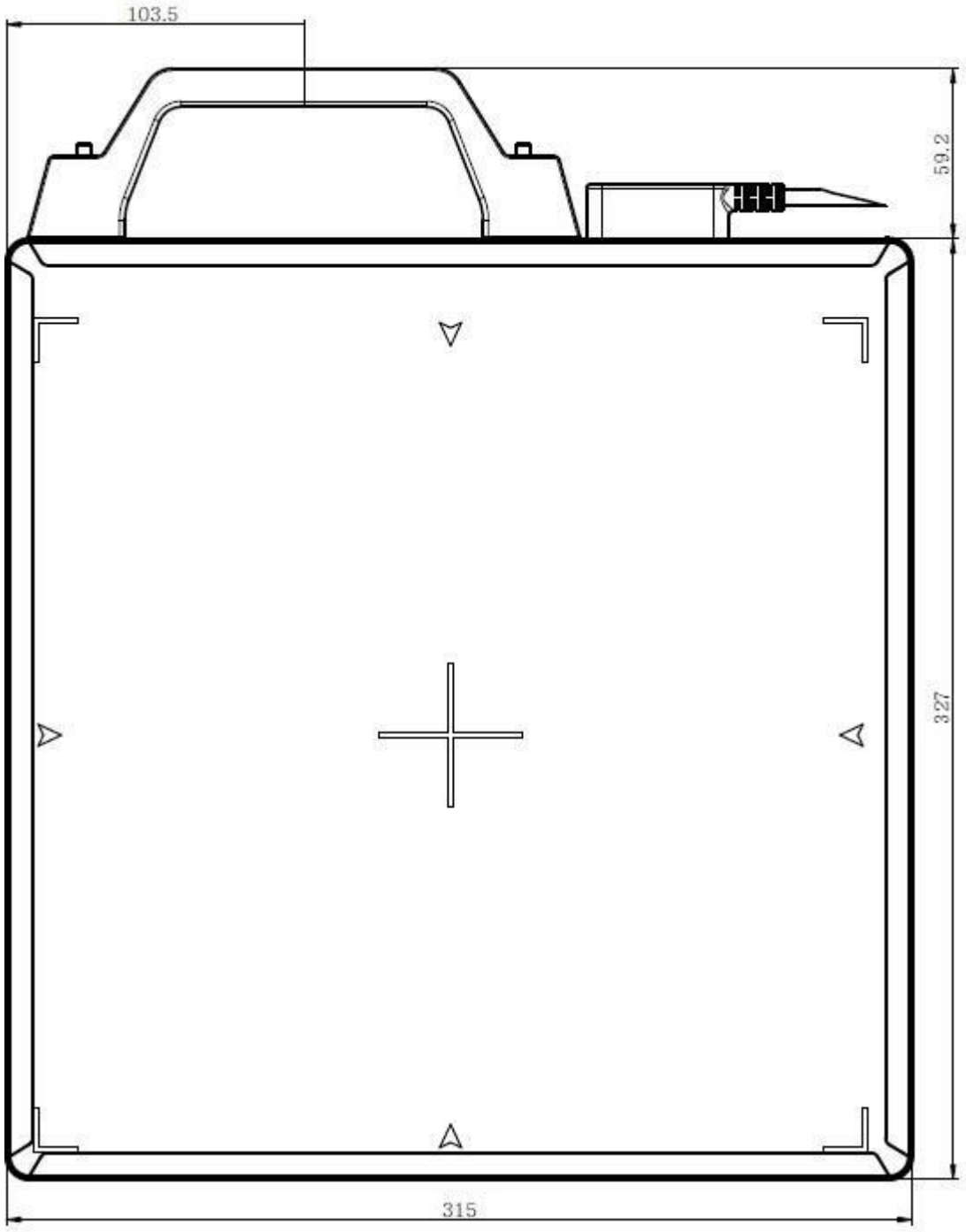
3.3. PRUDENT Dimensional diagram



(Prudent1717)



(Prudent 1417)

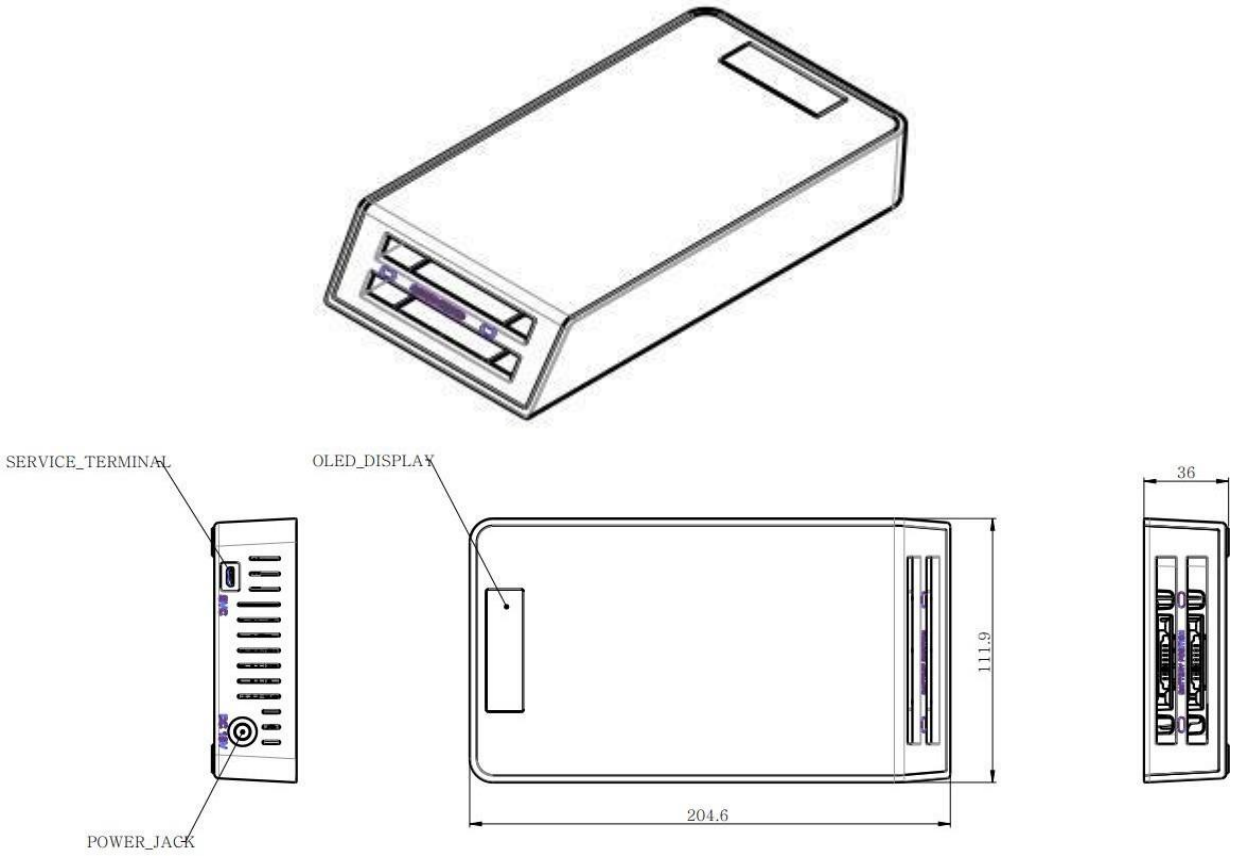


(Prudent 1212)

3.4. PICB Specifications

Dimensions(W x L x T)	204mm x 112mm x 36mm
Weight	300g
The following adaptor must be used.	
Manufacturer	Sinpro Electronics Co., Ltd.
Model	HPU63A-107
Input	100 - 240 V~, 47 - 63 Hz, 1.62 - 0.72 A
Output	Output: 18 V ⎓, 3.5 A

3.5. PICB Dimensional diagram



Unit: mm

4. Hardware Installation

4.1. Network adapter(LAN Card) Installation


*ONLY EXAMPLE (The figure may be different from the user's computer.)

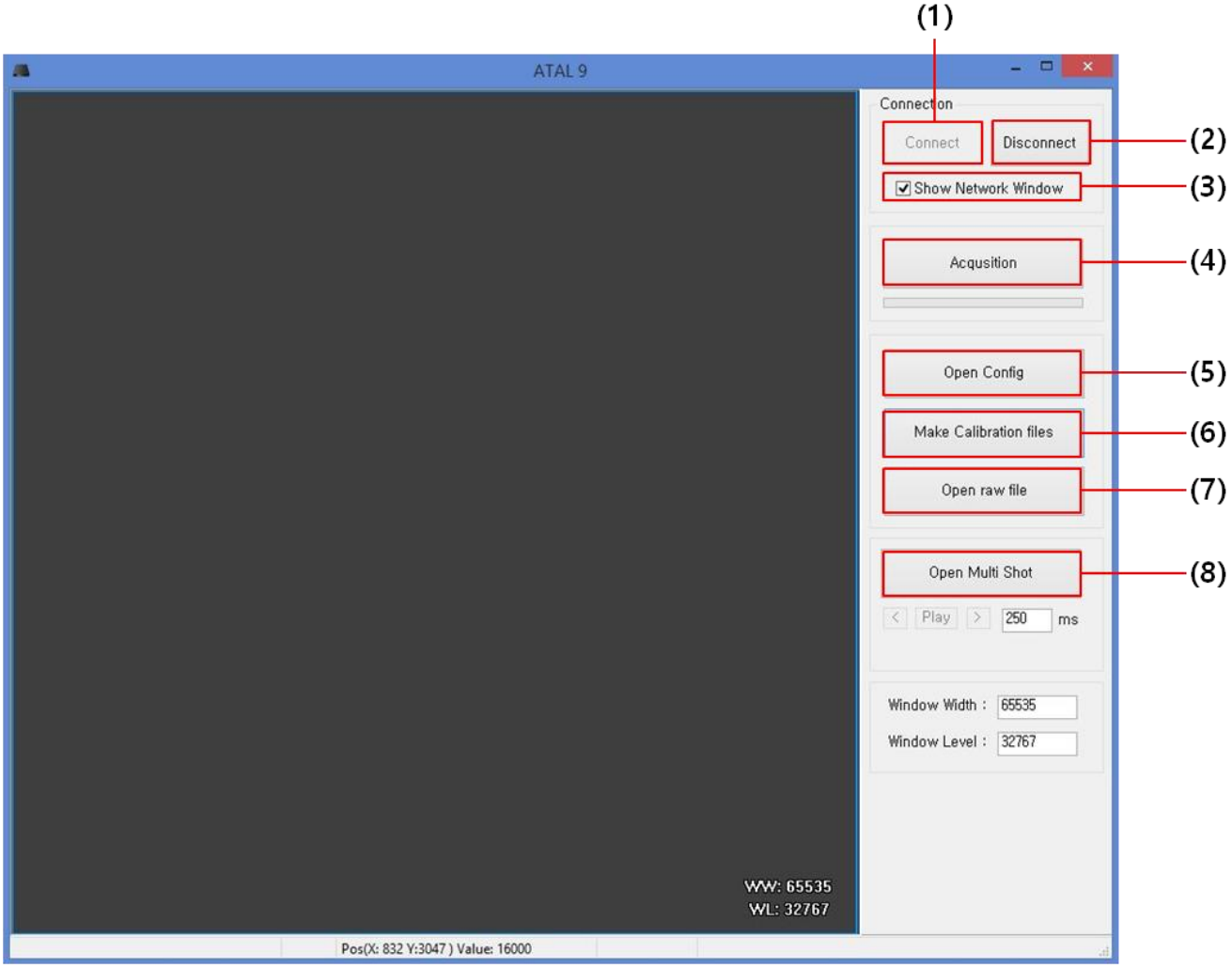
Before installing the workstation computer, it is necessary to install LAN card. It is possible to check empty slots if you open the case of the computer. Precisely install LAN card in PCIe slot. Users are able to install wireless LAN card if you need to have wireless connection between router and work station computer.

CAUTION!.

- PRUDENT system requires at least one PCIe slot. Check the number of PCIe slot when purchasing a workstation computer.
- The insecure installation of the cards may cause malfunctions of the system.

4.1.2. Sensorprobe

The set-up of Sensorprobe is necessary for the operation of PRUDENT.



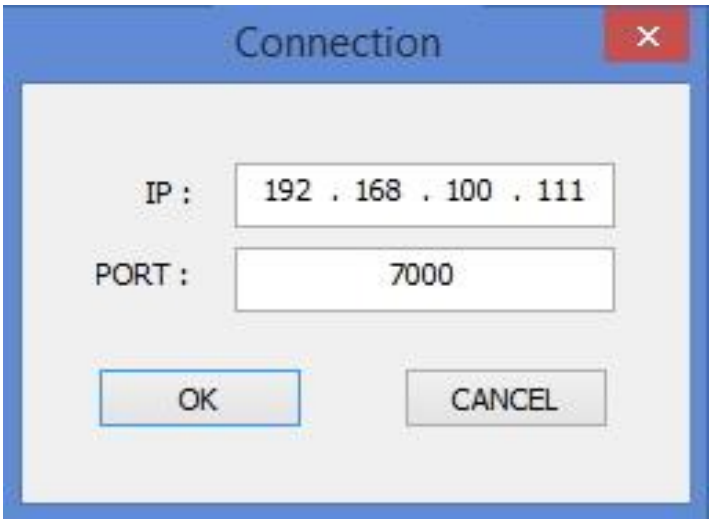
(1) Connection: Connect to PRUDENT
(2) Disconnection: Disconnect from PRUDENT
(3) Show Network Window: Open IP and Port number window
(4) Acquisition: Make PRUDENT ready to exposure
(5) Open Config: Verify configuration of PRUDENT
(6) Make Calibration files: Create calibration files
(7) Open raw file: Open raw X-ray images (***.raw)
(8) Open Multi Shot: Open multi-shot images (Only for multi-Frame Options)

4.1.2.1. Initial Connection Setting

Check **Show Network Window** message before connecting. Click **Connect** and then **IP and PORT** window will appear.

Select network window

This is to set up connecting ports between PRUDENT and the workstation computer.



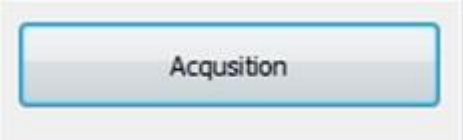
IP address: Set the IP address for detector.

Port number: Set the PORT number for detector

Tip!.	For the initial operation of Sensorprobe, follow the instructions thoroughly. After setting up IP and PORT once, the users may easily perform connection by clicking 'Connect' afterward unless Router changed or initialized.

4.1.2.2. Functions

The buttons will be activated when the connection process completed, and then Sensorprobe is going to work properly..

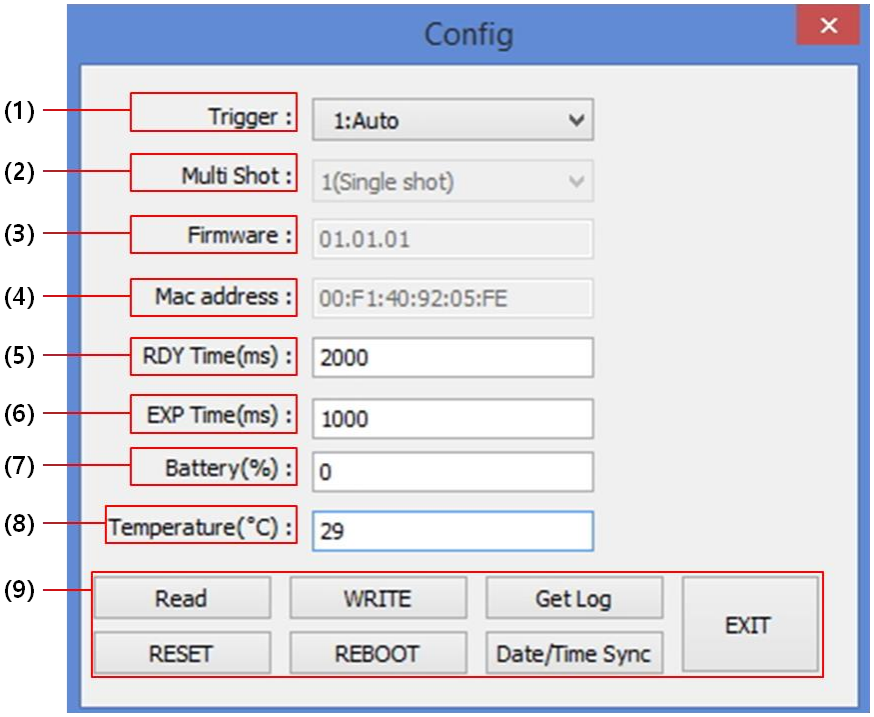


The user may obtain images without using other acquisition programs.

When shooting the x-ray after clicking the 'Acquisition' button, the progress bar will fill up with green color. This indicates that PRUDENT is getting an X-ray image

Tip!.	The quicker the exposure, the sooner the acquisition.

4.1.2.3. Open Config



(1) Trigger Mode: The trigger mode of PRUDENT 1 – Auto Mode 11 – Continuous Auto Mode 6 – Manual Mode 66 – Continuous Manual Mode	
(2) Multi Shot: The number of images acquired at a time	
(3) Firmware: The firmware version of PRUDENT.	
(4) Mac address: Media Access Control address of PRUDENT	
(5) RDY Time(ms): Push ready button(Manual mode).	
(6) EXP Time(ms): Push exposure button(Manual mode), exposure time(Auto mode)	
(7) Battery: Battery remains	
(8) Temperature : Temperature	
(9) Read: Read detector parameters. Write: Write detector parameters Get log: Bring log information	RESET: Reset the detector REBOOT: Reboot the detector Date/Time Sync: Synchronize date and time between detector and workstation

CAUTION!	It is strongly recommended that the user is not to modify the contents of Sensorprobe Config except authorized engineers from PIXXGEN. If setting is modified, it may result in malfunction.

4.1.2.4. Make Calibration files

The main function of Sensorprobe is the creation of a calibration file of the PRUDENT.
For more information, see ☞ **P.60 Chapter: 10. Calibration**

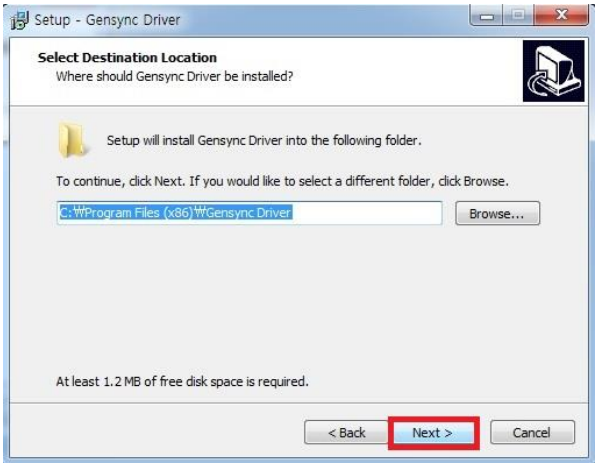
4.1.2.5. Open raw file

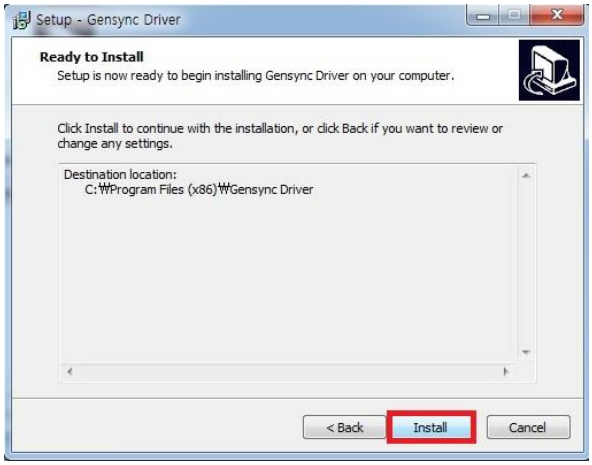
To open existing raw images a file route window will be shown up when clicking button.

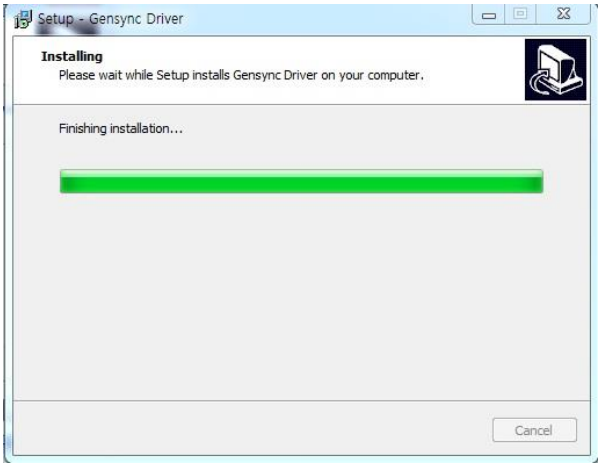
4.2. Driver Installation of PICB (For tethering use)

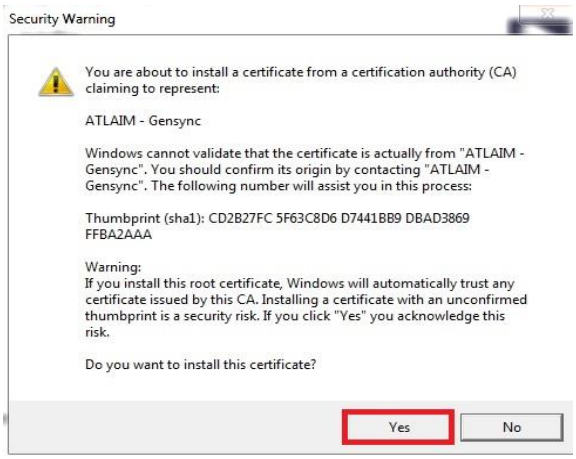
(1) Double click "setup_gensync_PIXXGEN.exe" file to install driver.

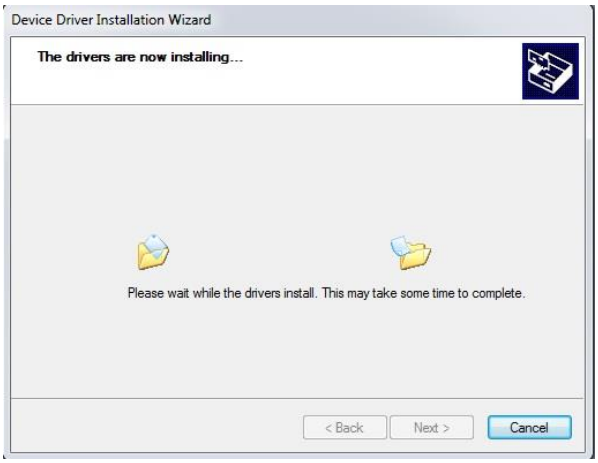
(2) Click the buttons in the red boxes referring to red boxes in the screen shots.











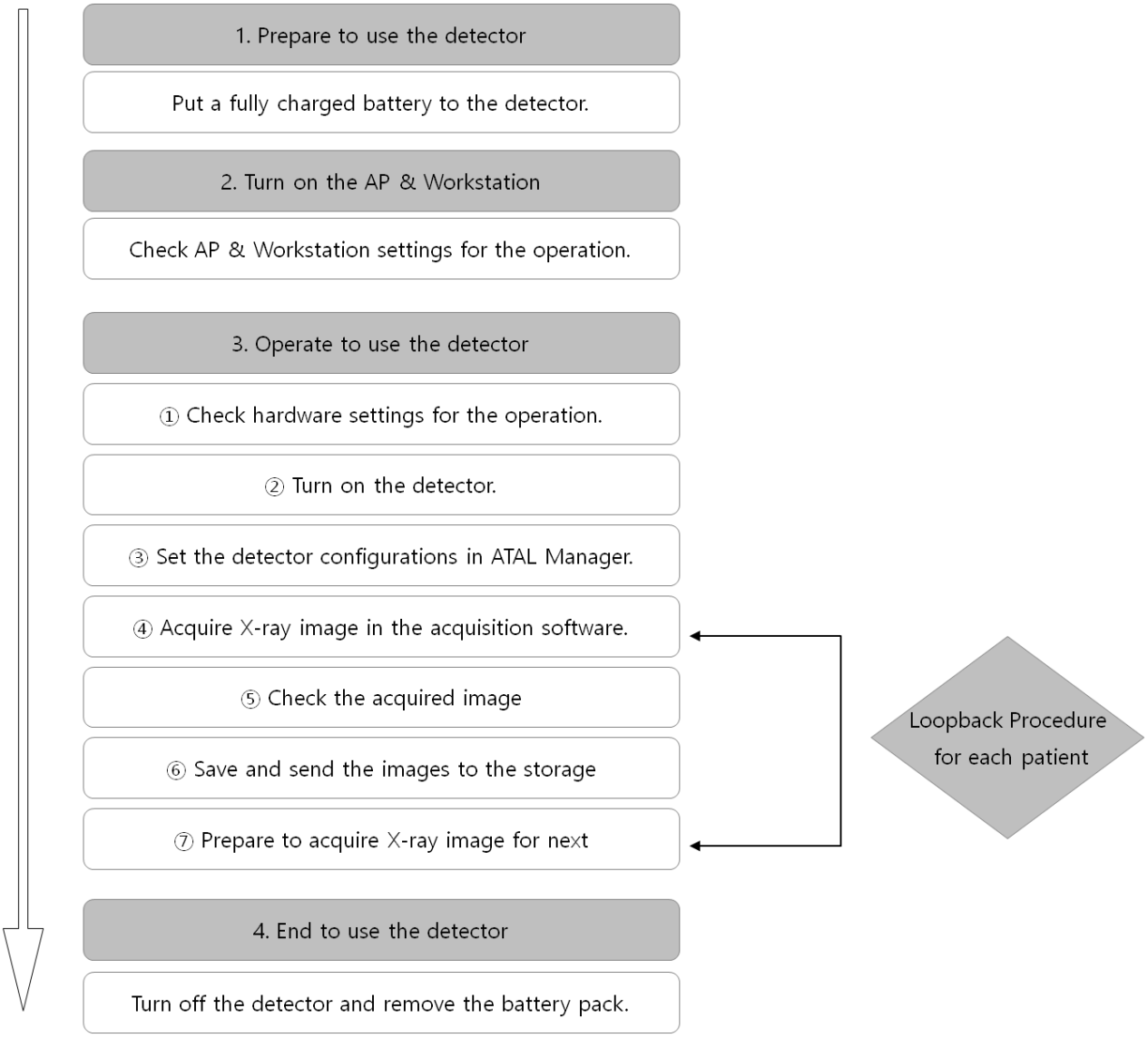
(3) Check the status in the green box whether it is installed properly.

CAUTION!	If the OS on work station is Windows 8, additional setting (Disable Driver Signature Verification) is required. Go to the "How to Disable Driver Signature Verification" and follow the instructions

5. Operation

5.1. General workflow

The following workflow indicates the procedures after startup of the workstation software and other system equipment

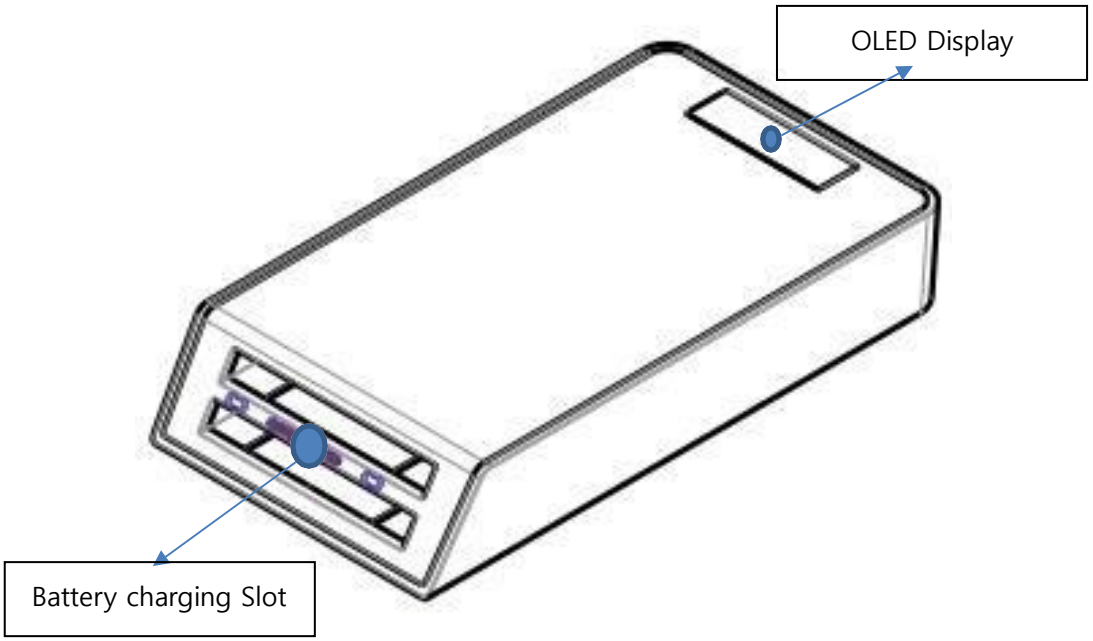


TIP!	Short beep sound: It indicates that power of PRUDENT is on properly. Long beep sound: It indicates that the OS of PRUDENT is booted properly.

5.2. Preparing to use the Battery Charger

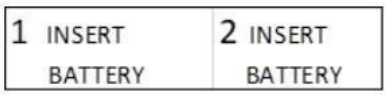
1. Insert the battery pack.

   (1) Insert the battery pack fully to the slot on battery charger.



   (2) Make sure the battery pack is securely inserted.

   (3) The battery charger status can be confirmed in the status lamps

OLED	Battery Charger Status
	Battery empty in slot
	Charging amount display
	Charging complete

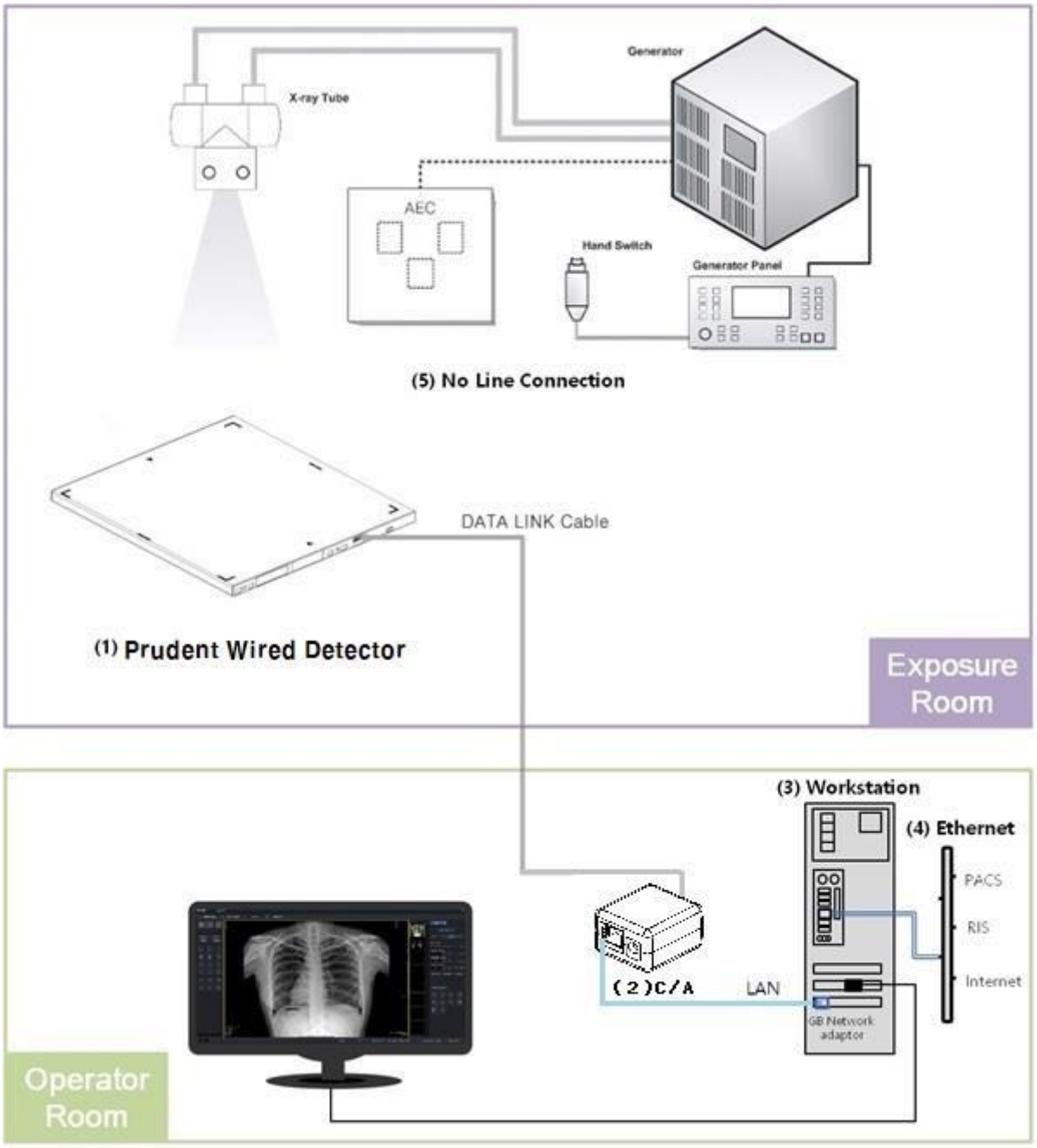
For charging:

1. Charging voltage: 16.78V / 1.5A
2. Charging time: 4 hours

6. Detector Installation

6.1. Wired Detector Installation

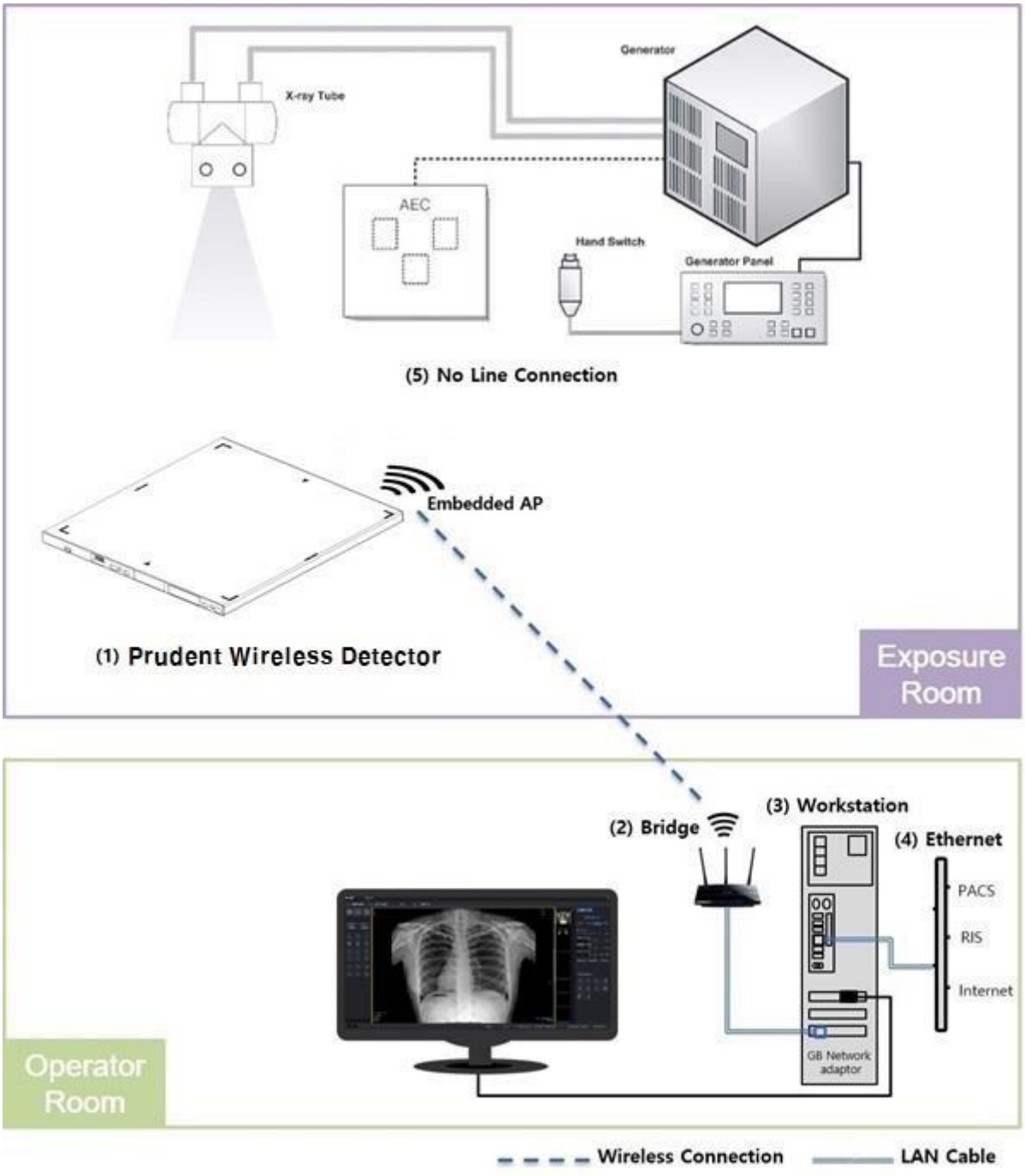
PRUDENT is used in wired configuration as illustrated below:



- (1)Detector ⇄ (2)PICB: Wired (HDMI: DC power, signal, digital image)
- (2)PICB ⇄ (3)Workstation: Wired (LAN: signal, digital image)
- (5)No interfaces between generator and PRUDENT in auto trigger mode (AED).

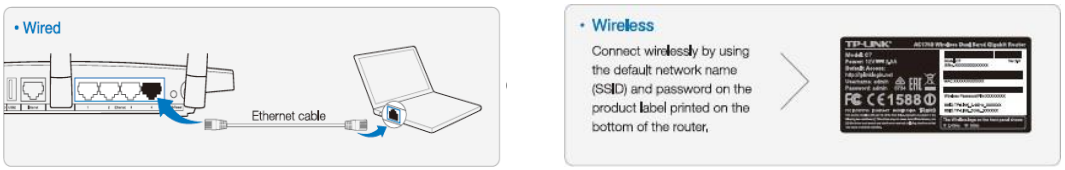
6.2. Wireless Detector Installation for AP Mode

Prudent is used in Wireless configuration as illustrated below:



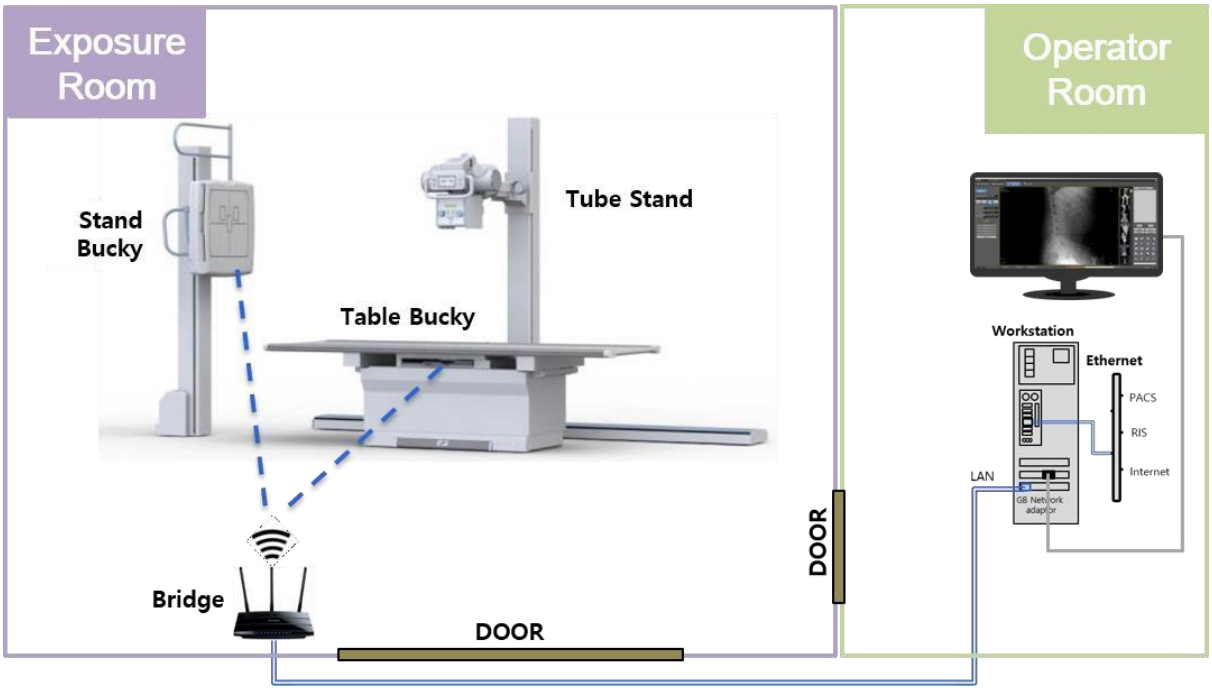
- (1) Detector (embedded Internal AP) ⇄ (2) Bridge: Wireless (signal, digital image)
- (2) Bridge ⇄ (3)Work Station: Wired or Wireless (signal, digital image)
- (5) No interfaces between generator and PIXX in Auto mode (AED triggered).

6.2.1. Installation for Station Mode



or

- Bridge ⇄ Work Station: Wired or Wireless (signal, digital image)

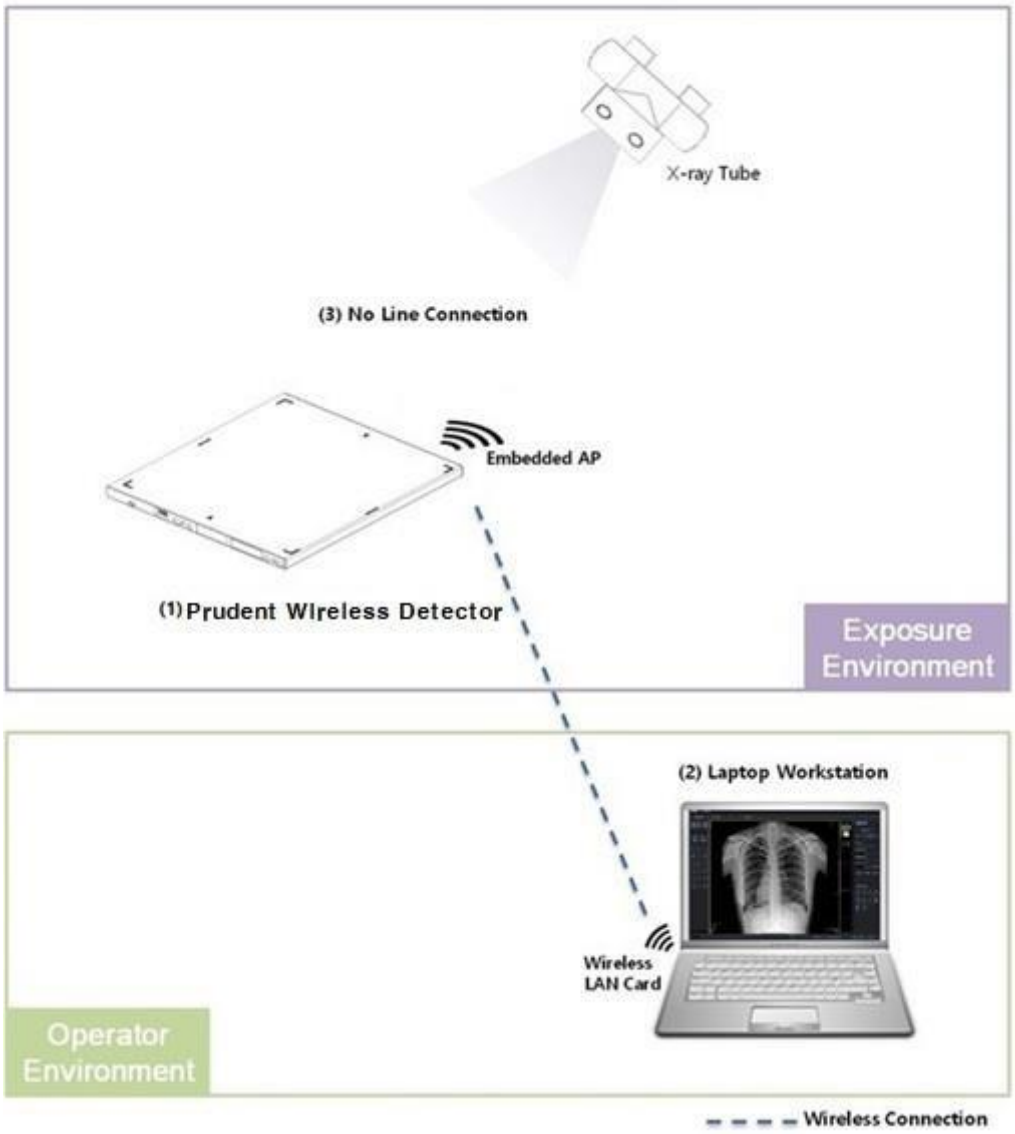


- Place the Bridge on the wall in the middle of Stand and Table Bucky.
- Elevate the Bridge away from floors. (Proper Height: To be horizontal with Table Bucky.)
- Position the Bridge antenna vertically, so that the antenna is standing straight up.

CAUTION!	A disconnection of wireless signal can be easily occurred depends on the location of antenna. It has to minimize the shadow zone by installing additional extended cable, so the product and the antenna can be opposable.

6.3. Direct Connection with Laptop PC (For Portable/Mobile X-Ray system)

It is recommended to install for industrial use, mobile use, outdoor use and portable devices. Prudent is used in direct connection configuration as illustrated below:



- (1) Detector (embedded AP mounted) ⇄ (2) Work Station: Wireless (signal, digital image)
- (3) No interfaces between generator and Prudent in Auto mode (AED triggered).

Using IEEE802.11ac wireless Network Adaptor is recommended.

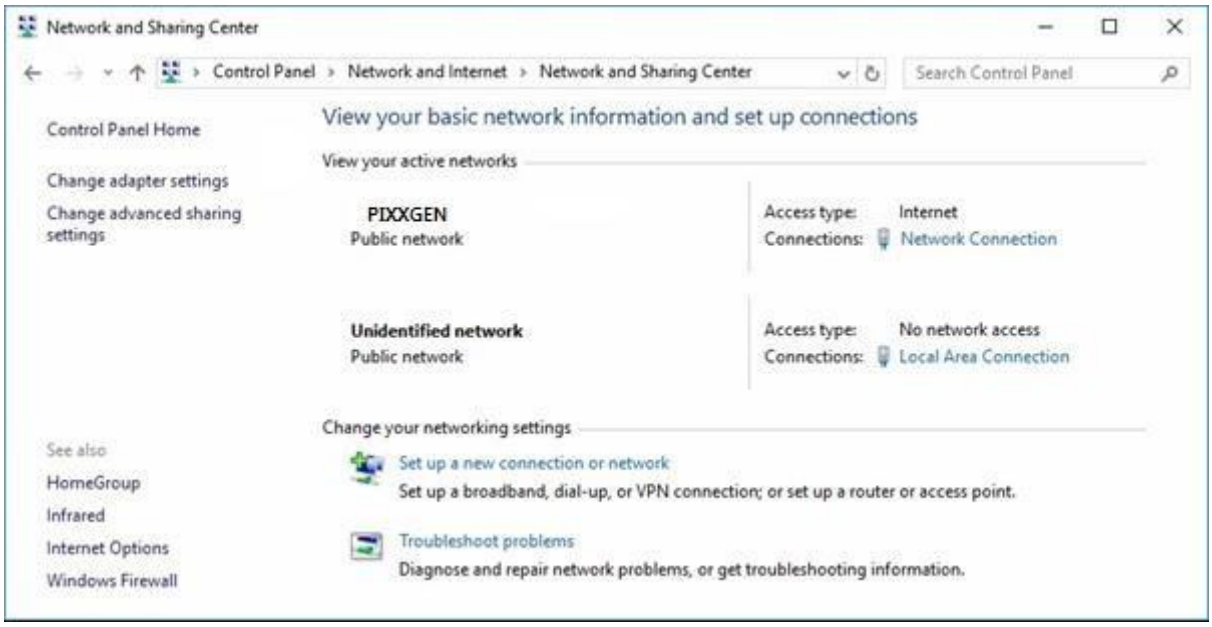
7. Detector Installation

7.1. Wired Detector

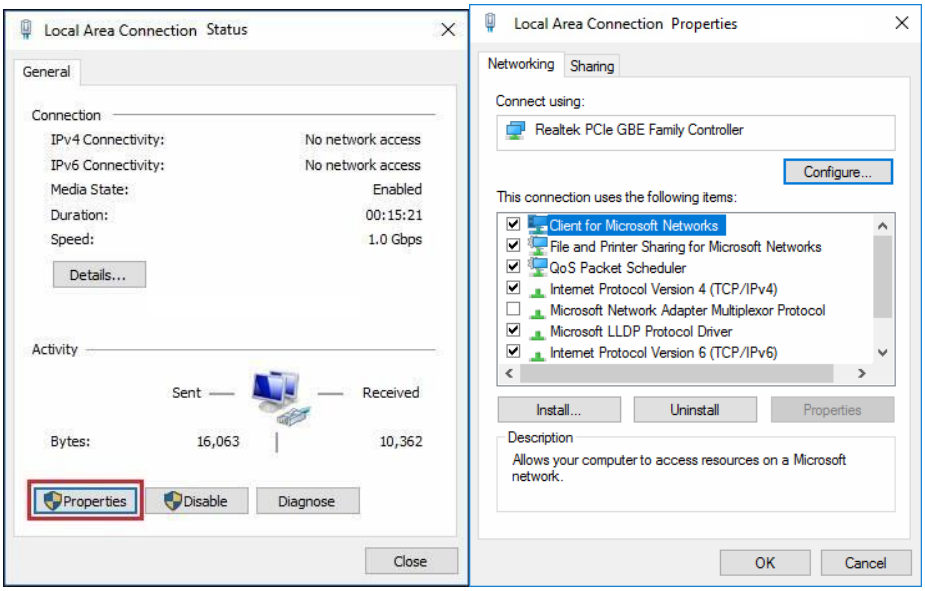
7.1.1. Network Setting

The settings between Prudent and Workstation

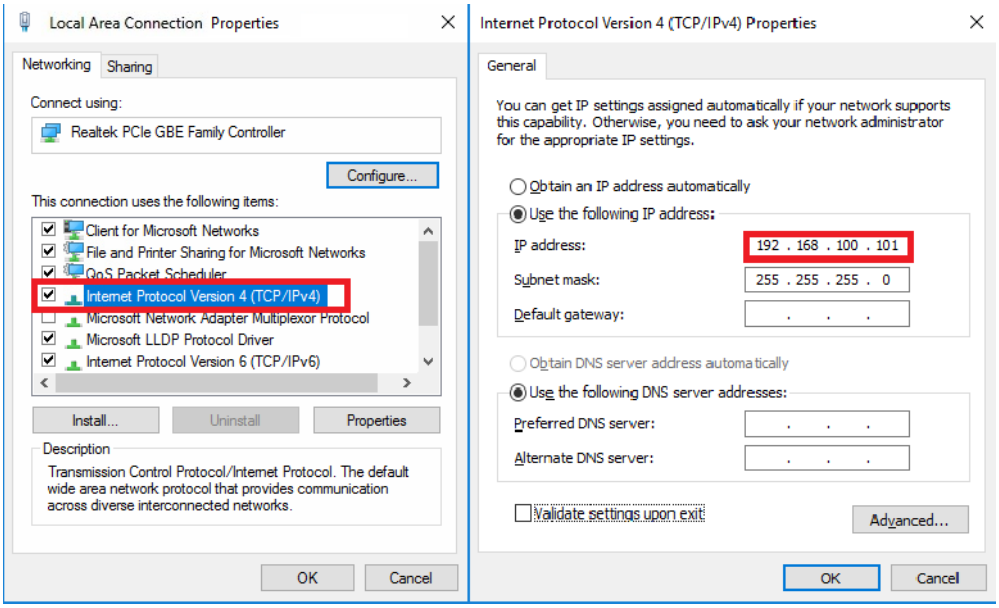
(1) Open the network and sharing center.



(2) Open the Network Adaptor properties



(3) Open TCP/IPv4 and set the static IP as 192.168.100.101~150. 192.168.100.111 is the wired network IP factory default of single detector.

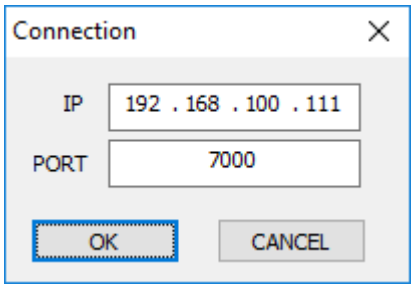


7.1.2. Initial Connection Setting

Check **Show Network Window** message before connecting. Click **Connect** and then **IP and PORT** window will appear.

Select network window

This is to set up connecting ports between PIXX and the workstation computer.



IP address: Set the IP address for detector.

Port number: Set the PORT number for detector

7.1.3. Multi Connection Setting

A setting method for using more than two detectors.

192.168.100.111 is the wired network IP. (Factory default of single detector)

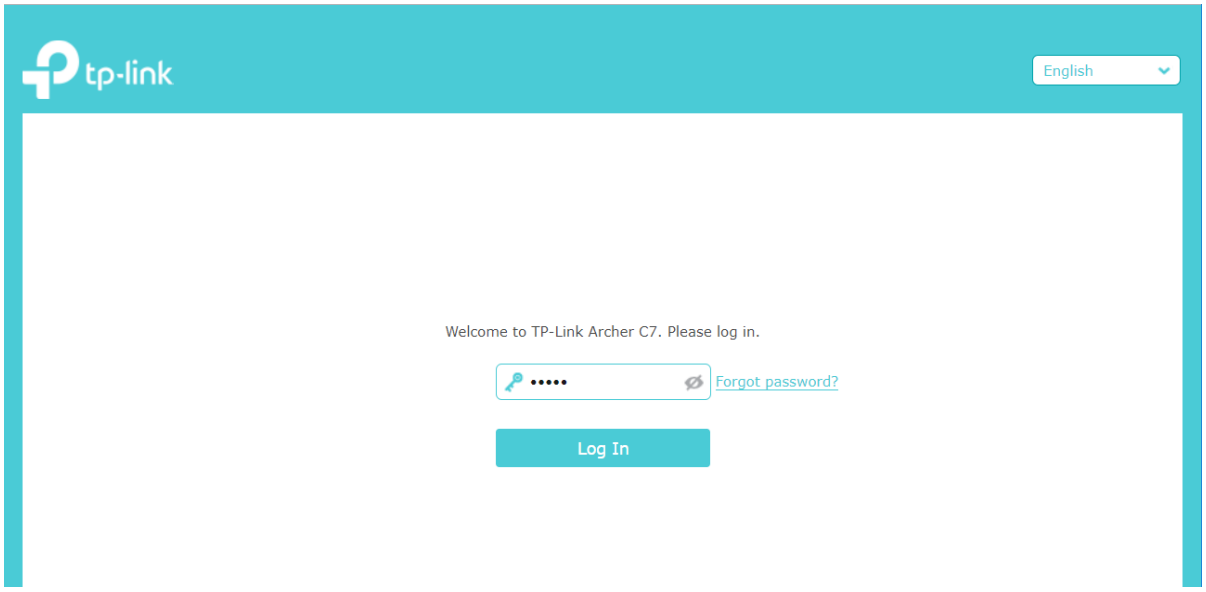
	Single	Dual	Triple
Detector IP	192.168.100.111	192.168.101.112	192.168.102.113
Port	7000	7000	7000
Network Adaptor IP	192.168.100.101	192.168.101.102	192.168.102.103

For changing Detector IP, it needs see ☞ **Appendix Wired, Bridge, Direct, and Wi-Fi Router (DHCP server) setting for Multiple detector.**

7.2. Wireless Detector

7.2.1. The settings between Bridge (Repeater) and PC

(1) Open a web browser (e.g., Internet Explorer, Chrome, Firefox, or Safari) and enter http://tplinklogin.net/ and then login to the system as an administrator (ID: admin / PW: admin).

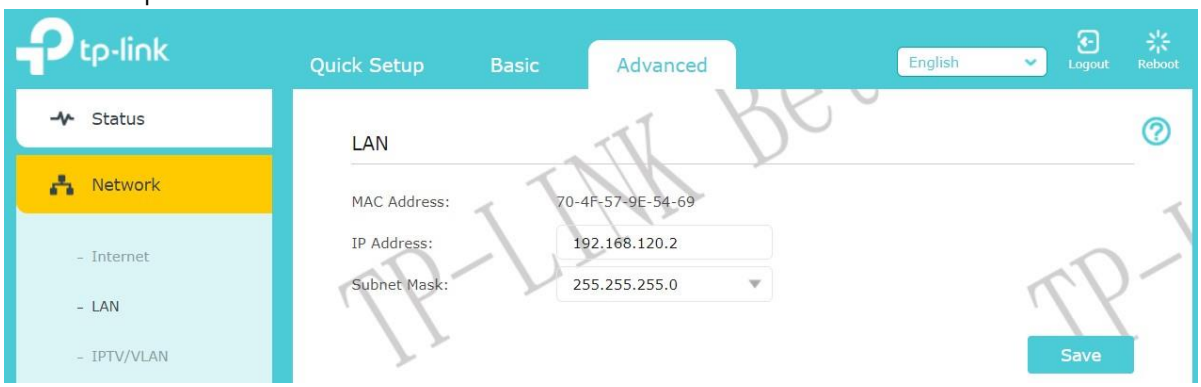


CAUTION!	The recommended product for Bridge of Wi-Fi Router is TP Link Archer C7. In this instruction, it has been instructed based on Archer C7 product. The rest of Wi-Fi Router are able to be used. However, if you like to use it, additional test is required.

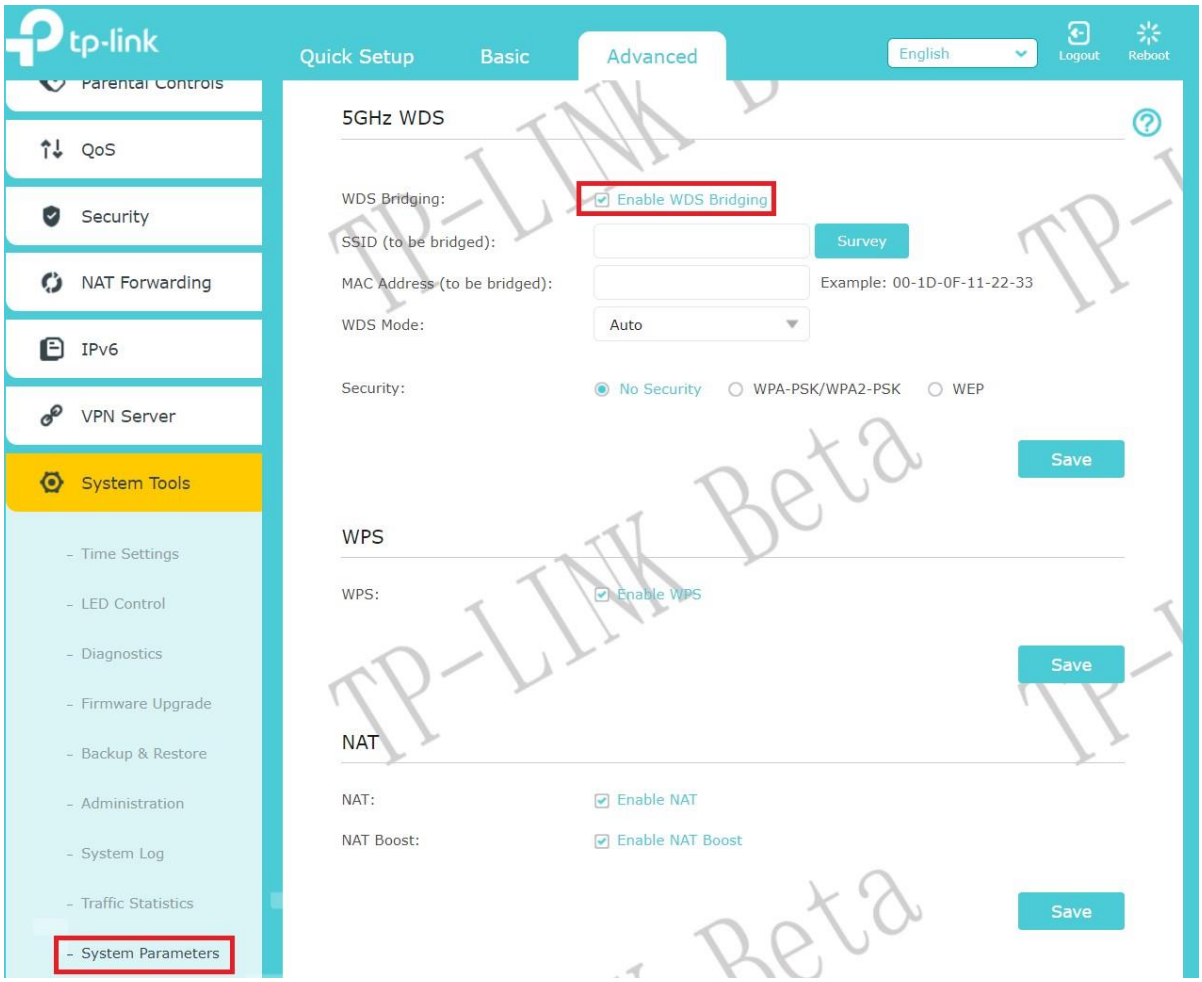
Tip!	When you set up Bridge at http://tplinklogin.net/ and if it is not able to enter to set up page, disable all Network Adopter at Network Adopter Setting except the Network Adopter that is connected Bridge. After completed the setting for Bridge, enable all the Network Adopter at Network Adopter Setting that you have disabled previously.

Tip!	When setting the Bridge (Repeater), set IP address as automatically in the TCP/IPv4

(2) Go to the **Advanced > Network > LAN**, and change the IP Address to **192.168.120.2** in order to prevent IP conflicts and then click the "**Save**" button.



(3) Go to the **Advanced> Wireless Settings**, and change the "**Wireless Network Name**" to "**PIXXAP**". And select "**Enable WDS Bridging**" And then click the "**Survey**" button.



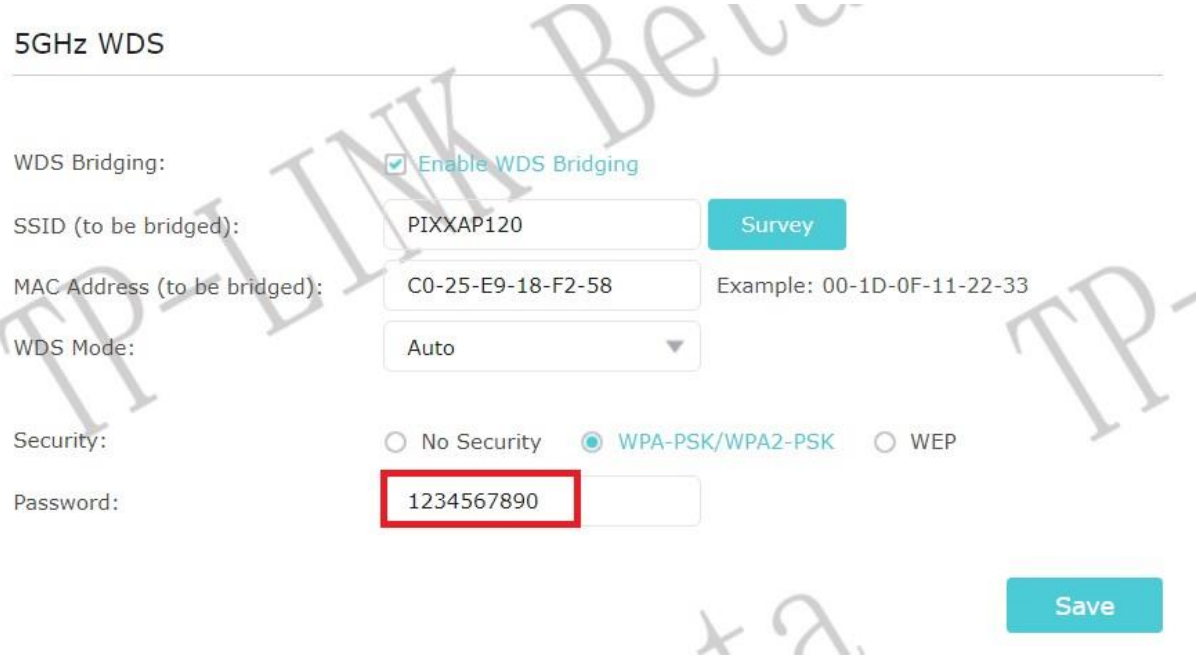
(4) Select "**PIXXAP120**" SSID from AP list, click the "**Choose**" button.

Survey

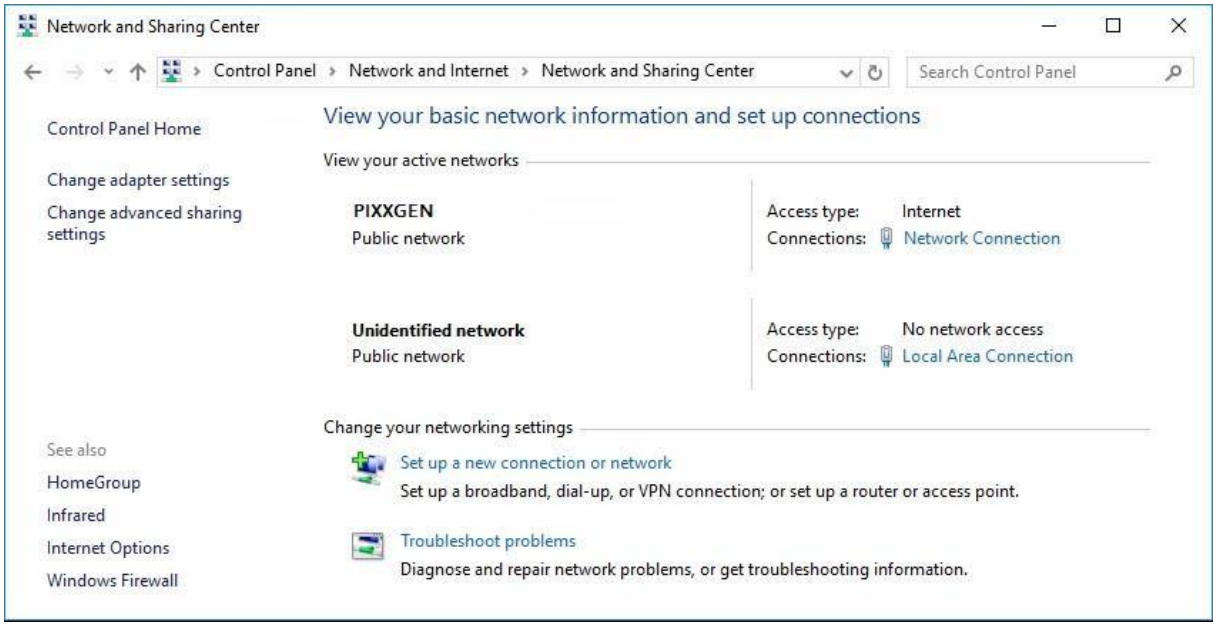
AP Number: 3 Refresh

ID	MAC Address	SSID	Signal	Channel	Security	Operation
1	64-E5-99-63-CD-10	PILAIM5G		149	PSK	Choose
2	C4-12-F5-6B-3A-56	PIAL501		36	PSK	Choose
3	C0-25-E9-18-F2-58	PIXXAP120		36	PSK	Choose

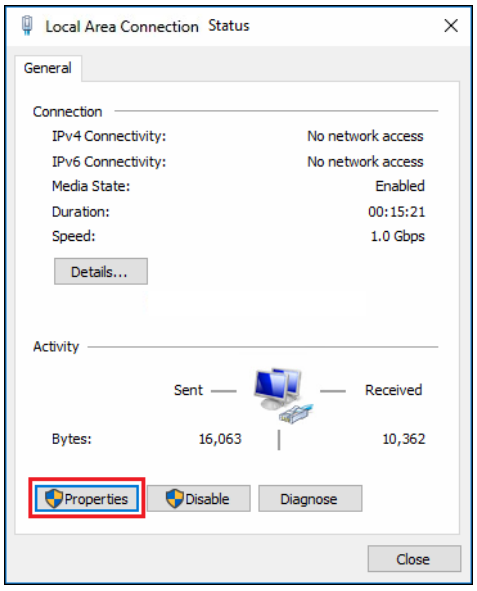
(5) Input the password "**1234567890**"and then click the "**Save**" button and reboot.

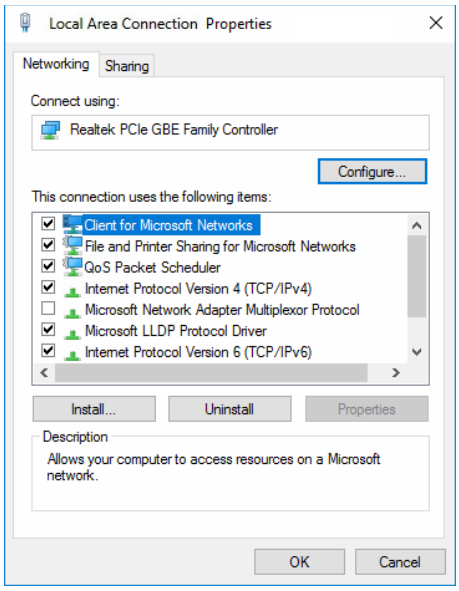


(6) Open the network and sharing center.

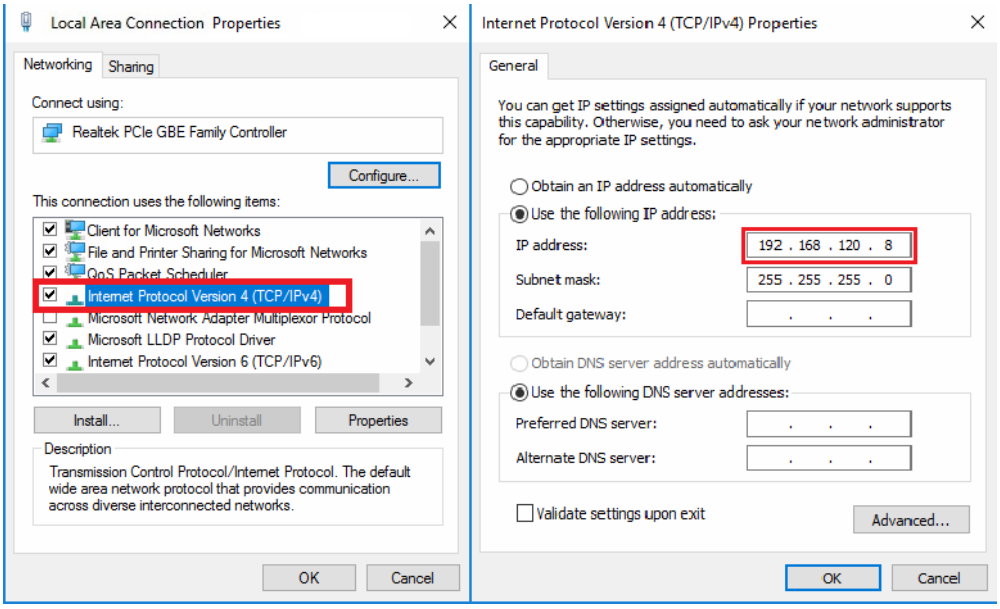


(7) Open the Network Adaptor properties





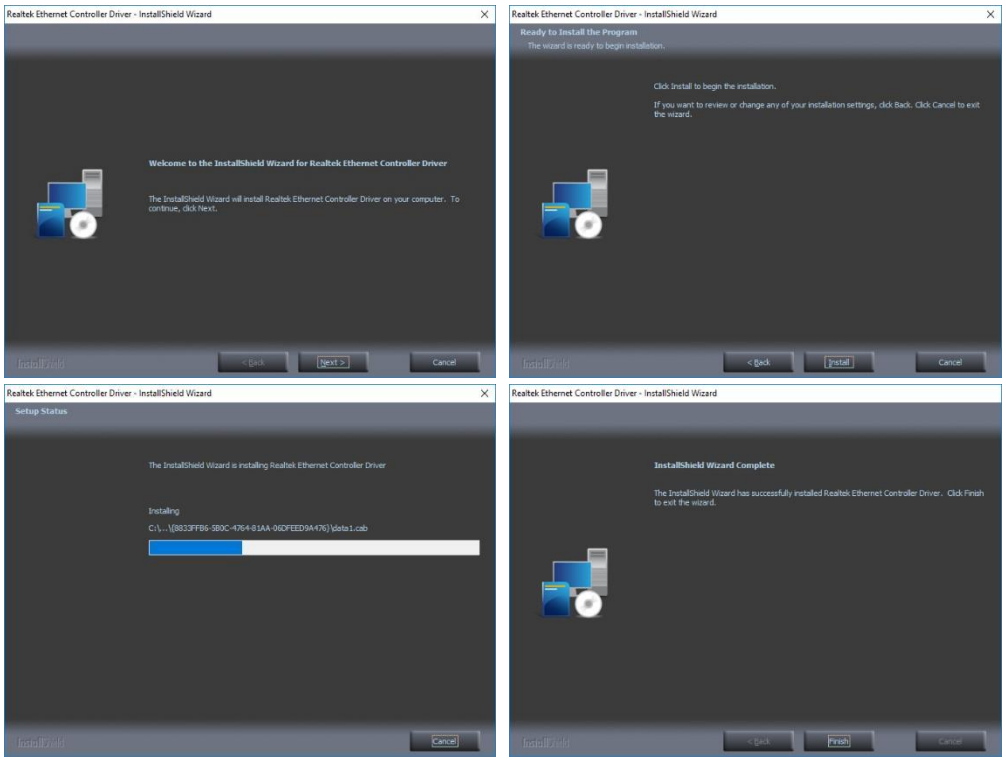
(8) Open TCP/IPv4 and set the static IP as 192.168.120.3~254.



7.2.2. Network adapter setting-Network Adaptor (Windows 7,8,10)

(1) Installation

- Insert driver CD
- Run install file following each OS version



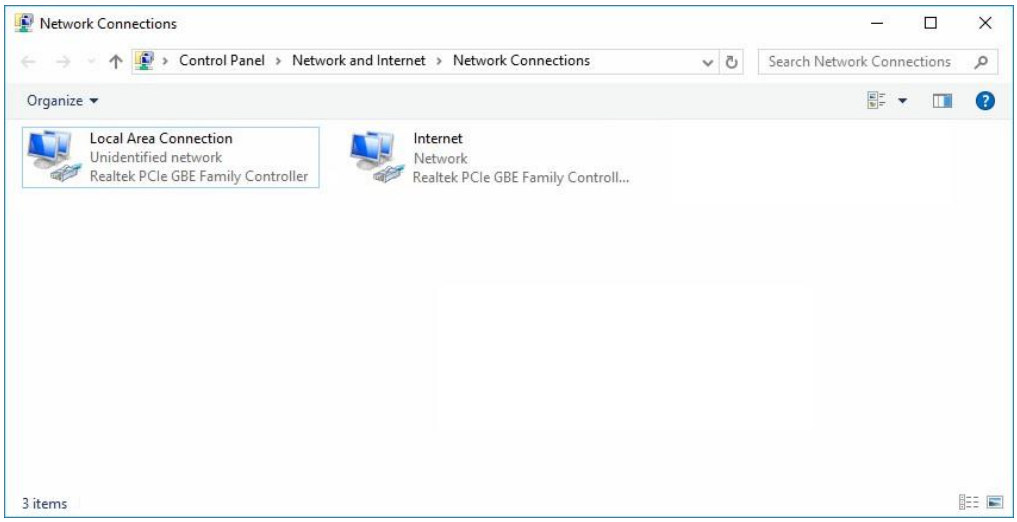
7.2.3. Advanced Network Set-up

This is to secure data streaming from disconnection.

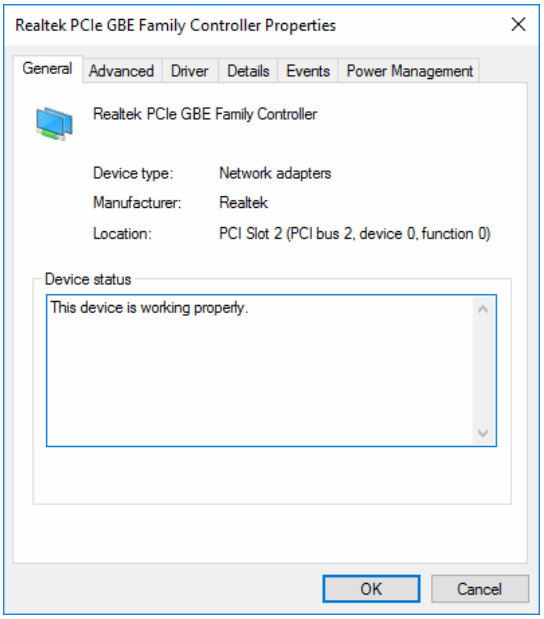
CAUTION!	For the user using own network adapter, it is essential to update the driver of network adapter and adjust the advanced network setting. Realtek network adapter in particular is sensitive to set-up. This set-up is to protect the network from freezing or slowing down. Improper set-up may result in data loss or damaged images or intermittent connectivity.

(1) To check the information of current network adapter, proceed to **Control Panel > Network and Sharing Center > Change adapter settings.**

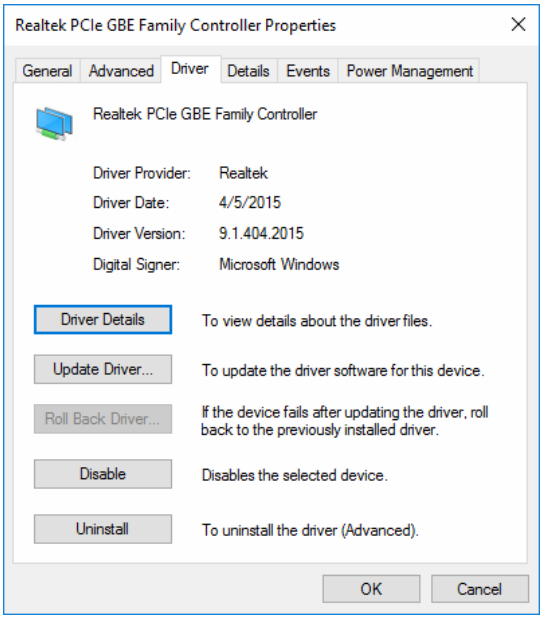
The network adapter connected to Prudent system appears as '**Unidentified Network**'.



(2) Run **Unidentified Network** and proceed to **Properties > Composition**.



(3) Proceed to **Driver** tab and check the version of current network adapter.

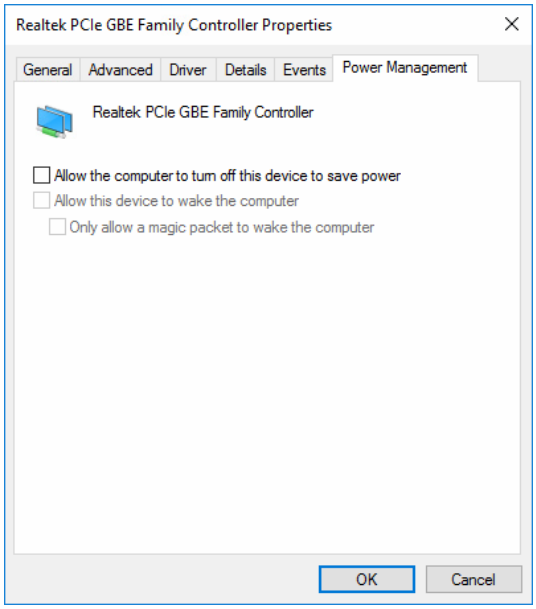


(4) The old version of network adapter driver that is already installed on the computer may influence the speed of network system.

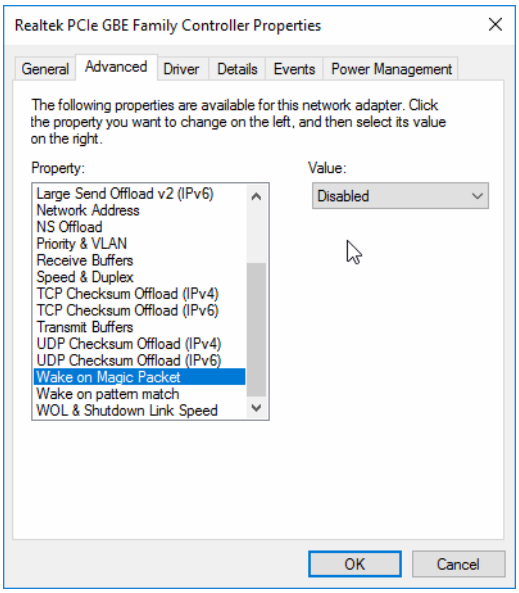
(5) Update the network adapter driver. The information of network adapter driver is available on the manufacturers' web sites below.

Tip!	http://www.intel.com Intel http://www.realtek.com.tw/ Realtek http://www.broadcom.com/ Broad.com.

(6) Uncheck all lists in the **Power Management** option.

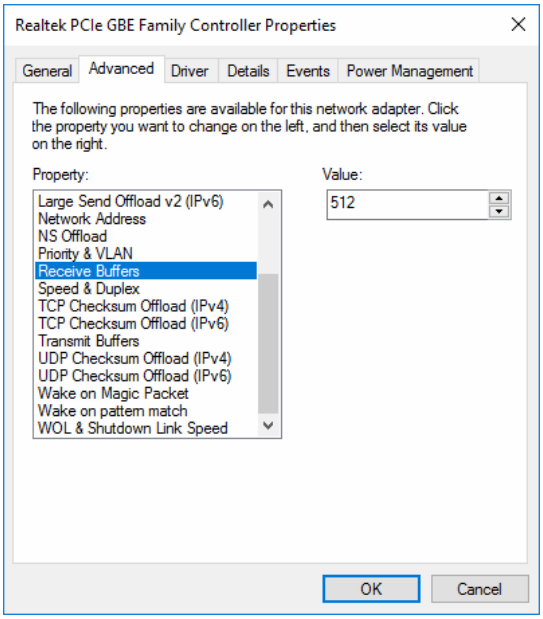


(7) Disable '**Wake on~**' and '**WOL**' options in the **Advanced** option.



(8) Change Receive Buffers value to **Maximum** value.

(Receive Buffers setting option of network adapter can be found in **Properties of Advanced/ Performance Option.)**



8. Calibration

8.1. Calibration Data Installation

CAUTION!	Allow at least 30 minutes to warm up for the maximum performance of instrument.

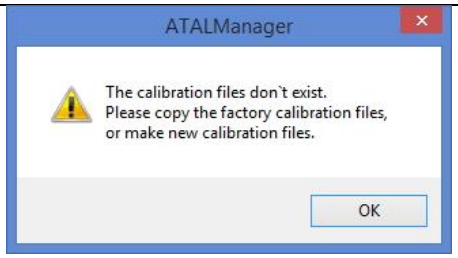
PRUDENT requires calibration data for best quality imaging. An optimal calibration data for PRUDENT has been provided on the PRUDENT USB. In case of lost or broken PRUDENT USB, however, the user may perform calibration with Sensorprobe.

Insert PRUDENT USB.
Copy **'Calibration Data'** folder.
Create **'C: //DR_data/'** folder, and paste **'Calibration data'** folder into the **'DR_data'** folder.

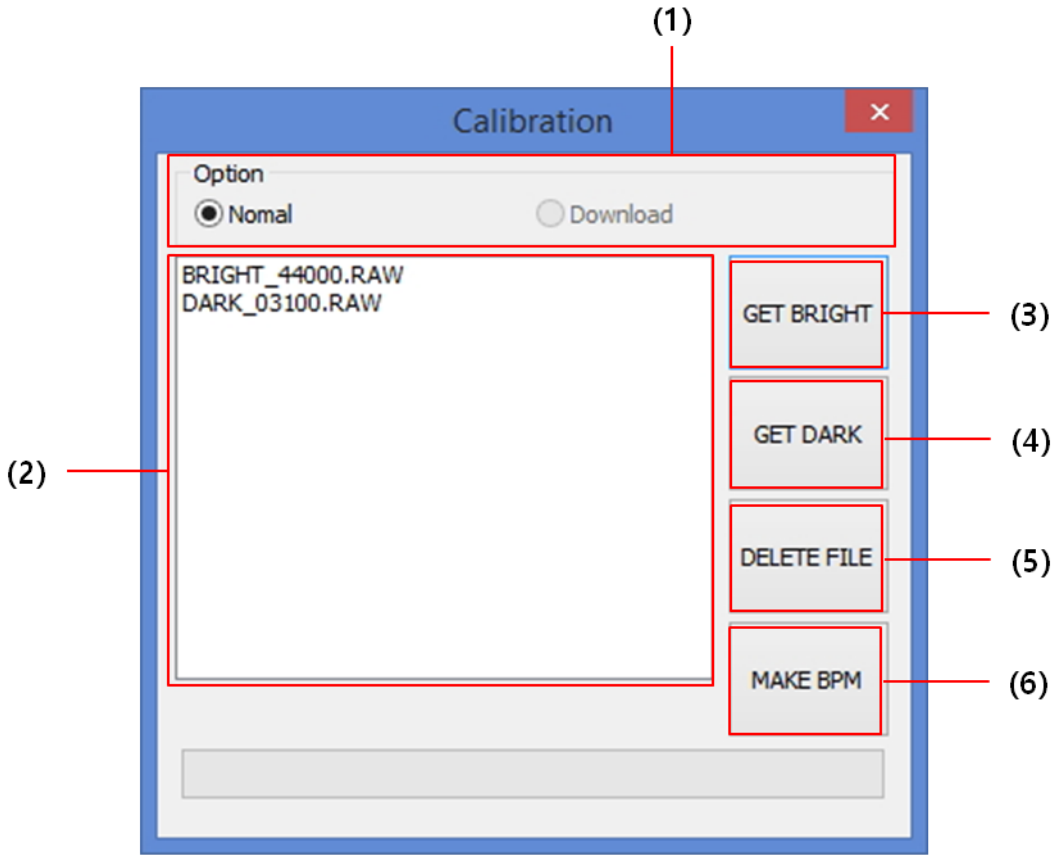
The calibration data destination folder varies depending on what acquisition program the user utilizes. Check the destination folder first when creating calibration data.

CAUTION!	Both 'SENSOR.ini' file and the calibration data must be saved in the same folder. Otherwise, PRUDENT will not be able to read the calibration data. For more information for 'SENSOR.ini' file, see Appendix: 'SENSOR.ini' file setting

Tip!.	These calibration data creation instructions are not necessary for the user who uses the calibration data provided.

CAUTION!	 If there is no calibration data in the designated destination, the warning message above will show up.

8.2. Detector calibration

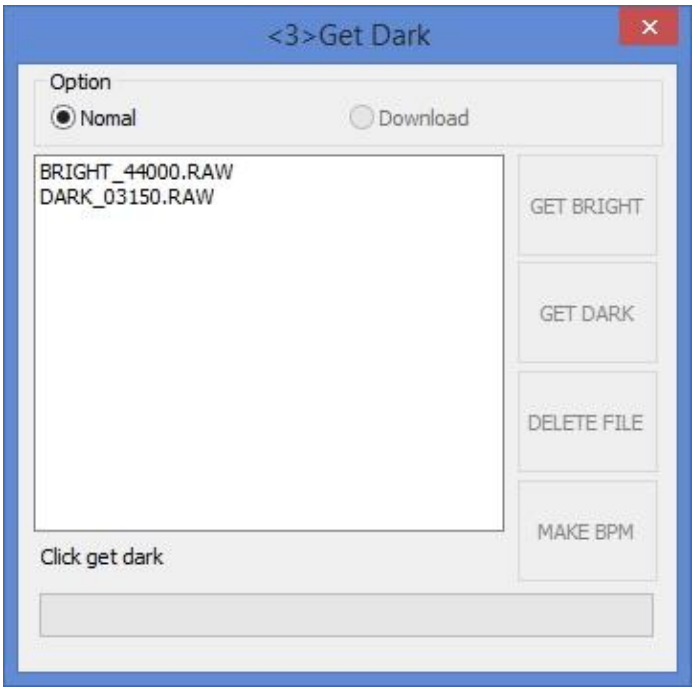


(1) Option: PRUDENT obtaining bright file with X-ray.
(2) Information: BRIGHT & DARK Information
(3) GET BRIGHT: PRUDENT obtaining bright file with X-ray
(4) GET DARK: PRUDENT obtaining dark file without X-ray.
(5) DELETE FILE: Deleting unnecessary files.
(6) Make BPM: Creating an image compensating file of PRUDENT by calibration data.

CAUTION!	Before data calibrating, check below first: - Collimator is fully opened. - X-ray tube and PRUDENT is centered together. - Keep distance 100 ~110cm (40 ~ 44") between X-ray tube and PRUDENT.

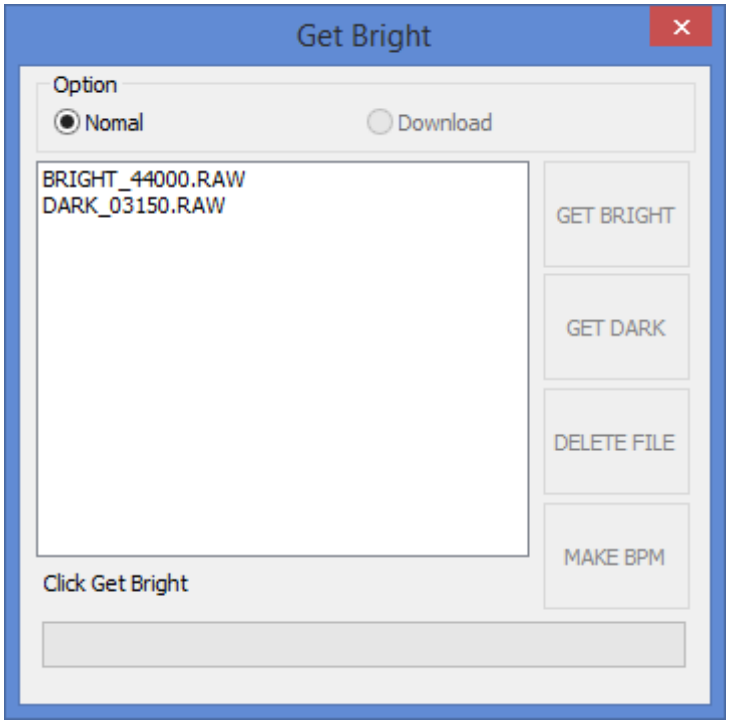
8.2.1 GET DARK

8.2.1.1. Click 'GET DARK'.



Several dark images are obtained when clicking 'GET DARK' button. And using those images, the process creates an optimized dark image. Obtained dark images will be named as 'dark_xxxxx.
(The average dark value of PRUDENT is around 3000 ~ 3300.)

8.2.2. GET BRIGHT

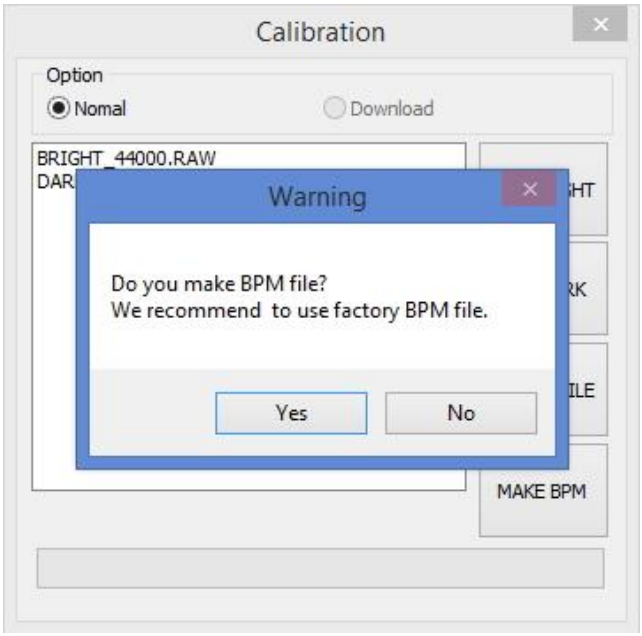


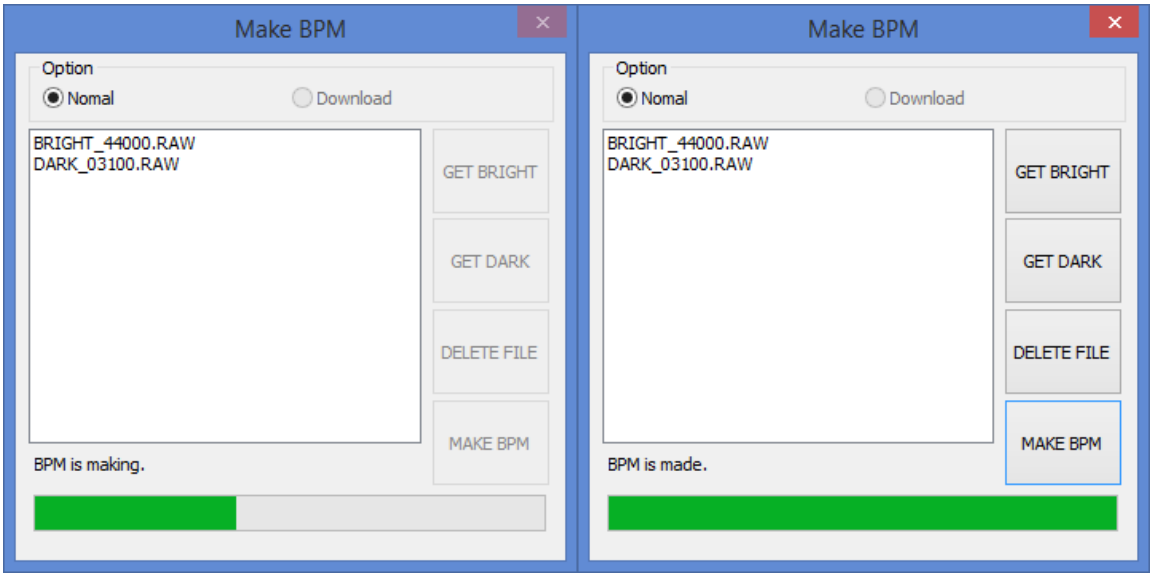
Bright file will be named as 'Bright_xxxxx' after GET BRIGHT process.
Bright value is proportional to the strength of X-ray (kV) and exposure time (mAs or sec).
Only one bright image is required for the calibration data of PRUDENT.
Delete unnecessary files by clicking 'DELETE FILE'

*Click [GET BRIGHT] button and exposure and X-ray after 2seconds

8.2.3. MAKE BPM

Create a BPM (Bad Pixel Map) file after obtaining dark and bright images. The BPM bar indicates the current progress.





CAUTION!	**DO NOT "MAKE BPM" YOURSELF.** Do not use MAKE BPM function after calibration. BPM file is provided. After calibration, copy BPM file from PRUDENT USB to the following folder – "C: //DR_Data/Calibration". In case the user performs MAKE BPM, there might be the deterioration of image quality.

Tip!.	If there is a visible line on the image, performing 5-minute calibration is recommended. Turn off PRUDENT and turn it on again after 1 hour. After previous process, perform 5-minute calibration after 5 minutes. The visible line on the image will be gone if the 5-minute calibration data is in use.

Appendix – Guidelines for Pediatric Subjects

1) Positioning the pediatric patient

Pediatric patients are not as likely as adults to understand the need to remain still during the procedure. Therefore it makes sense to provide aids to maintaining stable positioning. It is strongly recommended the use of immobilizing devices such as bean bags and restraint systems(foam wedges, adhesive tapes, etc.) to avoid the need of repeating exposures due to the movement of the pediatric patients. Whenever possible use techniques based on the lowest exposure times.

2) Shielding

We recommend you provide extra shielding of radiosensitive organs or tissues such as eyes, gonads and thyroid glands. Applying a correct collimation will help to protect the patient against excessive radiation as well. Please review the following scientific literature regarding pediatric radiosensitivity: GROSSMAN, Herman. "Radiation Protection in Diagnostic Radiography of Children". Pediatric Radiology, Vol. 51, (No.1): 141-144, January, 1973: http://pediatrics.aappublications.org/cgi/reprint/51/1/141.

3) Technique factors

You should take steps to reduce technique factors to the lowest possible levels consistent with good image acquisition. For example if your adult abdomen settings are: 70-85KVp, 200-400mA, 15-80mAs, consider starting at 65-75KVp, 100-160mA, 2.5-10mAs for a pediatric patient. Whenever possible use high KVp techniques and large SID(Source Image Distance).

Table 1 below can be used to estimate technique factors for various body builds. As the patient size increases, the KVp generally increases. Also depicted in Table 1 are the corresponding values of x-ray beam cross-sectional area and the estimated patient thickness in terms of water equivalence.

Table 1

Age	Head	Chest	Abdomen	Extremity (Forearm)
Newborn	67 KVp/2.0 mAs (110㎠/9.0㎝)	60 KVp/2.0 mAs (140㎠/8.0㎝)	66 KVp/2.0 mAs (200㎠/10㎝)	N/A
1-yr-old	72 KVp/2.0 mAs (160㎠/12㎝)	66 KVp/2.0 mAs (250㎠/9.0㎝)	70 KVp/4.0 mAs (300㎠/13㎝)	56 KVp/5.0 mAs (35㎠/1.8㎝)
5-yr-old	75 KVp/2.0 mAs (210㎠/14㎝)	70 KVp/2.0 mAs (430㎠/10㎝)	72 KVp/5.0 mAs (540㎠/15㎝)	60 KVp/5.0 mAs (84㎠/3.3㎝)
10-yr-old	77 KVp/2.0 mAs (240㎠/15㎝)	74 KVp/3.0 mAs (670㎠/13㎝)	75 KVp/6.0 mAs (820㎠/17㎝)	62 KVp/6 mAs (140㎠/5.0㎝)
15-yr-old	79 KVp/2.0 mAs (270㎠/16㎝)	78 KVp/4.0 mAs (780㎠/14㎝)	78 KVp/7.0 mAs (900㎠/20㎝)	65 KVp/6.0 mAs (200㎠/6.2㎝)
Adult	75 KVp/15 mAs (320㎠/20㎝)	120 KVp/2.0 mAs (1300㎠/15㎝)	75 KVp/15 mAs (1200㎠/22㎝)	65 KVp/8.0 mAs (200㎠/7.9㎝)

4) Dosimetry

Table 2 summarizes the key dosimetry parameters for the four types of radiographic examination for patients ranging from newborn to the adult. In each cell, the first value is the entrance skin air kerma(free-in-air) in uGy. The second term gives the energy imparted to the patient, expressed in uJ. In parentheses on the second line are the corresponding values of patient effective dose in uSv.

Table 2

Age	Head 100 μGy/78.2μJ (10 μSv)	Newborn Chest 77 μGy/66μJ (19 μSv)	Abdomen 100 μGy/140μJ (62 μSv)	Extremity (Forearm) NA
1-yr-old	120 μGy/165μJ (7.3 μSv)	96 μGy/160μJ (16 μSv)	230 μGy/580μJ (90 μSv)	130 μGy/9.5μJ (0.21 μSv)
5-yr-old	140 μGy/260μJ (5.9 μSv)	110 μGy/340μJ (18 μSv)	320 μGy/1500μJ (120 μSv)	160 μGy/44μJ (0.5 μSv)
10-yr-old	150 μGy/320μJ (4.3 μSv)	190 μGy/1100μJ (33 μSv)	420 μGy/3300μJ (160 μSv)	200 μGy/130μJ (0.87 μSv)
15-yr-old	150 μGy/400μJ (3.1 μSv)	280 μGy/2100μJ (36 μSv)	550 μGy/5100μJ (140 μSv)	220 μGy/240μJ (0.92 μSv)
Adult	1100 μGy/3200μJ (19 μSv)	150 μGy/2500μJ (34 μSv)	1100 μGy/13000μJ (290 μSv)	300 μGy/360μJ (1.1 μSv)

5) Other References for Pediatric Dosimetry

1. Size measurements are based on approximate mean values (averaged across males and females) from: McDowell, M.A.,C.D.Fryar, C.L. Ogden, and K.M.Flegal. 2008. Anthropomorphic Reference Data for Children and Adults, United States, 2003-2006. National Health Statistics Reports, 10, 1-48. Available for download at: http://www.cdc.gov/nchs/data/nhsr/hsr010.pdf. The weight given for the neonate subgroup is lower than the average to ensure that a broad range of sizes is adequately covered.

2. These suggested subgroups fall within the age groups identified in the guidance entitled "premarket Assessment of Pediatric Medical Devices"
(http://www.fad.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089742.PDF): neonate(birth-1 month), infant(1 month-2 yrs.) child(2-12 yrs), adolescent(12-21 yrs). For design and evaluation of radiological devices, patient size(i.e. height, weight, thickness) is a better indicator.

3. Based on reports of the lifetime incidence of cancer vs. age of exposure data, these pediatric subgroups defined by the Agency cover the region where the largest age dependence is expected for cancer risk. Risk decreases much less steeply as a function of age for individuals over 21years old. [See NAS National Research Council Committee to Assess Health Risks from Exposure to Low

Levels of Ionizing Radiation.2006. Health risks from exposure to low levels of ionizing radiation: BEIR VII phase 2. Washington, D.C.: National Academy of Sciences, National Academies Press.]

4. The following reference gives current data for anteroposterior and transverse body diameter for pediatric patients ranging in age from 0.5 to 20 years: Kleinman, P.L.,K.J. Strauss, D. Zurakowski, K.S. Buckley, and G.A. Taylor. 2010. Patient size measured as a function of age at a tertiary care children's hospital. American Journal of Roentgenology, 194, 1611-1619.

5. The following reference used cylindrical phantoms with diameters of 8,16,24, and 32cm to represent a neonate, 5year old, 12 year old, and adult patient respectively: Siegel, M. J., et al. 2004. Radiation dose and image quality in pediatric CT: effect of technical factors and phantom size and shape. Radiology, 233(2), 515-522.

6. Summary

- ✓ Image only when there is a clear medical benefit.
- ✓ Image only the indicated area.
- ✓ Use the lowest amount of radiation for adequate imaging based on size of the child(reducing tube output- KVp and mAs)
- ✓ Try to use always short exposure times, large SID values and immobilizing devices.
- ✓ Avoid multiple scans and use alternative diagnostic studies(such a ultrasound or MRI) when possible.

Appendix – Motion Radiography Procedure (Trigger 99)

1.DESCRIPTION

Traditional flexion/extension x-rays are obtained to rule out ligamentous injury. Motion radiography shows the same views as traditional Flexion & Extension of the: Spine (*All segments)* Knee, Shoulder, Elbow or Hip or the similar Internal/External Rotation views. The difference is that in addition to the two views normally acquired we will also obtain multiple images in between which can reveal pathology not seen in the two traditional views.

The logic is that the patient with suspected joint instability complains of pain when they move. It is reasonable to obtain the study while they move.

2.EQUIPMENT

The equipment required is:

- A traditional radiographic x-ray system
- A DR detector capable of opening and closing the acquisition window fast enough to perform the described images. Typically, it should be 4 frames per second at full resolution without pixel binning.
- Software capable of receiving, processing and displaying the acquired frames. The display should be static and motions image review.

3.HISTORY

Previous attempts at this have been done with fluoroscopy which, because of noise and lack of motion stopping, falls short of the required spatial & contrast resolution relegating it to the Chiropractic realm.

Current technology is to use synchronization of the x-ray (Pulse) and the window opening of the detector. This is a very valid approach but makes the study cost prohibitive for the very physicians that need it because they need a sophisticated x-ray system not present in the current Orthopedic practice. The Motion Radiography approach uses existing x-ray systems with an affordable DR Detector.

4.PROCEDURE

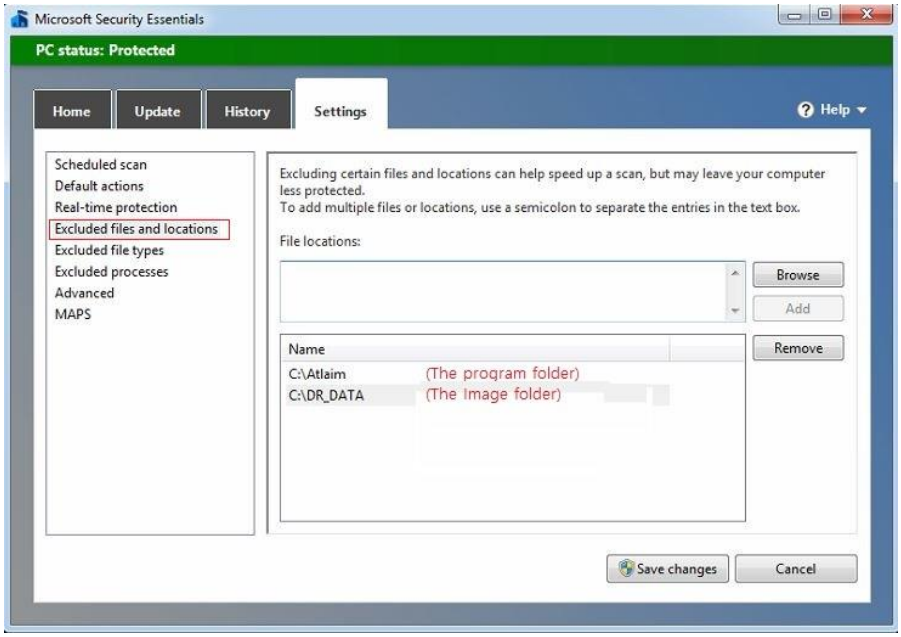
The procedure is the same as traditional Flexion Extension, so no additional training for a qualified medical professional is needed, but in order to do the motion radiographic procedure, the patient must know their part. The traditional studies have two views. These views are the start and finish of the Joint Motion Study. These should be demonstrated to the patient including the speed at which that patient can achieve movement between them.

In any case the study will be less than 4 seconds.

1. The x-ray technique should be the same or less than the traditional study. This is because there is persistence in the scintillator and during longer exposures this can be taken advantage of by decreasing mA. Experience will show the technologist how much to decrease the mA.
2. Once the time to go from the start position to the finish is determined it should be set on the generator control.
3. The frames per second should be determined by the physician based on how many views he believes are needed.
4. Then the technologist will position the patient in the "start" or first position. Have the patient move the body part to the second or "End" position at a comfortable speed. This should be repeated a couple of times.
5. Return the patient to the "Start" position and obtain the radiograph normally.

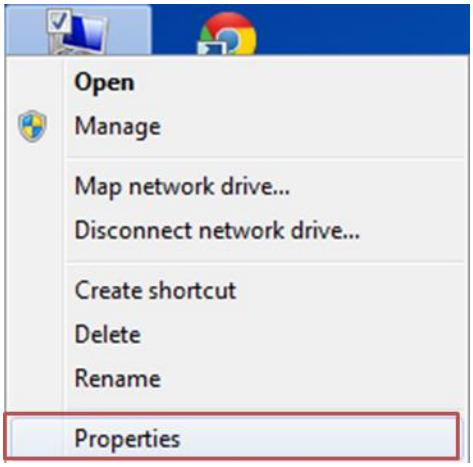
Appendix - Check Vaccine programs in your Workstation PC.

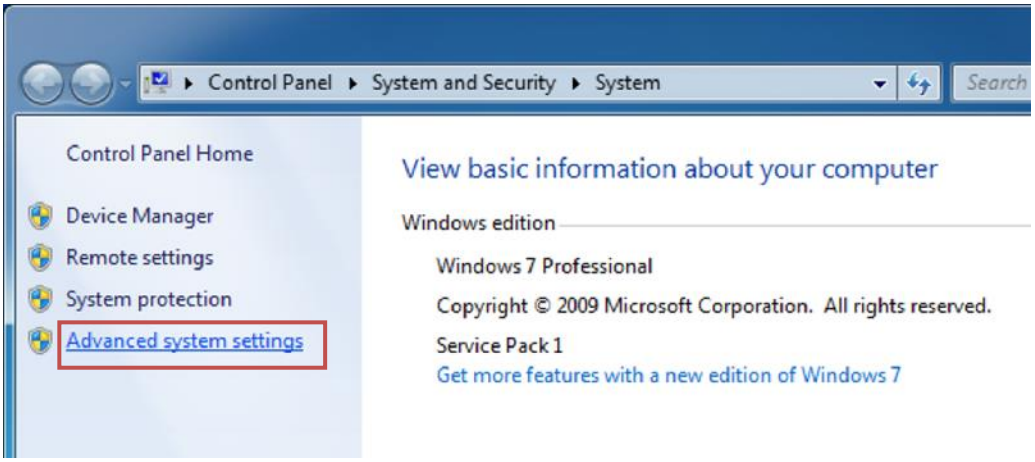
Some vaccine programs might block detector signal since they recognize our software as a virus or malware.
We strongly recommend removing vaccine programs except MS Essential.
When using MS Essential, please set up “Excluded files and locations” as shown below.

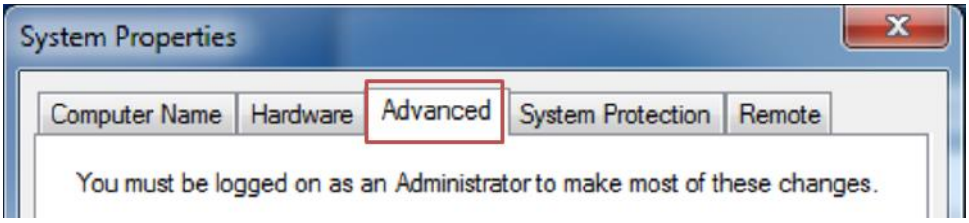


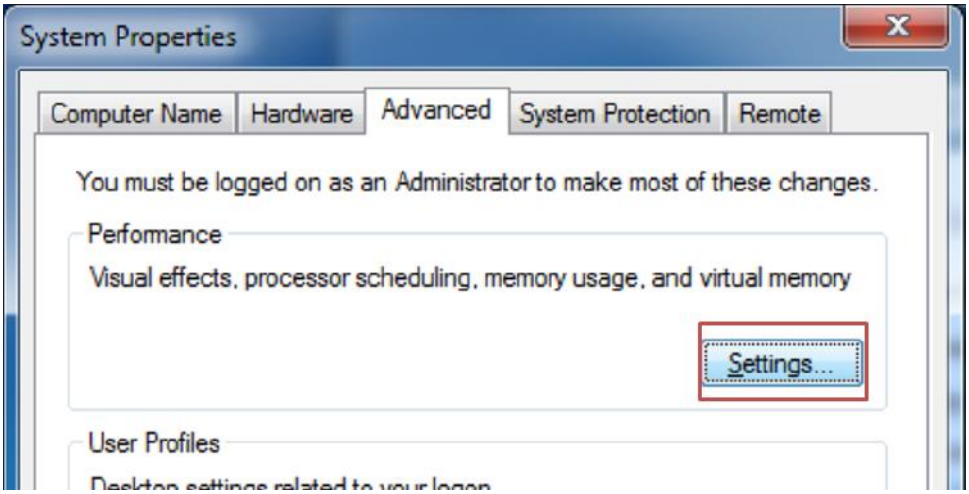
Appendix - Virtual Memory / DEP

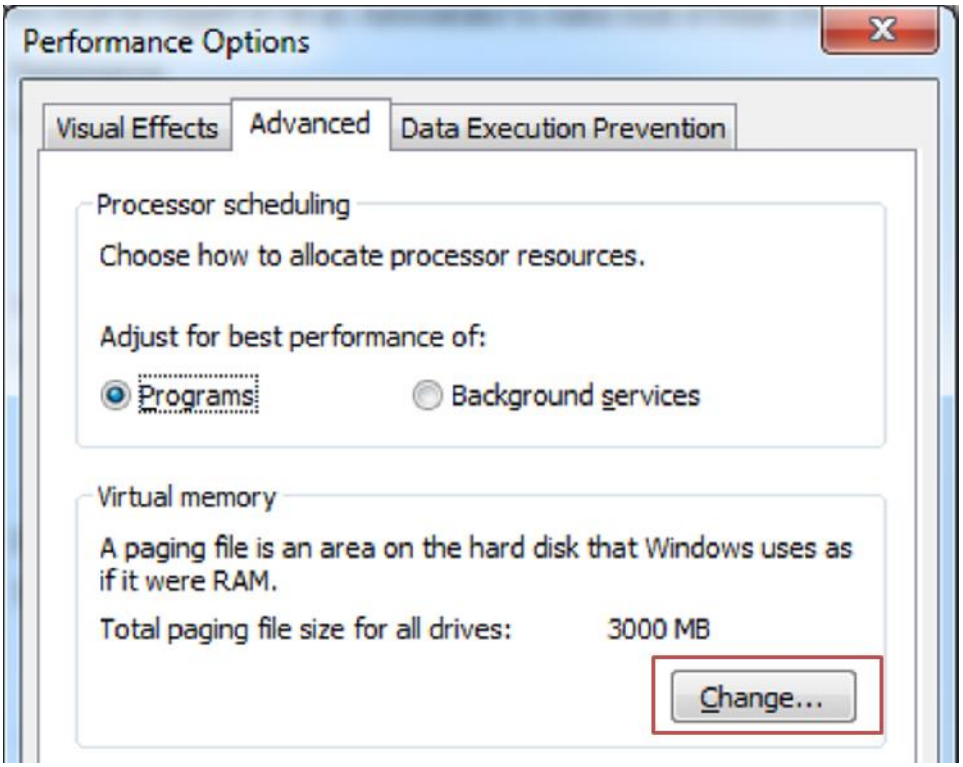
Virtual Memory Windows 7

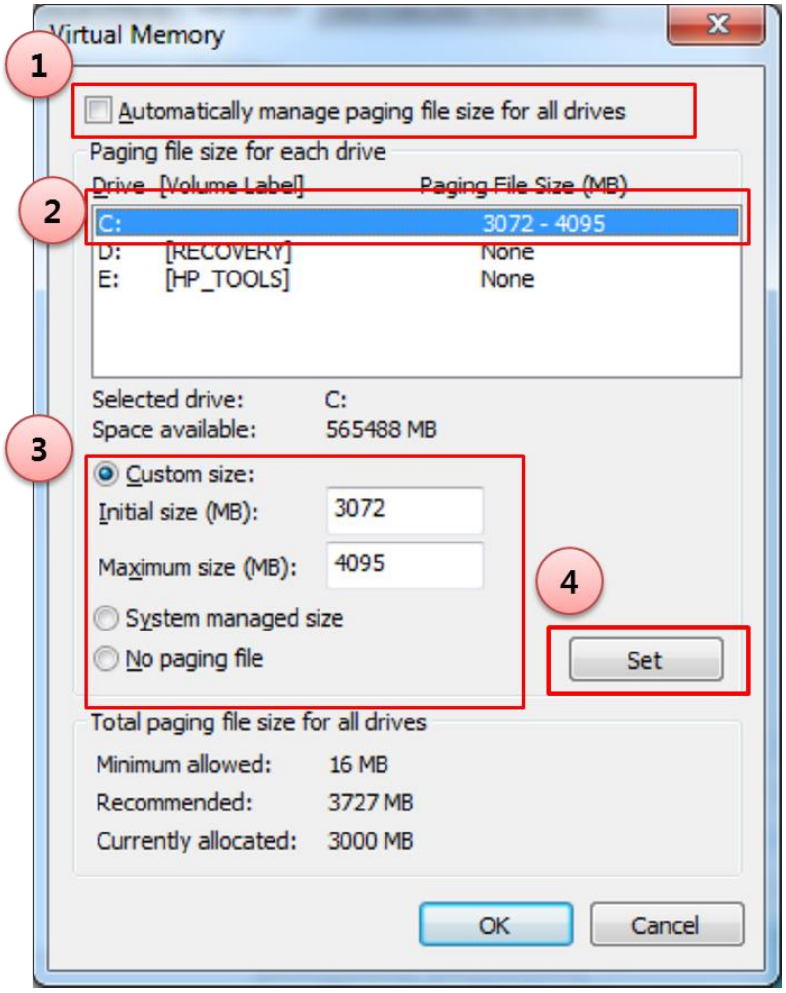




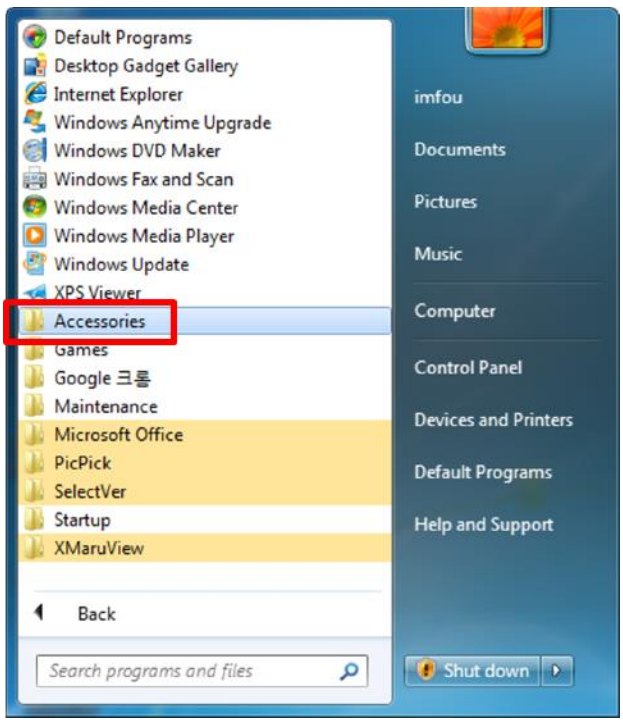


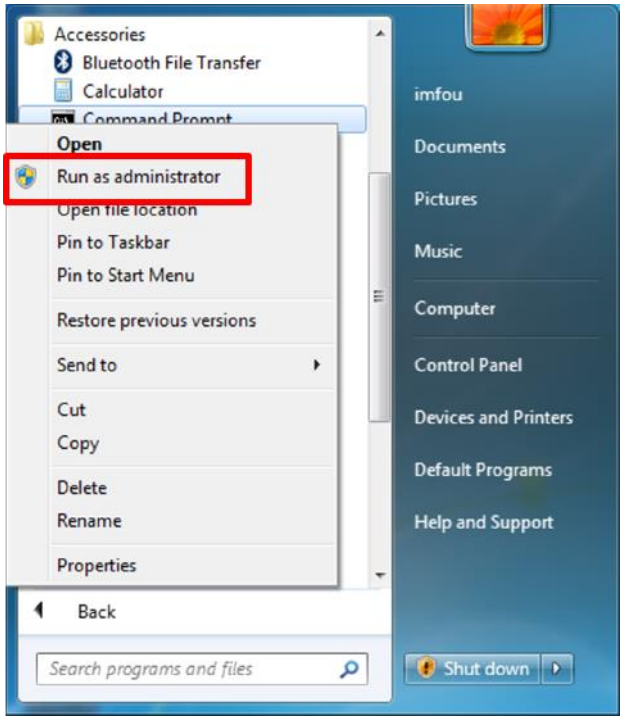


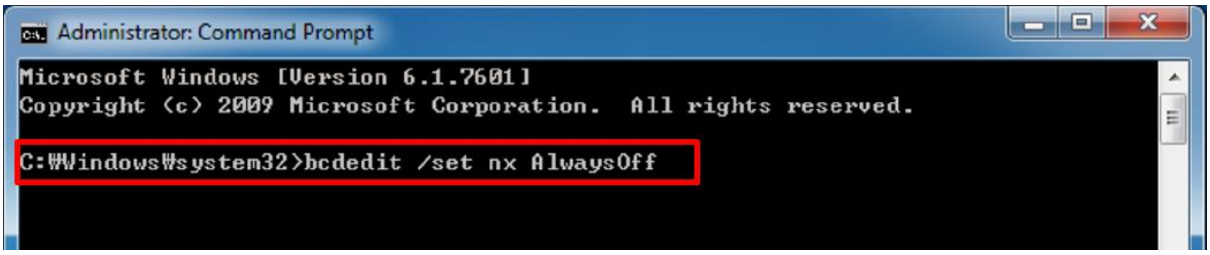


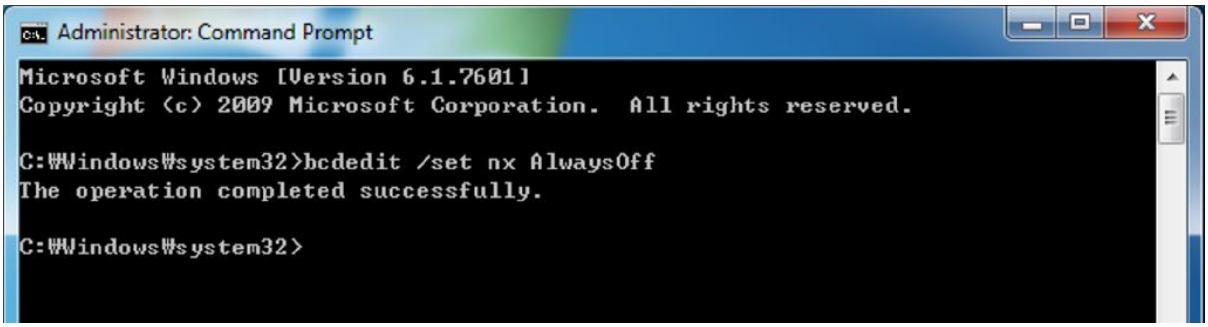


DEP Setup in Windows 7









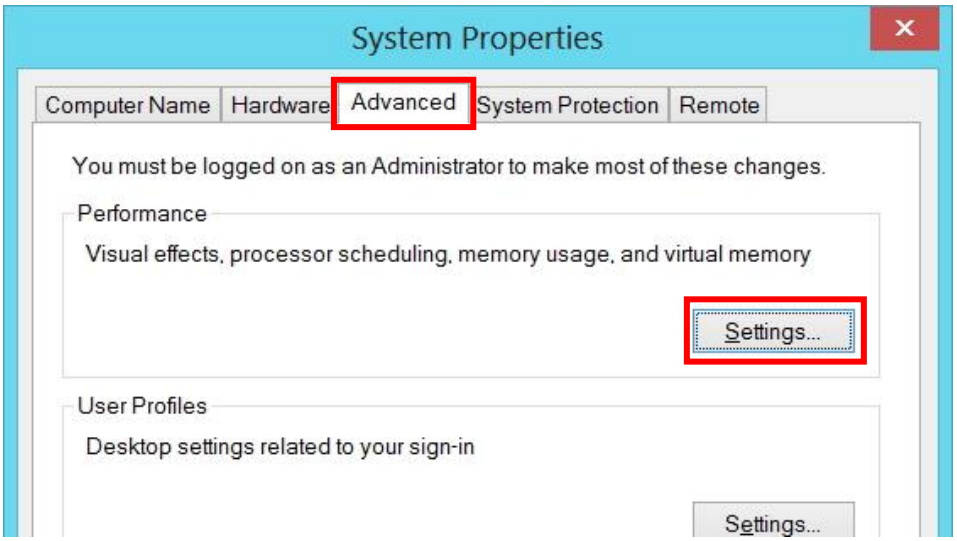
DEP Setup in Windows 8

- This function may not work exactly.
- There are CMOS disturbs this function to use, at that case you need to set DEP release in OS.

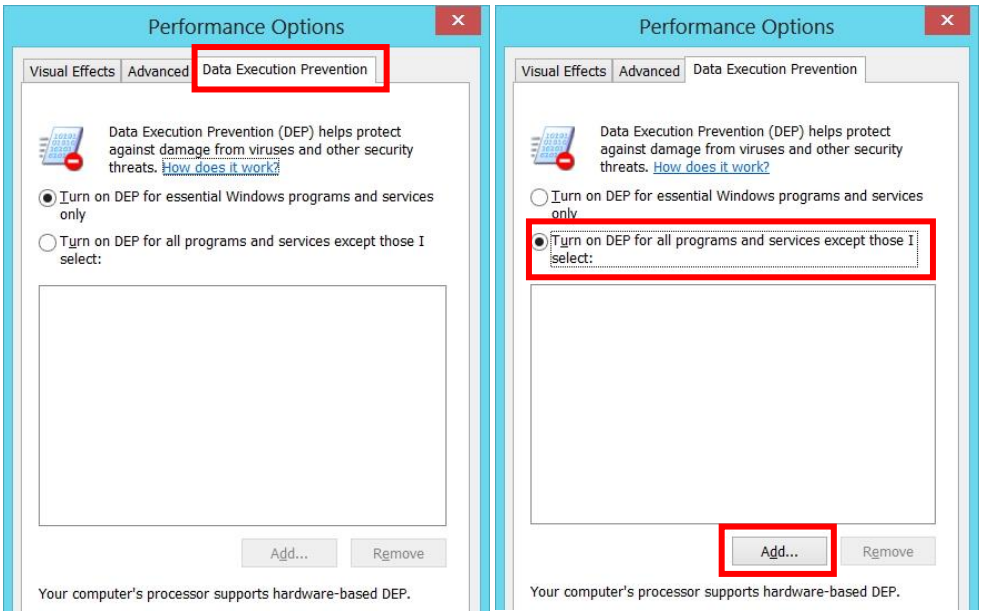
(1). System

Control Panel ➔ System and Security ➔ System

(2). Click the Advanced system Setting and then the System Properties window will be shown. And then move the Advanced Tab and click the Settings button of Performance

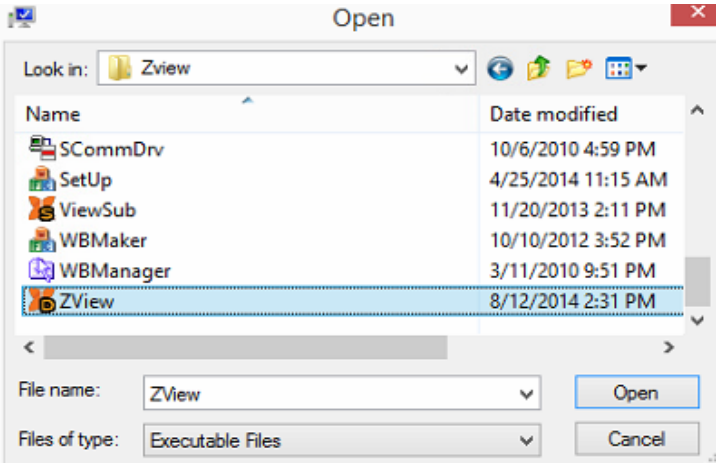


(3). When the Performance Options window show, move the Data Execution Prevention Tab and then select 'Turn on DEP for all programs and services except those I select'

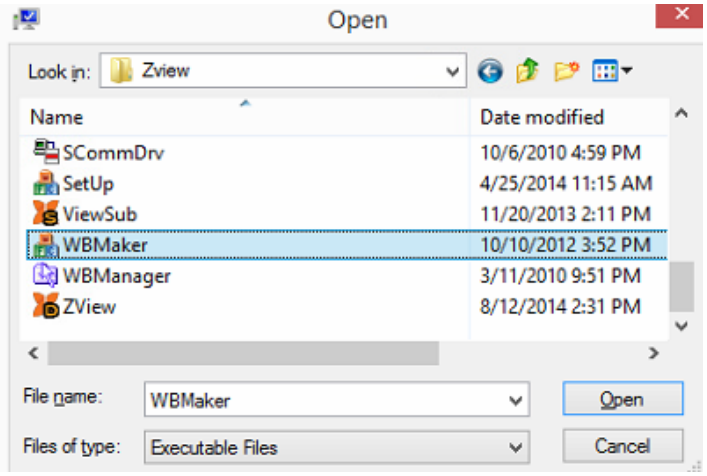


(4). Click the 'Add...' button and select two files as like below

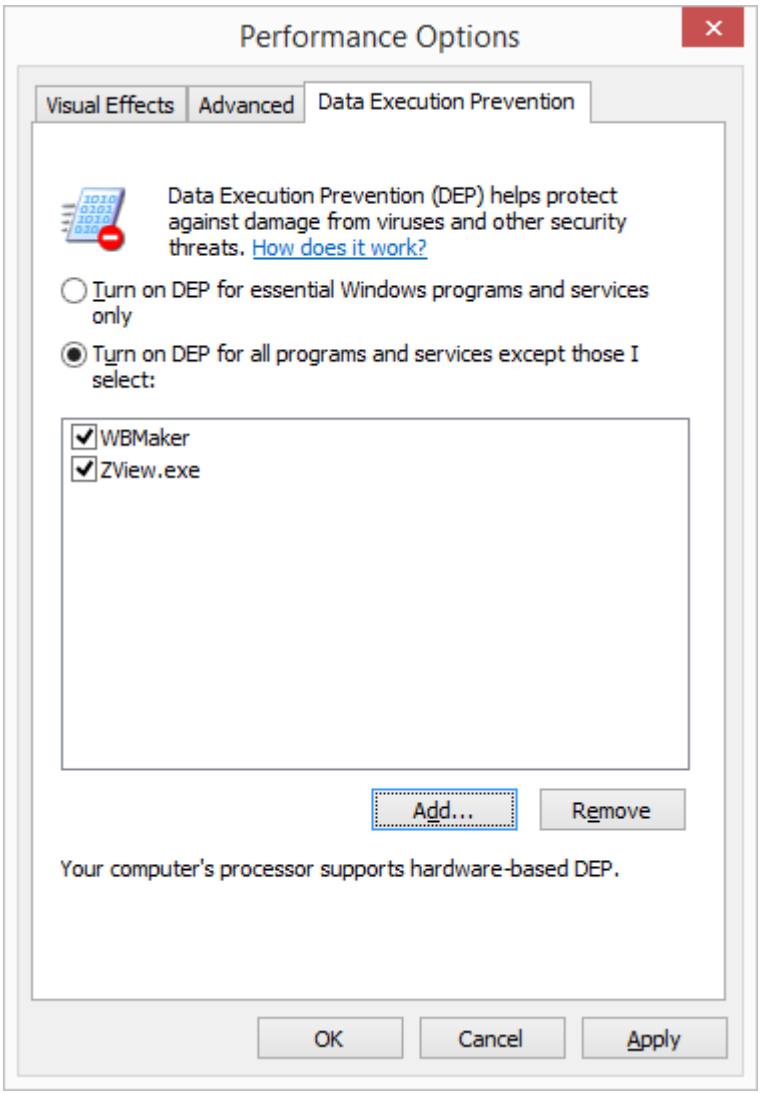
ZView.exe



WBMaker.exe



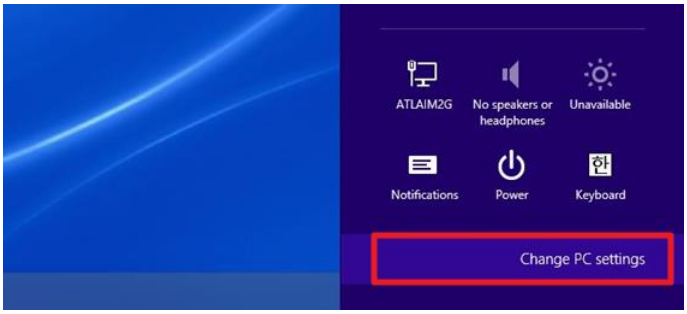
(5). Confirm the 'ZView and 'WBMaker' was included in List and then click 'Apply' button



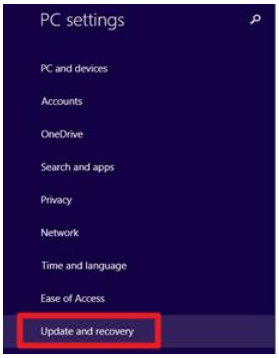
Appendix - How to Disable Driver Signature Verification

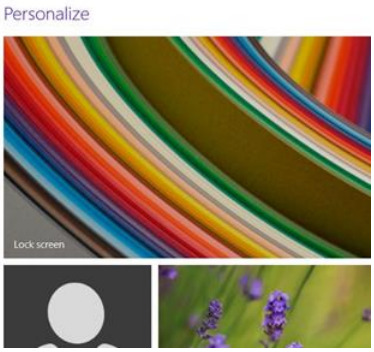
Press the Windows key + C keyboard combination to bring up the Charms Bar, and then click on the Settings Charm.

We need to head into the Modern Control Panel, so go ahead and click on the Change PC settings link.

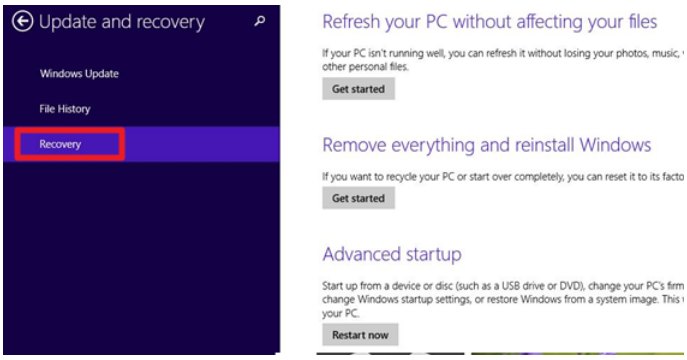


When the Control Panel opens, switch over to the "Update & recovery" section.

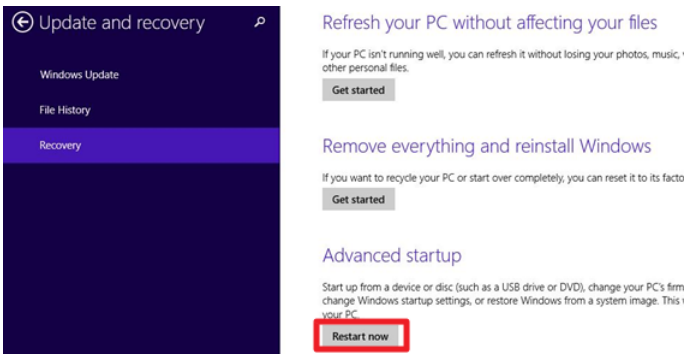




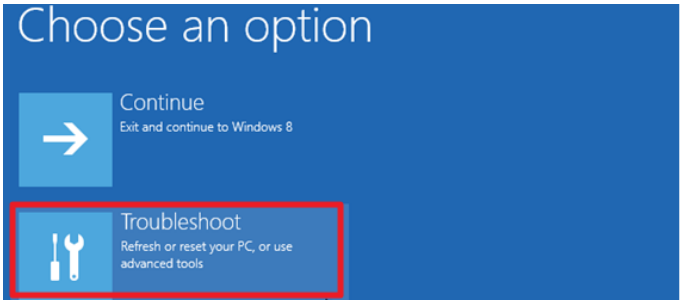
Then click on the Recovery option on the left hand side.



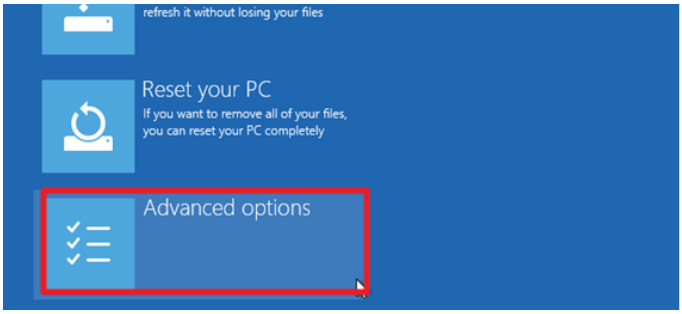
Once selected, you will see an advanced startup section appear on the right hand side. You will need to click on the "Restart now" button.



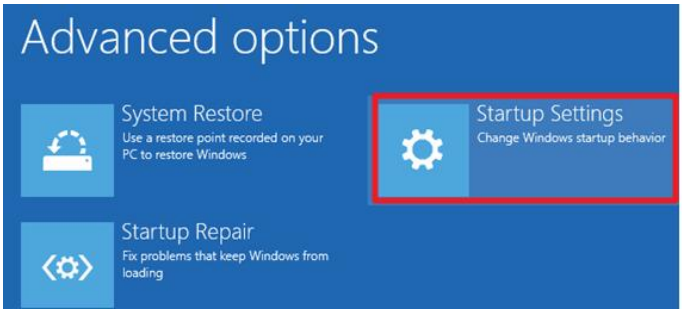
Once your Computer has rebooted you will need to choose the Troubleshoot option.



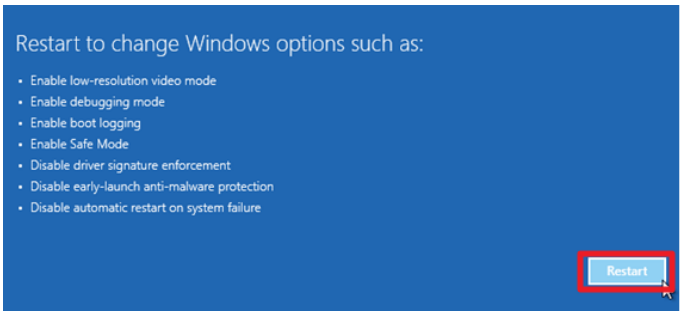
Then head into Advanced options.



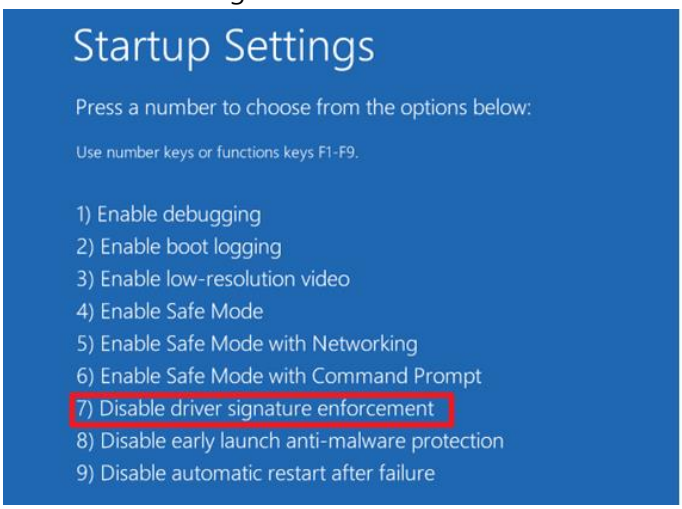
Then Startup Settings.



Since we are modifying boot time configuration settings, you will need to restart your Computer one last time.



Finally, you will be given a list of startup settings that you can change. The one we are looking for is "Disable driver signature enforcement". To choose the setting, you will need to press the F7 key.



That's all there is to it. Your PC will then reboot and you will be able to install unsigned drivers without any error message.

Appendix - Check List

	Is PICB's power on?
Status	PRUDENT is powered by PICB.
Tips	Check the Blue light at the front of PICB. If you still have the light turned off even though all problems are solved, consult with our friendly technical support team.

	Have you installed Gigabit NETWORK?
Status	PRUDENT demands gigabit communication for fast image transmission. It is essential to install gigabit network to operate PRUDENT system.
Tips	Check network driver version and network speed at network connection in the control panel. If the speed of network is not faster than 1 gigabit, see Chapter. 3-1 Network Adapter Setting. Should you still have lower speed than 1 gigabit, please contact the technical support team.

	Are all cables connected tightly?
Status	It is impossible to obtain clear images unless the calibration data saved correctly.
Tips	Check the calibration data in C://DR_data/Calibration data folder. If no data exists in the folder, create one. See Chapter. 8 Calibration for more information.

	Are all cables connected tightly?
Status	Be sure all the connecting cables are secured tightly. - HDMI cable Power supplying and data transmitting to PRUDENT - LAN cable Sending image to acquisition program - USB cable Connecting devices for manual mode
Tips	- HDMI cable

	Check the power indicating LED, and then review firmware version of PRUDENT in the Config folder of Sensorprobe. - LAN cable Check unidentified network at network connection in the control panel. - USB cable Proceed to the control panel, device Manager and check the Virtual Serial Port Should you have unidentified devices, be sure all cables are connected tightly. See Chapter. 3.2. and Chapter. 5. for more information. If you cannot solve the problems, contact the technical support team.

	Have you performed initial Sensorprobe set-up?
Status	Sensorprobe should be set up at first in order to link with acquisition program.
Tips	Check if PRUDENT is properly inked with the acquisition program. If not linked, see Chapter. 4-2 Sensorprobe, and set up Sensorprobe. Contact the technical support team, if you cannot solve the problems.

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