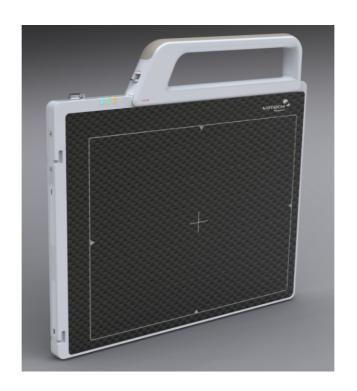


Medical Image Processing Unit

1012WCA

User Manual





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Attention

For improvement of product performance, supplementation, or follow-up of information; the contents of this manual are subject to change without separate prior notice.

Please note that our company has neither responsibility for any accidents nor obligation to do free repair service for any damage of the equipment due to user's mistake, which resulted from failure to follow the contents in this manual. Make sure to be familiar with the safety precautions and usage procedures. Also note that the product may slightly differ from the contents of this manual depending on specification.

The following marks are used for the effective use of the product in this manual.



Attention, consult accompanying documents.



This is used to emphasize essential information. Be sure to read this information to avoid incorrect operation.



This indicates hazardous situation which, if not heeded, may result in minor or moderate injury to you or others, or may result in machine damage.



This indicates a potentially hazardous situation which, if not heeded, could result in death or serious injury to you or others.

Federal Law restricts this device to sale by or the order of a radiologist or any other practitioners licensed by the law of the state in which that person practices to use or order the use of the device.

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Introduction

Overview

The 1012WCA is a wireless digital X-ray flat panel detector that can generate images of any part of the body. The wireless LAN((IEEE 802.11a/g/n) communication feature improves the operability, and high-speed processing. This X-ray imaging system consists of a scintillator directly coupled to an a-Si TFT sensor. It makes high-resolution, high-sensitive digital images.

Intended use

For U.S.A.

1012WCA Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for human anatomy including head, neck, spinal column, arm, leg and peripheral (foot, hand, wrist, fingers, etc.). It is intended to replace film based radiographic diagnostic systems and provide a case diagnosis and treatment planning for physicians and other health care professionals. Not to be used for mammography.

For European Union

This device provides digital X-ray imaging for diagnosis of disease, injury, or any applicable health problem. The image is obtained as the result of imaging X-rays passed through the human body with an X-ray flat panel detector and importing a digital signal output from the detector into the image processor.

Product features





- Wi-Fi (802.11a/g/n)
- Based on a-Si TFT active matrix
- Compact (18mm thickness) and light weight (Typ. 3.15kg)
- Limiting Resolution : 3.9 lp/mm
- 16-bit digital output
- Easy integration

Product components

• Medical Image Processing Unit

Photo	Item	Part Name	Quantity
	Detector	SD1012WCA	1
	Handle	-	1
	Battery pack	RB37WH	2
W. The state of th	Battery charger	RC120W	1
	Charger adapter	PMP120-13-3	1
	AGI	RA001A	1

Cables

Item	Part Name	Length	Quantity
Link cable	VRH076A	6m	1
P- Interface cable	VRH017A	8m	1
USB cable (A to B)	VRH078A	1.8m	1
AC Power cord	VRH018A/019A	1.8m	1

• Installation CD

- o Manual
- o Detector Library

• Option

- o Additional Battery
- Charger for the Car
- o Cover Bag
- o AP package

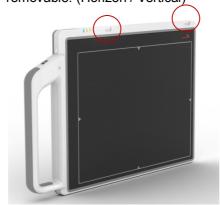
Components Description

The detector is designed to capture radiographic images.

Captured images are transmitted to PC using the wireless/wired connection.



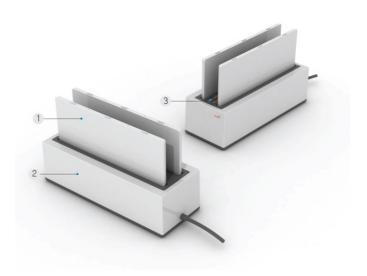
- 1. LED indicator: The LED indicates the state of detector.
 - i. Green on: Power on.
 - ii. Blue blinking: Wireless Connection.
 - iii. Orange on: Low battery.
- **2. Handle**: Hold this handle when carrying the sensor unit. It is removable. (Horizon / Vertical)



- 3. Handle unlock-lever: This is an unlock-lever to remove handle.
- **4. Link cable connector**: This is a connector for Wire communication

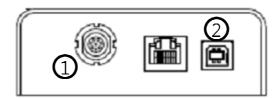
- and power supplying. Connect the detector to PC and SMPS(not provided) using Link cable.
- 5. CFRP(Carbon Fiber Reinforced Plastic): The part of the patient's body to which an image is to be taken should be placed against this plate.
- **6.** Power button: Power on / Power off switch.
- **7. Shock sensor**: Detector has built-in 4 Shock sensors. It detects and records impact and mishandling of fragile
- 8. Battery unlock-lever: This is an unlock-lever to remove battery.

(2) Battery & Charger



- 1. Battery: Lithium ion battery. The number of times being acquired image is 600 images(@ cycle time: 15s). The batteries last 2.5 hours and are rechargeable.
- **2. Charger**: Two port cradle type.
- 3. LED indicator:
 - i. Orange on : charging
 - ii. Green on: Charging is completed.

(3) AGI



- **1. Trigger connector:** This is a connector for synchronization between detector and generator. Connect the AGI to the generator using P-interface cable..
- **2. USB connector:** This is a connector for communication between AGI and PC. Connect the AGI to the PC using USB cable.



Warning

Environment of Use and Storage

Follow the specified process of operational instructions written in this manual for the safety of the users and patients.

Does not use or store the instrument near any flammable chemicals such as thinner, benzene, etc. Also, this instrument is not a category AP or APG equipment. If chemicals are spilled or evaporate, it may result in fire or electric shock through contact with electric parts inside the instruments. Also, some disinfectants are flammable. Be sure to take care when using them.

Connection

Do not connect the instrument with anything other than specified. Otherwise, it may result in fire or electric shock.

Handling

Always be sure to keep checking the condition of the system and the patient to ensure they are normal during the use of the instrument. If any problem is found, take appropriate measures, such as stopping the operation of the instrument, as required.

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.

Do not hit or drop the instrument. The instrument may be damaged if it receives a strong jolt, which may result in fire or electric shock if the instrument is used without being repaired.

When Problem Occurs

Should any of the following occur, immediately turn OFF the power of each instruments, unplug the power supply cord from the AC outlet, and contact Rayence representative or distributor.

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



Maintenance and Inspection

For safety reasons, be sure to turn OFF the power of each instrument when the inspections indicated in this manual are going to be performed. Otherwise, it may result in electric shock.

When the instrument is going to be cleaned, be sure to turn OFF the power of each instrument, and unplug the power supply cord from the AC outlet.

The instrument must be repaired by a qualified engineer only. If it is not repaired properly, it may cause fire, electric shock, or accident.

Caution

Environment of Use and Storage

Do not install the instrument in a location with the conditions listed below. Otherwise, it may result in failure or malfunction, cause fire or injury.

- Close to facilities where water is used.
- Where it will be exposed to direct sunlight.
- Close to air-conditioner or ventilation equipment.
- Close to heat source such as a heater.
- Prone to vibration.
- Insecure place.
- Dusty environment.
- Saline or sulfurous environment.
- High temperature or humidity.
- Freezing or condensation.

Do not place the storage case in a location with the conditions listed below.

- Where the cable of the sensor unit will be strongly pulled when the sensor unit is put into the case, otherwise, the cable may be damaged, resulting in fire or electric shock.
- Where someone might get their foot caught in the cable of the sensor unit. Otherwise they could trip over, resulting in injury

Handling

Do not spill liquid or chemicals onto the instrument or, in cases where the patient is injured, allow it to become wet with blood or other body fluids, as doing so may result in fire or electric shock. In such situation, protect the instrument with disposable covering as necessary.

Wipe the CFRP plate of the sensor unit with ethanol or glutaraldehyde solution to disinfect it each time a different patient uses the instrument, in order to prevent infection.

Turn off the power of each instrument for safety when they are not going to be used.

Maintenance and Inspection

For safety reasons, be sure to inspect the instrument before using it. In addition, carry out a regular inspection at least once a year.

Modifications

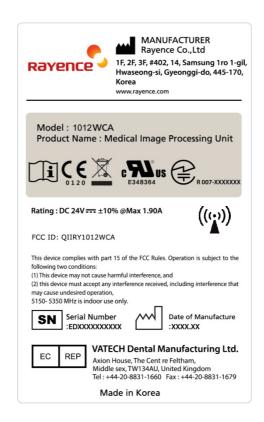
Any changes or modifications in construction of this device which are not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Marking and labeling symbols

Symbols	Meaning
Ţ <u>i</u>	Caution : "Attention, see instructions for use"
	Manufacturer
~~ <u> </u>	Date of manufacture
SN	Serial number
	WEEE : Waste Electrical and Electronic Equipment
EC REP	Authorized representative in the European Community
0120	CE symbol grants the product compliance to the European Directive for Medical Devices 93/42/EEC as a class II a device. Authorized by Notified Body SGS (code no.:0120) of British
((•))	non-ionizing radiation

Labels

Detector label



Battery Pack



Battery Charger



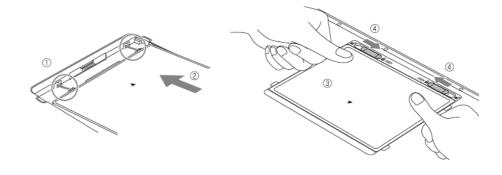
Notes for Using the Detector

Preparing

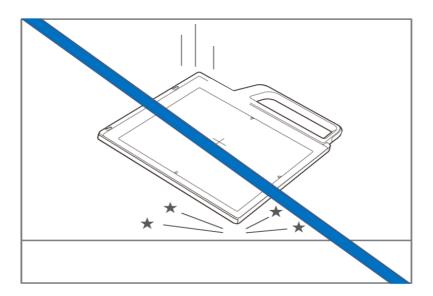
Fully charge the battery pack. Charge the battery on the day of examination or on the previous day.

- Battery slowly discharges even of not in use. The battery pack may have expired if it discharges immediately after being fully charged. You can purchase an optional battery pack to replace an exhausted one.
- Be sure to fully charge the battery before use.
 - * The battery charger, RC120W is designed for the dedicated battery pack.
 - When the detector will not be used for some time, remove the battery pack.

Attach the battery pack. Align the claw on the battery pack and the groove on the battery bay. Insert the battery pack fully. Push down the battery pack. Slide the lock lever toward (lock) side and lock it.

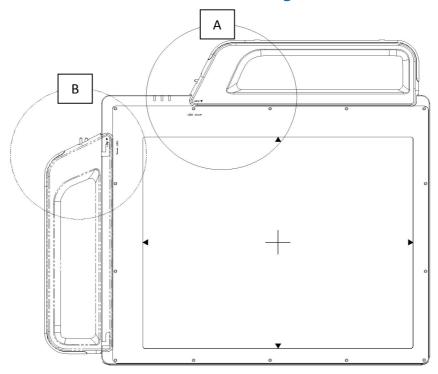


Handling

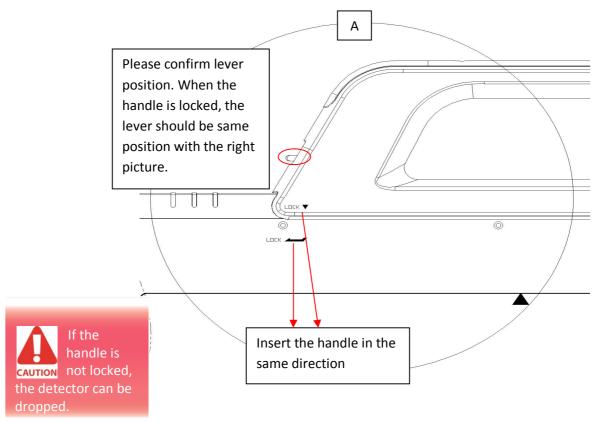


Handle the instrument carefully, as it may be damaged if something is hit against it, dropped, or receives a strong jolt.

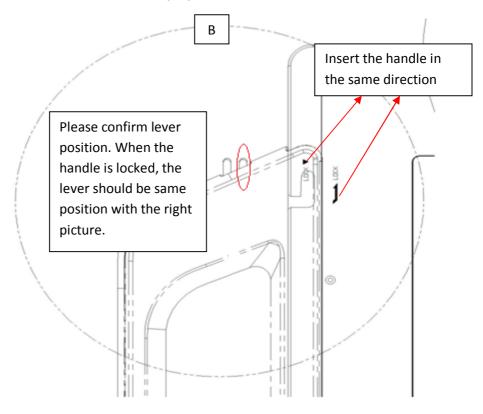
Handle Assembly



Handle Assembly Type 1



Handle Assembly Type 2



Before Exposure

Be sure to check the equipment daily and confirm that it works properly.

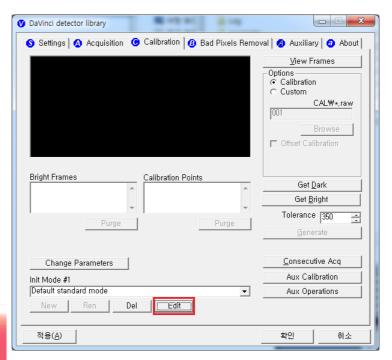
Sudden heating of the room in cold areas will cause condensation to form on the instrument. In this case, wait until condensation disappears before performing exposure. If the instrument is used with condensation formed on it, problems may occur in the quality of the instrument. When an air-conditioner is going to be used, be sure to raise/lower the temperature gradually so that a difference in temperature in the room and in the instrument does not occur, to prevent forming of condensation.

During Exposure

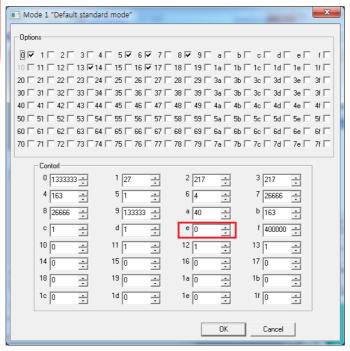
Do not use the detector near devices generating a strong magnetic field. Doing so may produce image noise or artifacts.

Do not apply excessive weight to the sensor unit. Otherwise, the sensor may be damaged.

Sleep Mode/Wake up



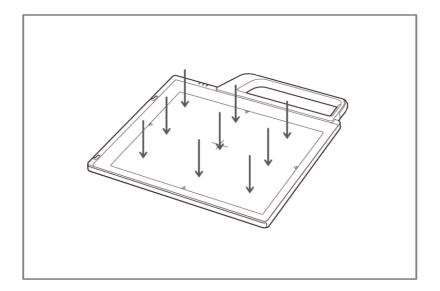
Do not change parameters except "Control e"



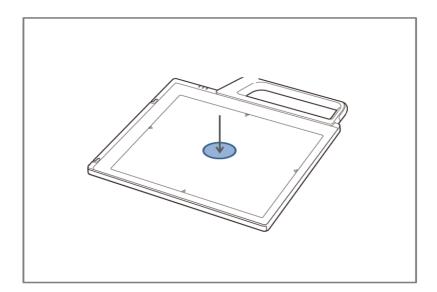
Control "e" parameter : sleep time

- 0 : disabled (default)
- 1:1 sec
- 2:2 sec ...
- 600:600 sec
- If you set sleep time, the detector goes to the sleep mode after "N" sec after acquiring image
 - If you want to wake up the detector, Press the power button(less than 1 second)

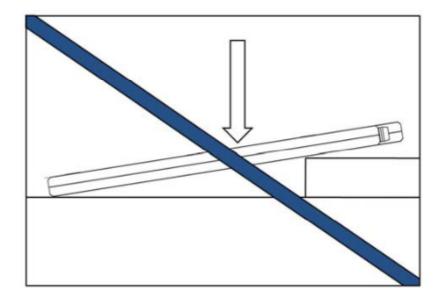
Limit of Load



Uniform load: 150 kg over the whole area of sensor window.



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



Be sure to use the sensor unit on a flat place so it will not bend.

Otherwise, the sensor may be damaged.

Disinfection and Cleaning

Do not spray the detector directly with disinfectants or detergents.

Do not use anything other than neutral detergent for cleaning the cover of the instrument. Otherwise, the coating will be corroded.

Others

Be sure to reconnect the cables to the proper connectors. Otherwise, the instrument may malfunction or may be damaged.

Technical Features

Mechanical Features

Size	395 x 337 x 18 mm		
Weight	2.85 kg (incl. Battery pack)		
Encapsulation Material	Mg		
Window Material	Carbon fiber plate with 1.4 mm thickness		

Electrical Features

Detector

Sensor Type	Amorphous Silicon with TFT (Single Panel)		
X-ray Converter	CsI:Tl		
Total Pixel Number	2080 × 2560 pixels		
Active Pixel Area	25.9 cm × 32.0 cm		
Active Pixel Number	2040 × 2520 pixels		
Pixel Pitch	127 μm		
Limiting Resolution	Max. 3.9 lp/mm		
Energy Range	40 - 150 kV		
A/D Conversion	16 bits		
Frame Rate	240 fph		
Preview Time	< 2.0 sec		
Charge Integration	unto 4 sos		
Time	upto 4 sec		
Max. Linear Dose	Typ. 60 μGy @ SID 1500 mm		
Saturation Dose	Typ. 70 μGy @ SID 1500 mm		
Data Interface			
- Wireless	Wi-Fi (802.11a/g/n)		
- Wire	Gigabit Ethernet		

- Under RQA5 condition (70kVp, 21mmAl)
- Preview time may vary by complex factors

Battery

Size	232.5 x 132.8 x 7 mm	
Weight	Typ. 0.3 kg	
Input	12.5 VDC	
Output	11.1 VDC	
Charging time	Typ. 2.5 hours	
Capacity	Typ. 3400 mAh	
The number of times	C00 images	
being acquired image	600 images	

The Battery level can be displayed on the LED status of battery.

If the battery level goes down under 25%, please charge the battery

Display	Battery level
	75~100 %
	50~75 %
	25~50 %
•••	0~25 %

Charger

Size	267.5 x 100 x 77 mm
Weight	Typ. 0.86 kg
Input	20 VDC
Output	11.1 VDC

Adapter

Size	160 x 76 x 43.7mm (cable length: 1.28m)
Weight	Typ. 0.92 kg
Input	100~240 VAC, 47~63 Hz, 1.4~0.6A
Output	20 VDC, Max 6.0A

Wireless Spec

Standard	802.11a/g/n compliance		
Peak Rate	300Mbps		
Frequency	2.4 GHz / 5 GHz		
Bandwidth	20MHz/40MHz		
MIMO	2x2		

- 5.15~5.25 GHz band is restricted to indoor operations only. (for FCC)
- 5.15~5.350 GHz band is restricted to indoor operations only. (for CE)
- 5.15~5.350 GHz is indoor use only. (for Japan)
- ※ Recommended Maximum operable distance : 7m (From the Access Point)

Environmental requirement

Item	Min.	Typ.	Max.	Unit	Note
Temperature	-10		50	$^{\circ}\mathbb{C}$	
Humidity	10		80	% H.R.	
Pressure	70		106	kPa	
Shocks (Wrapping condition)		10G (25G)			16ms, 1000times, in 6directions, non-Driving
Vibrations (Wrapping condition)		2G (10G)			10-150Hz, 10Sweeps, 1min/Octave, XYZ axis

X Regularly changed parts : Battery (warranty 6 months)

PC Requirements

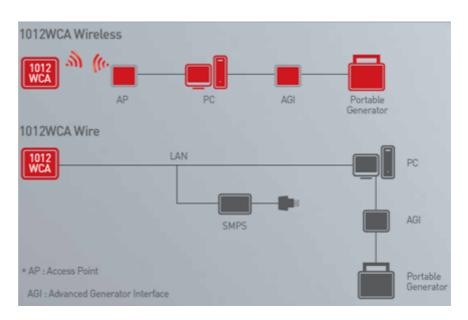
- Processor: At least Intel Pentium IV HT with 2.8GHz, Intel Core Duo / Core 2 or comparable AMD Dual Core processor
- At least 2 GB RAM
- At least 40 GB hard disk for the software, in addition to the required archive capacity for image storage
- Upper that Intel® PRO/100VE Network card
- Graphics card/monitor: Resolution of at least 1,280 x 1,024 pixels in True Color mode
- OS: Windows XP, vista, 7(32/64 bit)

Installation



The Detector is composed of sensitive electronic parts and components. It is recommended to use the product in a clean place and to exercise caution to ensure that it is not affected by dust or liquids. It is recommended to Use a dry and soft cloth to clean the detector housing.

General interface



Connection

Power Connection

- A. Connect the battery pack or power cable to the equipment.
- B. Connect the USB cable from your PC to AGI.
- ****** Be sure to sure only the dedicated battery pack, RB37WH for 1012WCA.

Wireless Communication

- A. AP Router(Line sharer) setting
 - SSID : Griffon
 - Internal network
 - IP address: 2.2.2.1
 - Subnet mask: 255.255.255.0
 - Dynamic IP allocation range: 2.2.2.2~2.2.254
 - Pre-Shared Key(Password): project302
 - Authentication methods : WPAPSK or WPA2PSK
 - Password methods: TKIP/AES
 - AP IP: 2.2.2.1
 - Channel (Frequency)
 - Avoid crowded channel
 (Using wireless detector under crowded channel result
 in low performance)
 - If available, Use 'Auto-Channel Selection' function of router to find optimal channel
- B. Reception Indicator

Link LED flickering

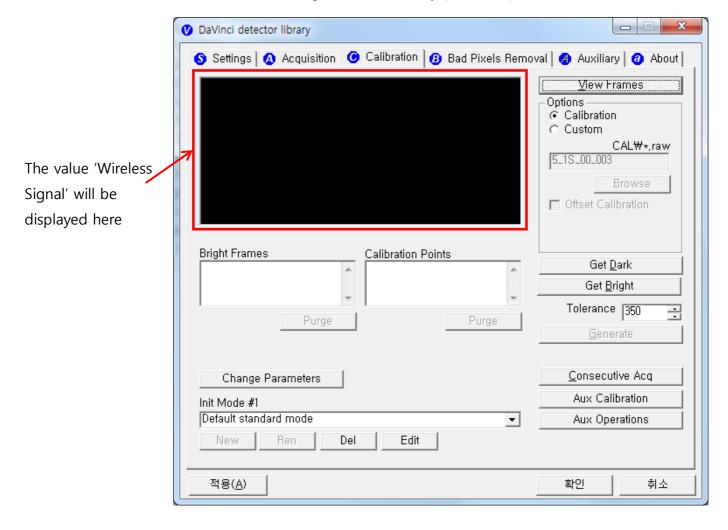
Blink Speed: Slow – Low link quality

Fast – High link quality

C. Checking Link Quality

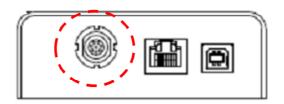
- After wireless connection is established, perform 'Get Bright' in 'Calibration' tap.
- Check the value named 'Wireless Signal' in black log screen.

 Wireless Signal = Link Quality (Max. 100)



Trigger Connection

A. Connect the P-interface cable to the generator

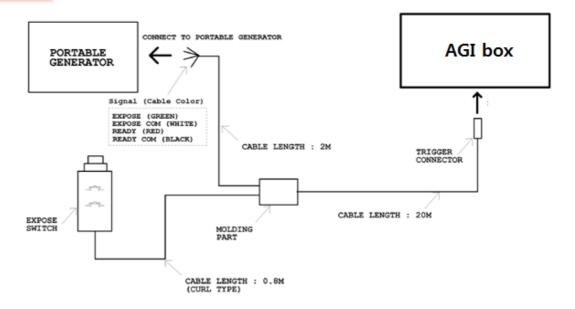




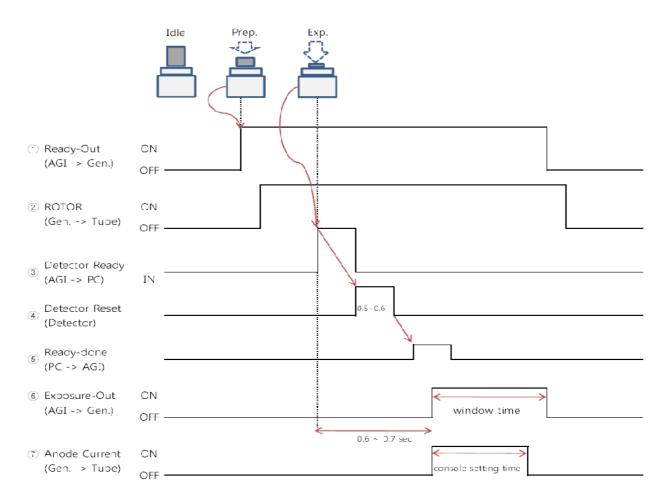
X-ray Generator Connection

Connect the P-interface cable between the AGI box and X-ray generator.

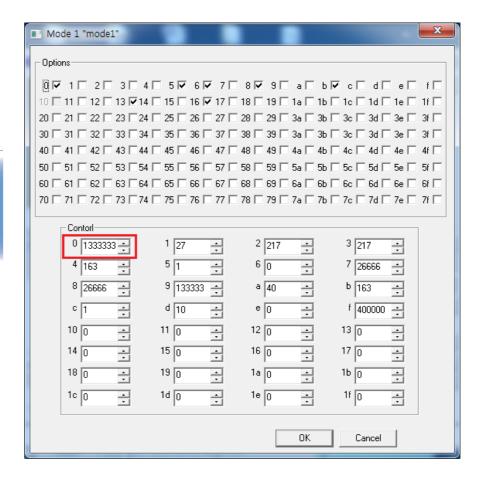
A. Wiring Mode 1: P-interface cable mode



Operating description



The window time can be changed. Refer to the following pictures



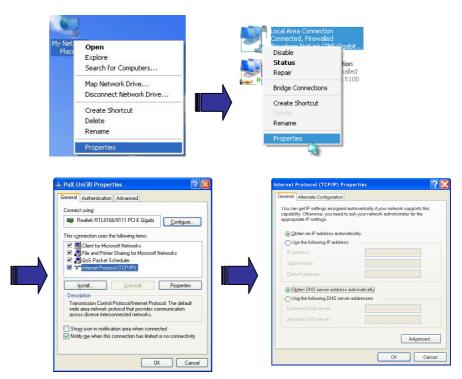


IP set up

[My Network Places] → [Properties] → [Local Area Connection]

- → [Properties] → [Internet Protocol (TCP/IP)]
- → [Use the following IP address]

IP address: Obtain an IP address automatically



IP address: Obtain an IP address automatically