



UMS4343-W

Digital Flat-Panel X-RAY Detector

User Manual for S4343-W

Samsung Electronics Co., Ltd.

This manual is provided for the installation and operation of S4343-W.

Please read this manual before the detector install and use.

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Revision History

Version	Date	Page	Revision
1.0	2013 April	-	1 st Edition
1.1	2013 Dec	α 37	The main revised item are as below - Table 1 OPERATING TIME TABLE
1.2	2014 May	α 28	The main revised item are as below - Changed Power Supply Box Input
1.3	2014 June	α 51 ~ 58	Add FCC Statement of Conformance Add EMC Declaration



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About this Manual

■ Symbols Used in This Manual

The specifications and details of this manual may be changed in order to improve the product or to enhance its performance

The following symbols are used throughout this manual to alert the user to the relevant safety instructions or to any useful information when using this system

Symbol	Name	Description
	Warning	Indicates content which, if you fail to follow the accompanying instructions, may cause death or serious personal injury.
	Caution	Indicates content which, if you fail to follow the accompanying instructions, may cause personal injury or damage to the product.
	Note	Provides users with additional information on the topic for better understanding.

Please note that our company does not take responsibility for any accidents and is not obligated to do free repair service for any damage of the equipment due to the user's negligence which results from failure to follow the contents in this manual. Make sure you are familiar with the safety precautions and usage procedures. Also note that the product features may slightly differ from the contents of this manual depending on the specifications.

■ Intended for use

S4343-W, Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy targeting both adult and children. It is intended to replace film based radiographic diagnostic systems and provide more precise case diagnosis and treatment planning on a real time basis for physicians and radiologists. Not to be used for mammography and direct cardiac application.

■ User Requirements



CAUTION

- This equipment should be only operated by users who have received professional medical education and training, such as physicians, radiologists, and other medical specialists.
- Please read the user manual and the safety information carefully before using this equipment. Operating the equipment without reading the safety information may result in personal injury to the patient or to yourself.

■ Service Center

- Korea : Service Center 080-022-9797
- Overseas : Contact the local distributor.

Head Quarters

- 129 Samsung-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, Korea

Factory

- 129 Samsung-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, Korea

1. SAFETY INSTRUCTIONS



Safety Instructions

In this chapter, information of safety instructions and regulations are provided. It is provided to protect users of the system from unintended safety hazard and prevent property damage,

please read thoroughly and keep instructions. If additional training is required, consult your dealer or the service center of the manufacturer.














WARNING

Before using this system, please read safety instructions thoroughly. The manufacturer is not responsible for any damages and accidents caused by violating such safety instructions or regulations.

■ System Symbols

Table 1 shows the symbols related to maintaining the safety of the patient and the user.

	Alternate current
	Direct current
	Protective earth (Ground)
	Off (power : disconnect from the main switch)
	On (power : connect to the main switch)
	Identifies terminals which, when connected together, bring various parts of a piece of equipment or of a system to the same potential.
	Indicates content which, if you fail to follow the accompanying instructions, may cause personal injury or damage to the product.
	Indicates that the dangerous factors can be occurred caused by High Voltage.
	Indicates that the accompanying operating instructions in the manual must be followed to operate the equipment safely.
	TYPE B Applied part
	Marks it contains radio transmitting device.








	Avoid contact with water
	No unauthorized or unlawful modification
	Waste electrical and electronic equipment (WEEE)
	Temperature limitation
	Marks fragile device that requires full attention when handling.
	Manufacturer
	EC Representative

Table 2 SPECIAL SYMBOL

■ System Maintenance Checkpoints

To ensure the system performance and usability along with safety, regular maintenance and checking the condition are required. To secure safety of both patient and operator and to ensure the performance of the system, check the system on a regular interval. For periodic inspection of the system, consult your dealer or the manufacturer's service center.

No.	Item	Category	Checkpoints	Check Interval	Remark
1	Noise / Vibration	In use	Check noise and vibration from each operating parts of the system.	1 year	
2	Power Supply box	While in use	Check the power supply box voltage while the equipment s turned off.	1 year	
3	Appearance	While in use	Run a visual inspection to check if the appearance shows any abnormalities, such as loosened bolts or had grips, transformation, etc. while the equipment is turned off.	1 year	
4	Cables	Before Using	Check cable runs for worn out cables, damage or short circuited, broken wires, etc. while the equipment is turned off.	6 months	
5	Grounding	While in use	Check the earth-grounding is intact, not broken or loosened terminal. (Grounding resistance should be below 0.1Ω.)	1 year	
6	Installation Checkpoints	When Installing	When installing, check that the equipment is leveled and firmly fixed.	1 year	

Table 3 SYSTEM MAINTENANCE CHECKPOINTS



WARNING

When inspecting on checkpoints requiring no power, please make sure to keep the system turned off.

Classification

- The type of protection against electric shock: Class I equipment
- The degree of protection against electric shock: Type B applied part
- The degree of protection against ingress of water: Ordinary equipment
- The method(s) of sterilization or disinfection: Not applicable
- The degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE: Not applicable
- Mode of operation: As momentary continuous operation

■ General Safety

Before using the equipment, the user should check that:

- All components are connected correctly.
- All components are operational when the system is powered on.
- Neither the patient nor the user is present in the examination room when powering the equipment on.



- If any electrical or mechanical fault occurs, stop using the system immediately.

You can identify faults from the display or warnings.



- Please consult the manufacturer before connecting a component from another system to this system. Any auxiliary device connected to the system must be IEC certified (data processing equipment: IEC60950-1, medical electrical equipment: IEC60601-1). Also, if the auxiliary device is connected to a signal I/O port, it should comply with IEC60601-1 and/or IEC60601-1-1.



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



- Medical equipment requires periodic maintenance and management. For more information, refer to 1. Maintenance, Cleaning and Disposal.



- If an error message appears while the system is in use, it may stop operating. When an error message appears, contact the service center



- The manufacturer will not accept liability for:
 - Fault, damage or personal injury incurred as a result of the user incorrectly performing maintenance on the system
 - Personal injury incurred due to the user's carelessness
 - Fault, damage or personal injury incurred due to use of an ancillary device which is not provided by the manufacturer.



- When Problem Occurs

Should any of the following occur, immediately turn OFF the power of each instruments, unplug the power cable from the AC outlet, and contact SAMSUNG 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.



- This detector should be used by selected users. If not you fully aware of the factor of exposure, the manual, and the schedule of organization, This could be dangerous for the patients and users.

■ Electrical Safety



- In compliance with IEC 60601-1, this medical equipment complies with the requirements for Safety class I, type B.
- This system must be used in an environment complying with the requirements of the IEC.



- Do not remove the safety cover of this system needlessly. When it is removed, the high voltage current inside the system may cause electric shock.



- Be careful to ensure that no liquids enter the system.



- 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.



- Be sure to turn OFF the power of each instrument before connecting or disconnecting the cables. Also, do not handle them with wet hands. Otherwise, you may get an electric shock that may result in death or serious injury.



- Do not cut or process the cables. Also, do not place anything heavy, including the instrument on it, step on it, pull it, bend it, or bundle it. Otherwise, the cable may be damaged, which may result in fire or electric shock.



- Be sure to hold the plug or connector to disconnect the cable. If you pull the cable, the core wire may be damaged, resulting in fire or electric shock.



- Do not turn ON the system power when condensation is formed on the instrument. Otherwise, it may result in fire or electric shock.



- Do not spill liquid or chemicals onto the instrument or, in cases where the patient is injured, do not 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.

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 cable from the AC outlet. Otherwise, fire or electric shock may result.



- 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

■ Mechanical Safety



- Never remove the cover (Detector, Power Box, Recharger, Battery Pack, and Adapter) or cables unless directed to do so by a professionally trained engineer.



- When an examination is in progress, auditory and visual communication between the patient and the system user must be possible at all times.



- Be careful not to pinch any part of your or the patient's body or clothing while using the system.



- 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 it being repaired.

■ Fire Safety



- Do not operate the system in a location where there is a danger of fire.



- In the event of a fire, stop the entire system immediately and disconnect the power cable. Make sure to extinguish the fire with a carbon dioxide fire extinguisher.

■ Safety from Explosion



- Do not operate the system in a location where there is a danger of explosion. This system is not designed to be used in a location where there is a danger of explosion, and does not comply with the AP/AGP standard.

■ Label



- For information on the types and attachment locations of the Detector Component labels, refer to Labels.

■ Maintenance, Cleaning and Disposal

➤ Maintenance

- Inspect the equipment periodically for patient and user safety.
- The instrument must be repaired by a qualified engineer only. If it is not repaired properly, it may cause fire, electric shock, or accident.

➤ Cleaning



- Always turn off the equipment completely before cleaning.



- Do not open the cover and insert liquids into the system.



- When cleaning the exterior of the system, use a soft cleaning cloth dampened with tepid Water and soap. Do not use detergents or chemical solutions.



- While a maintenance personnel is cleaning the room, cables connected to the equipment may be lifted or pulled.

When lifting , or pulling cables, the connection with the equipment may be disconnected causing malfunction, electric shock, or danger of fire. Also, water may be absorbed into the equipment if mopped with a damp cloth, which may cause electric shocks or fire.



- If the equipment generates abnormal noises, contact the service center immediately. The user must not arbitrarily disassemble, repair, or modify the equipment. Fire or electric shock may result.



- 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.

➤ Correct Disposal of This Product (Waste Electrical & Electronic Equipment)

(Applicable in countries with separate collection systems)



This marking on the product, accessories or literature indicates that the product and its electronic accessories should not be disposed of with other household waste at the end of their working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate these items from other types of waste and recycle them responsibly to promote the sustainable reuse of material resources.

Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can take these items for environmentally safe recycling.

Business users should contact their supplier and check the terms and conditions of the purchase contract. This product and its electronic accessories should not be mixed with other commercial wastes for disposal.

➤ Environment of Use and Storage



- Does not use or store the instrument near any flammable chemicals such as alcohol, 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.



- 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 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 is put in the case. Otherwise they could trip over, resulting in injury.

■ Disclaimer

- The manufacturer assumes no liability for any failure or damage which may occur by using other company's products
- The manufacturer assumes no liability for any failure or damage that may occur from installing, relocating, modifying, maintaining, or repairing the equipment by any personnel other than designated personnel by the manufacturer.
- The manufacturer assumes no liability for any accidents or damage on the equipment which may occur due to operations performed without following the relevant precautions or instructions in this manual..
- The manufacturer assumes no liability for any failure or damage due to natural disasters such as fire, earthquake, flood, and lightning.
- The manufacturer assumes no liability for erroneous diagnostic criteria or results.
- The manufacturer assumes no liability for any failure or damage which may occur due to operations performed for any purposes other than its intended use.
- This equipment should be operated under the specified conditions. The manufacturer assumes no liability for any failure or damage which may occur due to operations performed under conditions other than those specified in this manual. For more information on the operating conditions, refer to Appendices.

2. SYSTEM OVERVIEW

System Overview

System Purposes

The S4343-W is a portable digital X-ray flat panel wireless detector that can generate Images of any part of the body. This X-ray imaging system consists of a scintillator directly coupled to an a-Si TFT sensor.

S4343-W can be used for radiographic imaging of human body parts such as head, Chest, spinal, abdominal, particular, hand, foot, and other internal organs. However, do not use the system for mammography purposes.

Radiated X-rays through the body is processed to produce radiography by the detector. Converted electric signal is processed by the signal processor to amplify and digitize data And the result is transferred to the workstation.

■ Product components

Item	Part Name	Qty	Description
1	Detector	1	Front view of the device
2	Power Supply Box	1	Source of necessary electricity
3	Battery Recharger	1	To recharge an extra battery
4	Battery Pack	2	Source for wireless connection
5	Recharger Adaptor	1	Source of the battery pack recharger
6	Main Cable	1	To connect x-ray detector with Power Supply Box
7	AC Adapter Cable (Optional)	1	AC 110 / 220V power cable For battery pack recharger adaptor

Table 4 COMPONENTS



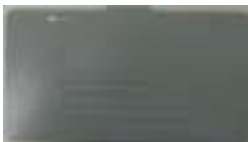
Detector



Power Supply Box



Battery pack Recharger



Battery pack



Recharger Adapter



Main Cable



AC Adapter Cable
(Optional)

※ Regularly changed parts : nothing

Comment [오전1]: DC 24V 삭제 사진

■ Examination Room Components

The components of S4343-W can be divided into the examination room components and the control room Components in accordance with their installation locations.

The below figure 1 shows S4343-W Examination Components.



Detector



Power box



Main cable

Figure 1 EXAMINATION ROOM COMPONENTS

Comment [오전2]: DC 24V 삭제반영

All examination room components of the system should be used inside a shielded environment.

■ Control Room Components

The control room for S4343-W is configured as shown in Figure.

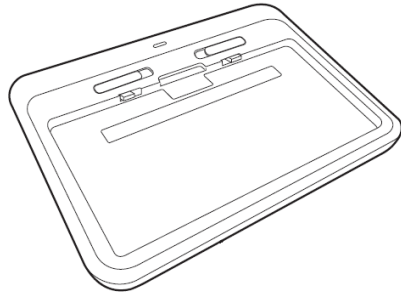


FIGURE 2 RECHARGER



FIGURE 3 RECHARGER ADAPTER

3. SYSTEM COMPONENTS

■ System Components

■ Detector



FIGURE 4 WIRELESS DETECTOR

This Flat-Panel, wireless digital X-ray detector is designed for generating images of any part of the body. It makes high-resolution, high-sensitive digital images.

➤ Overview

The S4343-W is a portable digital x-ray flat panel detector that can generate images of any part of the body. 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.

➤ Product features

- Based on a-Si TFT active matrix
- Compact (15 mm thickness) and light weight (less than 3.7 kg)
- High resolution : ~ 3.57 lp/mm
- 15-bit digital output
- Easy integration

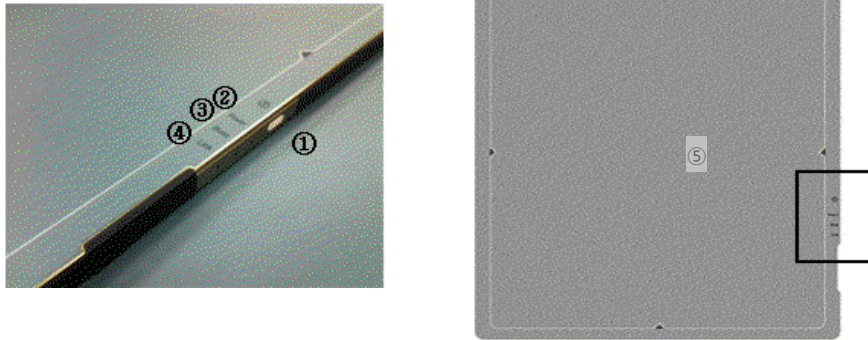


FIGURE 5 INDICATE LED

Item	Description
Detector	① Power ON/OFF Button
	② Power Status Indicator → Blue colored indicator is constant when Power ON
	③ Internal Processing Status Indicator → Green colored indicator flashes during internal processing
	④ Interface Link Indicator → Wired mode : Blinking in Blue while connecting with workstation → Wireless mode : Green colored indicator is constant
	⑤ Active Pixel Area: This is an area which converses X-ray through the patient into the image.

Table 5 LED STATUS

You cannot get the patient body image from the outside of domain.

➤ Notes for Using the Detector

- Handling

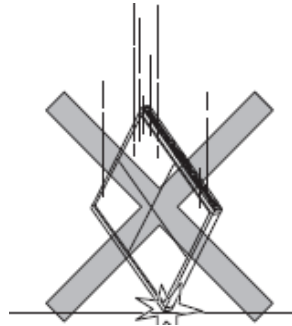


FIGURE 6 DO NOT DROP

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

Embedded Mechanical shock sensor specification is 100G.

- Before Exposure

If the instrument is used with condensation formed on it, problems may occur in the quality of the instrument.

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.

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 apply excessive weight to the sensor unit. Otherwise, the sensor may be damaged.

The detector and patient must be taken from a fixed state. Otherwise, the performance may be degraded.

- Limit of Load

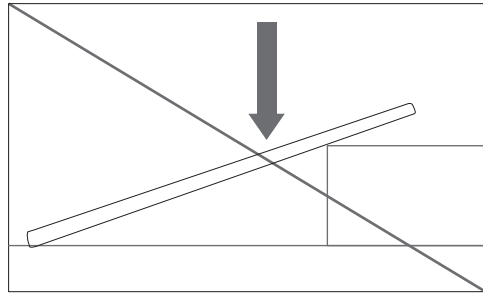


FIGURE 7 Be CAREFUL OF DETECTOR LOCATION

Be sure to use the sensor unit on a flat place so it will not bend.
Otherwise, the sensor may be damaged.

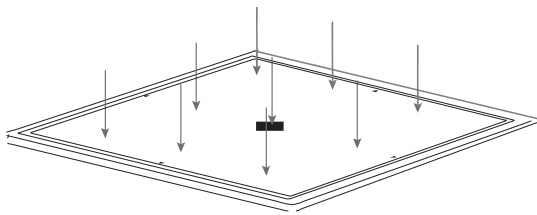


FIGURE 8 KEEP WEIGHT DISTRIBUTED EVENLY

- Uniform load

Supposing the distribution of the detection part on S4335-W, Do not load over 150Kg.

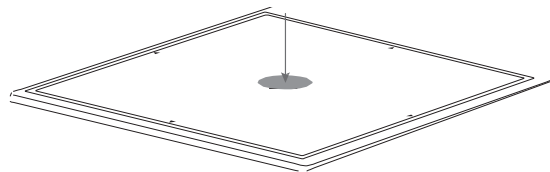


FIGURE 9 AVOID LOCALIZED WEIGHT

- Others



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



- Never use with other power supplies and cables. Use DEPS9601 only

- During Cleaning

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

- Storage

- Be sure to store the sensor unit a safe place where it will not fall or drop
- When not using the portable detector on the flat place or using the detector on the uneven Place, Be cautious for damage.

■ Power Supply Box

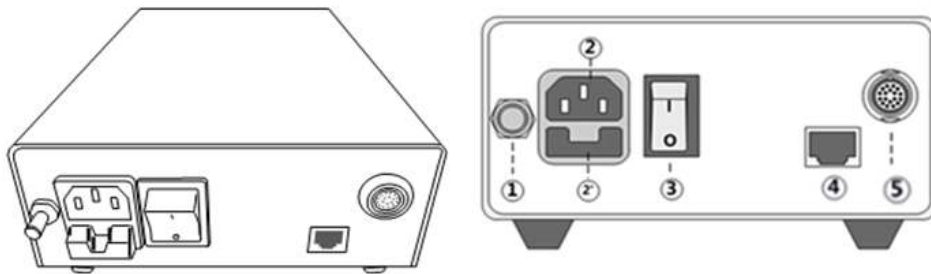


FIGURE 10 POWER SUPPLY BOX

Item	Description
Power Supply Box	① Grounding Jack : Common Ground or Earth
	② AC Inlet: AC Power Plug (2' - Fuse socket) Input AC Socket Type : IEC60320 C14 Type Input AC Socket : 6220(SCHURTER)
	③ Power switch: Power On/Off switch → Green colored indicator is constant when Power ON
	④ LAN port : LAN cable connector
	⑤ Main Cable Connector : connecting power supply with detector

Table 6 POWER SUPPLY BOX DESCRIPTION

■ Main Cable

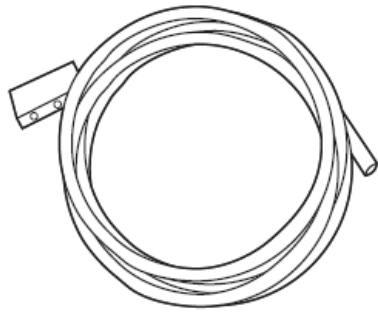


FIGURE 11 MAIN CABLE

This cable connects the detector to the power supply box.



WARNING

Because the instrument's cable is long, take care so cables do not get tangled during use. Also, be careful not to get your feet caught in the cable.



WARNING

Do not pull the cable by force. And If the cable gets tangled, do not pull the main body of portable detector by force. Otherwise, the cable is damaged and causes fire or electric shock.

■ Battery Recharger

The battery recharger is used for S4343-W. You can recharge the battery and check the charge condition.

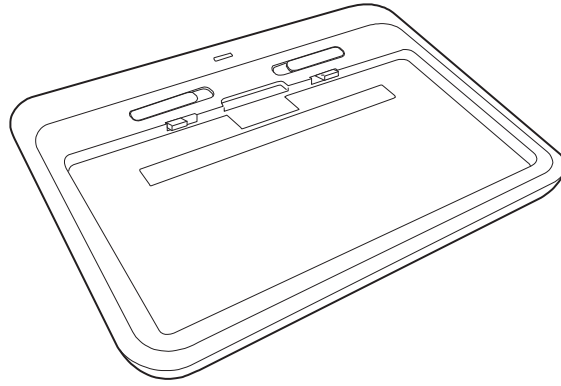


FIGURE 12 BATTERY RECHARGER

1. LED: Indicates the condition of charge. This is turned off when the power is disconnected or is not recharged.
2. The Battery recharger Terminal
3. Knob: It is used to detach a battery from the recharger.

Indicates as follows When the battery recharges, When the battery is recharging, it changes red into green according to the level of charge.

LED	The status of battery Recharger
• Red	• Fast charging mode (Until About 90%)
• Green	• Normal charging mode (About 85% ~ 100 %)
• Blue	• The error of charging

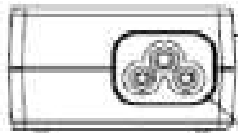
Table 7 BATTERY RECHARGER INDICATE LED



If LED light is blue during recharging the battery, stop recharging the battery immediately and check whether there are Impurities or not in the battery recharger Terminal (②).

Despite taking action on upper step, if LED light is still blue, stop recharging the battery.

Recharger Adapter



Input AC Socket Type : IEC 320 C6 Type.

➤ The use

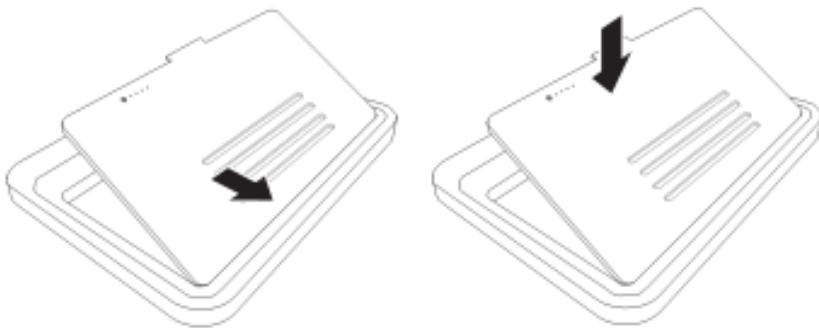


FIGURE 13 BATTERY INSERT

After the Adaptor (AD-9019S) connects to Power cord, be sure to connect it to Adaptor terminal on the back side of Recharger

Be sure to insert the battery to recharger until it sounds clack.

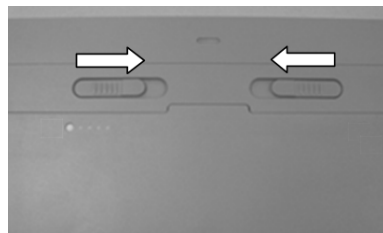


FIGURE 14 BATTERY LOCK

Comment [오전3]: 배터리 외부단자 삭제

Be sure to push inside two knobs to the end when the battery detached from the recharger.



- When using the S4343-W battery recharger, always use the battery (SDB-3S1PA) provided by Samsung Electronics Co. Ltd..



- When using Battery recharger, Be sure to use Adapter (AD-9019S) Provided by Samsung Electronics Co. Ltd..

- When moving the S4343-W battery recharger, always separate the power and battery pack



- When using the S4343-W battery recharger, Always be cautious about touching liquid, impurities. In case of short trouble.

- Do not disassemble the battery recharger.



- When using the S4343-W battery recharger, be sure to comply with the user environment. The performance of S4343-W battery can be down and the durability can be shorter.



- Be sure to use the S4343-W battery recharger in the Control Room. This battery recharger is not designed to use in the Examination Room.



- When not using the S4343-W battery recharger for a long time. Always do separate the battery recharger from the Power.



- When inserting the battery to the battery recharger, Be careful of being caught clothes or impurities.

■ Battery



Comment [오전4]: 배터리 외부단자 삭제

FIGURE 15 BATTERY

This is the battery for using the S4343-W (Detector) by wireless communications

This light usually turns off. If you push the circle button, you can check the condition of battery as follows below.

- When using,

LED	Battery residual display
LED 1,2,3,4 light on	76 % ~ 100 %
LED 1,2,3 light on	51 % ~ 75 %
LED 1,2 light on	26 % ~ 50 %
LED 1 light on	11 % ~ 25%
LED 1 Dimming (About 0.5sec interval)	Under 10%

Table 8 BATTERY RESIDUAL DISPLAY

- When recharging,

LED	Battery residual display
LED 1,2,3 light on LED 4 Dimming	76 % ~ 100 %
LED 1,2 light on LED 3 Dimming	51 % ~ 75 %
LED 1 light on LED 2 Dimming	26 % ~ 50 %
LED 1 Dimming	11 % ~ 25%
LED 1 Dimming (About 0.5sec interval)	Under 10%

Table 9 BATTERY INDICATE LED



- Be sure to recharge the battery by using the S4343-W (Detector) or the battery recharger (DEPS-9606) provided by Samsung Electronics Co. Ltd..



- If the battery is needed to be stored for a long period, battery should be removed from the application and stored in a place where humidity and temperature are low.



- While the battery is charged, used and stored, keep it away from object materials with static electric chargers.



- If the terminals of the battery become dirty, wipe with a dry cloth before using the battery.



- Be sure to use the battery in the environment designated by Samsung. Otherwise, the life of battery can be short



- Stop using the battery if the battery becomes abnormally hot, disorder, discoloration, deformation, or abnormal conditions is detected during use, charge, or storage.



Don't short circuit (+) and (-) terminals with metallic object intentionally.



- Not be sure to touch liquid on the surface of the battery.



Don't pierce the battery with a sharp object such as a needle, screw drivers.



- Do not hit the battery with heavy objects.



- Don't step on the battery and throw or drop the battery on the hard floor to avoid mechanical shock.



- Don't disassemble the battery or modify the battery design including electric circuit.

4. OPERATING THE SYSTEM HARDWARE

■ Operating the System Hardware

■ IP set up

[My Network Places] → [Properties] → [Local Area Connection] → [Properties] → [Internet Protocol (TCP/IP)]

→ [Use the following IP address]

IP address : 192 . 168 . 197 . 20 (Console PC)

Detector IP address is 192. 168. 197. 80 (default)

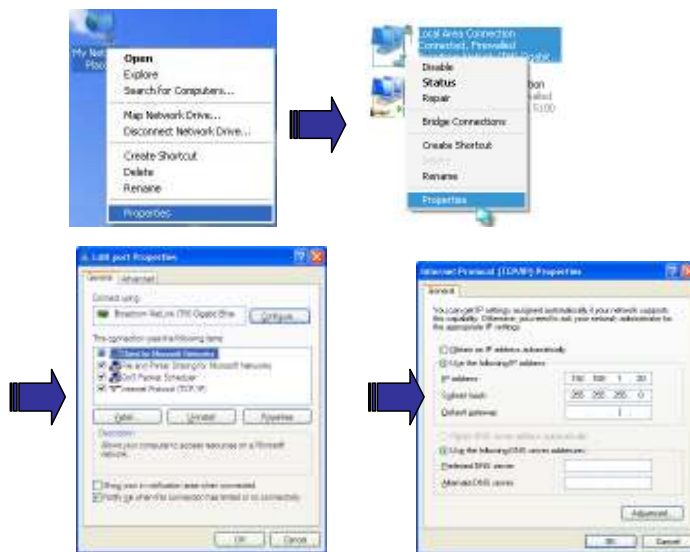


Figure 16 IP SET UP

It is possible to change IP address, but it shouldn't be the same as the detector IP address.

■ Checking Connection

Check LED on the detector & power supply

Ping test: [Start] → [Run] → ping -t 192.168.197.80

■ Operation

➤ Switching power on / off

This equipment is turned on by the Power Button of each component.

Table 9 lists the methods for checking the power on status of the system components.

Comment [오전5]: 배터리 외부단자 삭제

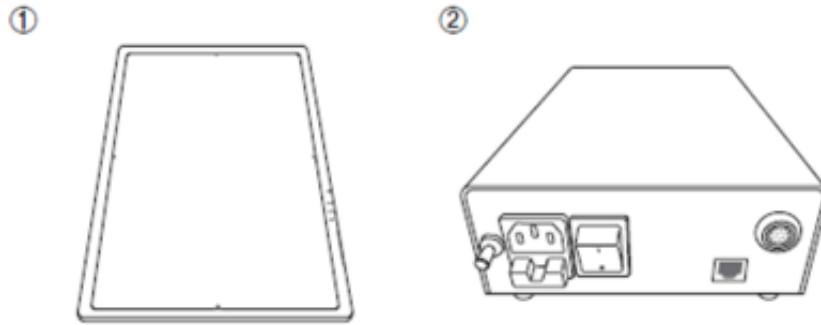


FIGURE 17 POWER APPLIED COMPONENTS (S4343-W)

Component	Power button location	To check the power status
Detector	Power switch on the bottom of the right side	Dimming blue power LED
Power supply Box	The front side of Power supply box	Green power LED

Table 10 CHECKING THE POWER STATUS OF COMPONENTS (S4335-W)

All connection should be done, before turn on the power supply box.

Turn on the power of the detector power supply box, workstation.

The green light of the LED indicator on the detector is on, the detector power is on.

The blue light of the LED indicator on the detector is blinking, the detector is getting prepared to work and initialize.

Turn off the power of the detector power supply box

When Detector is not turned on, be sure to check the Connection, the status of Battery and installation at first.



Below table 10 for turning off each component.

Component	Power Button Location	To check the power status
Detector	On the bottom of the right side	Blue power LED is turned off.
Power supply	The front side of PSU	Green power LED is turned off.

Table 11 POWER OFF STATUS

■ Operating description

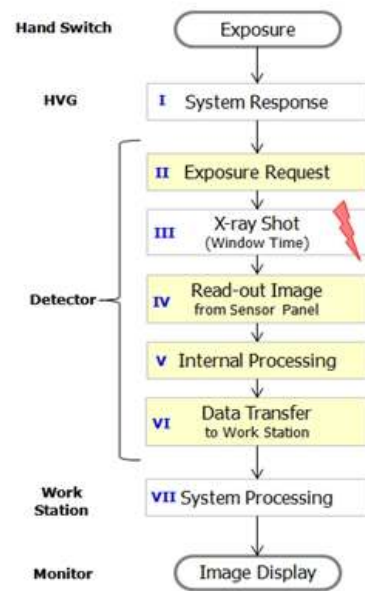


Figure 18: TIMING CHART

Item	min.	typ.	max.	unit	
Exposure request time (II) Before x-ray pulse start	-	-	0.5	sec	
Exposure window	-	0.5	4.0	sec	
Image transmitted after exposure done (IV + V + VI)	Wireless	4.2	4.7	-	sec
	Wired	-	2.35	2.80	sec
Image cycle time for exposure of 0.5sec	8	-	-	sec	
Booting time	-	24	40	sec	

Table 12 OPERATING TIME TABLE

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FCC Statement of Conformance

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.

IC Information

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:

- (1) This device may not cause interference, and
- (2) This device must accept any interference, including interference that may cause undesired operation of the device.

Cet appareil est conforme avec Industrie Canada RSS standard exempts de licence(s), Son utilisation est soumise à Les deux conditions suivantes:

- (1) cet appareil ne peut pas provoquer d'interférences et
- (2) cet appareil doit accepter Toute interférence, y compris les interférences qui peuvent causer un mauvais fonctionnement du dispositif.

Tests for EMC and RF including wireless EMC were performed according to the standards in the following table below.

Item	Standards
EMC	IEC 60601-1-2
Wireless EMC	EN 301 489-1 EN 301 489-17
RF	47 CFR Part 15C 47 CFR Part 15E EN 300 328 EN 301 893

EMC Declaration

1. Compliance Statement

This equipment complies with IEC 60601-1-2 EMC standards for medical devices.

This equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the user manual.

Do not use any wireless devices, including cellular phones, near the system. All wireless devices, whether they comply with the EMC standard or not, may emit electromagnetic interferences and cause the system to malfunction when they are used nearby.

This equipment should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the equipment should be tested and verified in order to ensure normal operations in the configuration in which it will be used.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

All interconnect cables to peripheral devices must be shielded and properly grounded, except when technologically prohibited. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference.

EMC Cable List

Port No.	Name	Type*	Cable Max. > 3 m	Cable Shielded	Comments
Signal					
1	Tether cable	I/O	7.0	Shielded	None
*Note: I/O = Signal Input or Output Port (Not Involved in Process Control)					

The use of cables or accessories other than those specified may result in increased emissions or decreased immunity.

Should any interference (EMC) be detected with other equipment, please position other equipment away from this one.

When using this system on a patient with an implantable pacemaker or an implantable cardioverter defibrillator, the patient must be informed that continuous X-ray exposure in pulse form may cause the pacemaker or cardioverter defibrillator to malfunction.

When using this system, ensure that X-rays are not exposed directly onto the patient's implantable pacemaker or implantable cardioverter defibrillator, and that the exposure time is kept as short as possible.

This equipment may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

This device contains wireless module.
 "FCC ID : A3LWIDT30Q"



Restriction of use of Wi-Fi using 5 GHz bands(5150 - 5350 MHz) "In the EU, the Wi-Fi function in this equipment should not be used outdoors.

≡ Wired & Wireless Interface

Wired	Standard	IEEE 802.3 compliant
	Physical data rate	10/100/1000 BASE-T
Wireless	Standard	IEEE 802.11 a/b/g/n WI-FI
	Frequency	2.4GHz/5GHz dual
	Modulation	OFDM with BPSK, QPSK, 16 QAM, 64 QAM, DBPSK, CCK
	Security	Open, WEP, WPA/WPA2 PSK, WPA/WPA2 Enterprise
	Physical data rate	<ul style="list-style-type: none"> •IEEE 802.11a : 6-54Mbps •IEEE 802.11b : 1-11Mbps •IEEE 802.11g : 6-54Mbps •IEEE 802.11n : 6.5-300Mbps
Power Output (EIRP)	For 2.4 GHz band : 13.80 dBm For 5 GHz Lower sub-band : 14.76 dBm For 5 GHz Higher sub-band : 12.39 dBm	

Table1

Guidance and manufacturer's declaration- Electromagnetic emissions		
This Wireless Detector is intended for use in the electromagnetic environment specified below. The user of this Wireless Detector should assure that it is used in such an environment		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	This Wireless Detector 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	This Wireless Detector is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
Harmonics emission IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Wireless Detector or shielding the location.

Table2

Guidance and manufacturer's declaration- Electromagnetic immunity			
This Wireless Detector is intended for use in the electromagnetic environment specified below. The customer or the user of this Wireless Detector should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC61000-4-2	±6 kV Contact ±8 kV Air	±6 kV Contact ±8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical fast Transient / burst IEC61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) Magnetic field IEC61000-4-8	3.0 A/m	3.0 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short Interruptions and Voltage variations on power supply input lines IEC61000-4-11	<5% U _T (>95% dip in U _T) for 0.5cycle 40% U _T (60% dip in U _T) for 5 cycle, 6 cycle 70% U _T (30% dip in U _T) for 25 cycle, 30 cycle <5% U _T (>95% dip in U _T) for 5 sec	<5% U _T (>95% dip in U _T) for 0.5cycle 40% U _T (60% dip in U _T) for 5 cycle, 6 cycle 70% U _T (30% dip in U _T) for 25 cycle, 30 cycle <5% U _T (>95% dip in U _T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of this Wireless Detector requires continued operation during power mains interruptions, it is recommended that this Wireless Detector be powered from an uninterruptible power supply or a battery
Note: U _T is the a.c. mains voltage prior to application of the test level.			

Table3


Guidance and manufacturer's declaration- Electromagnetic immunity			
This Wireless Detector is intended for use in the electromagnetic environment specified below. The customer or the user of this Wireless Detector should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of this Wireless Detector, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{V_T} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_T} \right] \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = \left[\frac{7}{E_T} \right] \sqrt{P} \text{ 800 MHz to 2,5 GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m 80 MHz to 2,5 GHz	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this Wireless Detector is used exceeds the applicable RF compliance level above, this Wireless Detector should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this Wireless Detector.			
^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table4

Recommended separation distances between portable and mobile RF communications equipment and this Wireless Detector			
This Wireless Detector is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this Wireless Detector can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this Wireless Detector as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E1}\right]\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.67	11.67	23.34
For transmitters rated at a maximum output power not listed above, the recommended separation distance <i>d</i> in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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 Suppleme