TRIMAX

User Manual for the TRIMAX 43C Detector

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Notices and Conventions

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Note:
Notes provide additional information, such as expanded explanations, hints, or reminders.

Important:
Important highlights critical policy information that affects how you use this manual and this product.

CAUTION:
Caution points out a potentially hazardous situation which, if not avoided, might cause minor or moderate injury.

Authorized Representative (European Union)

EC REP

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FRANCE

Importer for European Union

Carestream Health Netherlands B.V.

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The Netherlands

CAUTION:

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

CAUTION:

If you witness or become aware of a potential safety issue with this equipment, take the appropriate safety measures and report this to your Carestream Service representative immediately.

Disclaimer

- Carestream shall not be liable to the purchaser of this product or third parties for any damage, loss, or injury incurred by the purchaser or third parties as a result of fire, earthquake, any accident, misuse, or abuse of the product.
- Carestream shall not be liable for any damage, loss, or injury arising from unauthorized modifications, repairs, or alterations to the product or failure to strictly comply with Carestream's operating and maintenance instructions.
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- It is the responsibilities of the user or physician to maintain the privacy of image data and provide medical care services. Carestream shall not be responsible for the legality of image processing, reading, and storage nor shall it be responsible for loss of image data for any reason.
- Information regarding the specifications, compositions, and appearance of this product is subject to change without prior notice.

Copyright

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Publication History

1 Safety and Regulatory Information

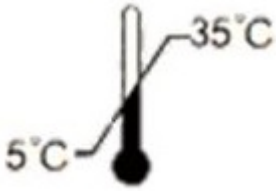
Symbols

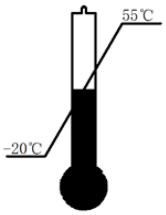
Symbols and Conventions

	 **WARNING:** This is used to identify conditions under which improper use of the product may cause death or serious personal injury.
	This is used to indicate a prohibited operation.
	This is used to indicate an action that must be performed.

Labels and Markings on the Equipment

	This indicates that the product has passed CE certification and is followed by the CE number.

SN	This is used to identify the manufacturer's series number, which is after, below, or adjacent to the symbol. The series number usually consists of 19 digits as shown in the following example: **1A2A3A4 B1B2 C1C2 L M1M2 D1D2 Y1Y2 X1X2X3X4** • 1A2A3A4 - Product code • B1B2 - Derived classes • C1C2 - Version • L - Production site • M1M2 - Month • D1D2 - Day • Y1Y2 - Year • X1X2X3X4 - Numerical order
	This indicates the name and address of the manufacturer.
EC REP	This indicates the name and address of a Carestream authorized representative in the European region.
	This indicates consulting the user guide for general information.
	Safety sign: Dangerous Voltage
	Handle with care.
	This indicates operational temperature limits.

	This indicates storage temperature limits.
FCC	This indicates the product radiates a wireless signal.
	Package symbol: Fragile
	Package symbol: Keep away from sunlight.
	Package symbol: Keep dry.
	This indicates the humidity limits.
	Keep the product upright.
	Do not roll the transportation packaging.
	This indicates the stacking limit number.
	FDP is allowed to withstand 100 kg on its surface.
Rx only	Device is for prescription use only.
IP	IPX1 for working surface only.

Cautions

Environment for Installation and Use

Environment for Installation and Use

WARNING:
Do not use or store the product near flammable chemicals such as alcohol, thinner, benzene, etc.

Chemicals that are spilled or evaporated may result in fire or electric shock through contact with electric parts inside the product. Also, some disinfectants are flammable. Be sure to take care when using them.

WARNING:
Do not connect the equipment with anything other than the specified connectors to avoid fire or electric shock.

WARNING:
Keep all patients with active implantable medical devices away from the product.

Installation and Environment of Use

CAUTION:
Do not install the product in any of the locations listed below to avoid failure, malfunction, falling, fire, or injury.

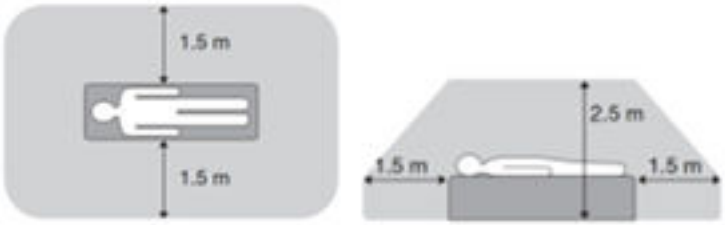
- Close to facilities where water is used
- Where there is exposure to direct sunlight
- Close to the air outlet of an air conditioner or ventilation equipment
- Close to a heat source such as a heater
- Where the power supply is unstable
- In a dusty environment
- In a saline or sulfurous environment
- Where temperature or humidity is high
- Where there is freezing or condensation
- In areas prone to vibration
- On an incline or in an unstable area

CAUTION:
Do not allow cables to become tangled to avoid a malfunction of the product.

Do not get your feet caught by a cable to avoid tripping and injury.

Installation and Environment of Use

CAUTION:
Non-medical equipment such as battery chargers and access point and infrared register tools cannot be used in the vicinity of a patient.



Power Supply

WARNING:
Do not operate the product with a power supply other than the one indicated on the rating label to avoid fire or electric shock.

WARNING:
Do not handle the product with wet hands to avoid electric shock that could result in death or serious injury.

Power Supply

WARNING:
Do not place heavy object on cables and cords. Co not pull, bend, bundle, or step on them to prevent damage to the sheath. Do not alter them.

Avoid damage to the cords, which could result in fire or electric shock.

WARNING:
Do not supply power from the same AC outlet to more than one product to avoid fire or electric shock.

WARNING:
Do not turn on system power when condensation has formed on the equipment to avoid fire or electric shock.

WARNING:
Do not connect multiple portable socket outlets or extension cords to the system to avoid fire or electric shock.

Power Supply

WARNING:
Connect this product only to a power supply with protective earth to avoid fire or electric shock.

WARNING:
Do not use the adapter cord when connecting the panel to a patient.

Power Supply

WARNING:
Securely insert the power cord into the AC outlet to avoid a contact failure.

If a contact failure occurs or if metal objects come in contact with the exposed metal prongs of the plug, fire or electric shock may result.

WARNING:
Be sure to turn off the power before connecting or disconnecting the cords to avoid an electric shock that could result in death or serious injury.

WARNING:
Be sure to hold the plug or connector to disconnect the cord.

If you pull the cord, the core wire may be damaged, resulting in fire or electric shock.

Power Supply

CAUTION:

- Always connect a three-core power cord plug to a grounded AC power outlet.
- Keep the outlet free of obstacles for easy access to disconnect the plug at any time and in an emergency.
- Be sure to ground the product to an indoor grounded connector. Be sure to connect all the grounds of the system to common ground.

CAUTION:
Do not use any power source other than the one provided with the product to prevent leakage that could result in fire or electric shock.

Handling

Handling

WARNING:
No modification is allowed. Never disassemble or modify the product to avoid fire or electric shock.

The product incorporates parts that may be hazardous or cause electric shock Touching them may cause death or serious injury.

WARNING:
Do not place an object on top of the product. The object may fall and cause an injury.

Metal objects such as needles or clips that fall into the product or spilled liquid may result in fire or electric shock.

WARNING:
Do not strike, drop, or cause a strong jolt to the product to prevent damage and avoid fire or electric shock.

Handling

WARNING:
Do not place the product and pointed objects together to prevent damage.

If so, it should be used in Bucky.

WARNING:
Have the patient take a fixed posture and do not let the patient touch parts unnecessarily.

If the patient touches connectors or switches, it may result in electric shock or malfunction.

CAUTION:
Do not spill liquid or chemicals onto the equipment. Do not allow an injured patient's blood or body fluids contact with the equipment.

Doing so may result in fire or electric shock.

Handling

In such a situation, protect the equipment with a disposable cover as necessary.

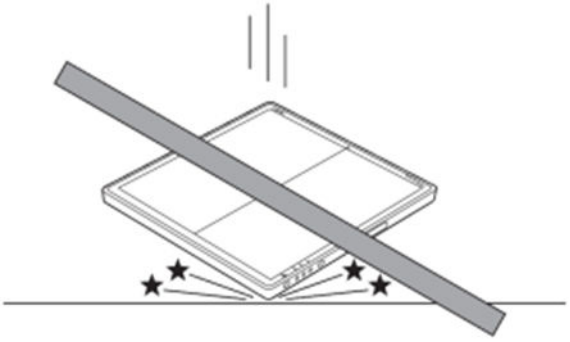
CAUTION:
For safety Turn OFF the power and remove the plug for all equipment when not used.

CAUTION:
Handle the product carefully.

Do not submerge the product in water.

CAUTION:
The internal image sensor may be damaged if struck or dropped. If the product is dropped, the drop sensor inside would record and the product would not be under warranty.

Handling



CAUTION:

Do not place excessive weight on the panel to avoid damage to the internal image sensor and an incorrect image.

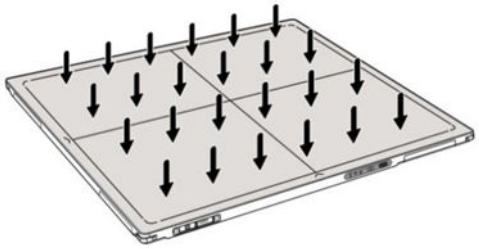
Patients stand on the product temporarily, and the intended weight can be 135 kg.

Based on the internal TFT character, cannot load the dynamic forces due to loading from persons

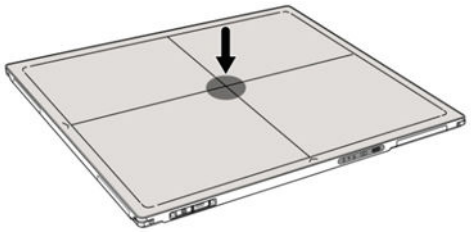
Load Limit

Handling

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



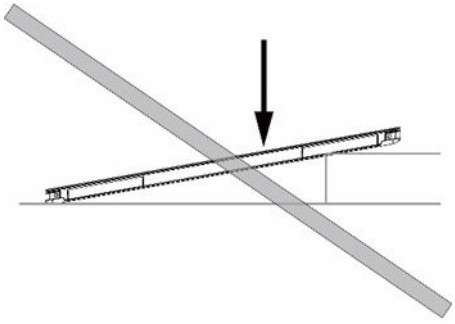
Local load:100 kg on an area 4 cm diameter



Handling

CAUTION:

Be sure to use the product on a flat surface to prevent the product from bending and doing damage to the internal image sensor. Be sure to securely hold the product while using it in an upright positions to prevent the product from tipping or flipping over, resulting in injury to the user or patient damage to the inner device.



Keep the same pressure on the product when acquiring an image to avoid an incorrect image.

Handling

CAUTION:

- Do not use the product close to fire or in high temperature.
- Do not invert the positive and negative poles.
- Do not allow the product to make contact with metal to avoid a short circuit.
- Do not insert sharp objects into the battery.
- Do not strike the battery.
- Do not stand on the battery.
- Do not use the battery outside of the guidelines.
- Do not dispose of the battery or change the inner structure.
- Do not submerge the battery in water. When in use, do not allow the battery to have contact with water. Store the battery in a dry place.
- Use a charger to charge the battery following the GB 9706.1 Standards provided.
- Do not replace the battery provided with one from another company.
- Do not use a damaged charger to charge the battery.
- Only qualified personnel may replace the battery inside the main unit.
- Do not touch the output connector for the adapter.
- Do not remove the battery when the detector is powered on only with the battery.
- Replace the DC power cable if either of the following occurs:
  - An arc occurs at the detector interface when connecting the cable
  - The power indicator is not illuminated after connecting the cable

Maintenance and Inspection

WARNING:

- Turn off the power of the product and disconnect the power cord of the adapter before cleaning.
- Never use alcohol, ether, and other flammable cleaning agent for safety. Never use methanol, benzene, and acid to avoid corrosion on the equipment.
- Do not place the product in liquid.

Maintenance and Inspection

WARNING:

Make sure that the surface and connectors are dry before turning on the product to avoid fire or electric shock.

WARNING:

Clean the power cord connector periodically. Disconnect the connector from the AC outlet. Use a dry cloth to remove dust or dirt from the connector, its periphery, and the AC outlet.

If the cord is kept plugged in for a long time in a dusty, humid, or sooty place, dust around the plug will attract moisture; this could cause insulation failure that may result in a fire.

WARNING:

For safety reasons, be sure to turn off the power when performing the inspections indicated in this manual to avoid electrical shock.

When a Problem Occurs

WARNING:

When a Problem Occurs

If any one of the following occurs, immediately disconnect the power cord of the adapter or battery, and contact your sales representative or local dealer:

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

Medical Equipment Classification

Type of protection against electrical shock	External electrical power source equipment Class I Equipment (medical approved adapter) Internal electrical power source equipment (battery)
Degree of protection against electrical shock	Type-B applied part
Degree of protection against ingress of water	IPX1
Mode of operation	Continuous operation
Flammable anesthetics	Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide Not suitable for use in an oxygen-rich environment

Standards

ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
IEC 60601-1:2005/AMD1:2012	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014/EN60601-1-2:2015	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances v Requirements and tests
IEC 60601-2-54:2018/EN 60601-2-54:2019	Medical electrical equipment — Part 2-54: Particular requirements for the basic safety and essential performance of X ray equipment for radiography and radioscopy
IEC 62133-2:2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes — Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications — Part 2: Lithium systems
IEC 62220-1-1:2015/EN 62220-1-1:2015	Medical electrical equipment — Characteristics of digital X-ray imaging devices — Part 1-1: Determination of the detective quantum efficiency - Detectors used in radiographic imaging
IEC 62304:2006/AMD1:2015	Medical device software — Software life-cycle processes
IEC 62366-1:2015/IEC 62366:2007/EN62366:2008	Medical devices — Part 1: Application of usability engineering to medical devices
IEC 60601-1-6:2010+A1:2013	Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability
EN ISO14971:2012	Medical device — Application of risk management to medical devices
ANSI/AAMI ES60601-1:2005/ (R)2012+A1:2012+C1:2009/(R)2012+A2:2010/ (R)2012	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)

CAN/CSA-C22.2 No.60601-1:14	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
ISO 15223-1:2016/ EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General requirements

Emissions and Immunity Compliance to the IEC60601-1-2 Standard

Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment
RF emissions	CISPR 11 Group 1, Class B	The TRIMAX 43C 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.
Harmonic distortion	IEC 61000-3-2 Class A	The TRIMAX 43C Detector is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	

Electromagnetic Immunity

Emissions Test	EMC Standard	Test Levels
		Professional healthcare facility environment
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM field	IEC 61000-4-3	3 V/m 80 MHz–2.7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to Proximity Fields From RF Wireless Communications Equipment
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Proximity Fields From RF Wireless Communications Equipment

Test Frequency (MHz)	Band (MHz)	Test Levels
		Professional healthcare facility environment
385	380–390	Pulse modulation 18 Hz, 27 V/m
450	430–470	FM, ±5kHz deviation, 1 kHz sine, 28 V/m
710	704–787	Pulse modulation 217 Hz, 9 V/m
745		
780		
810	800-–960	Pulse modulation 18 Hz, 28 V/m
870		
930		
1720	1700–1990	Pulse modulation 217 Hz, 28 V/m
1845		
1970		
2450	2400–2570	Pulse modulation 217 Hz, 28 V/m
5240	5100–5800	Pulse modulation 217 Hz, 9 V/m
5500		
5785		

Input AC Power Port

Emissions Test	EMC Standard	Test Levels
		Professional healthcare facility environment
Electrical fast transients/burst	IEC 61000-4-4	±2 kV 100 kHz repetition frequency

Emissions Test	EMC Standard	Test Levels
		Professional healthcare facility environment
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1kV
Surges Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1kV, ±2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V, 0.15 MHz–80MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips	IEC 61000-4-11	0 % UT; 0.5 cycle At 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 ° and 315 °
Voltage dips	IEC 61000-4-11	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0 °
Voltage interruptions	IEC 61000-4-11	0 % UT; 250/300 cycles

Signal Input/Output Parts Port

Emissions Test	EMC Standard	Test Levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Electrical fast transients/burst	IEC 61000-4-4	±1 kV 100 kHz repetition frequency

Emissions Test	EMC Standard	Test Levels
		Professional healthcare facility environment
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V, 0.15 MHz–80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz

Reference Cables Provided Against EMC

Cable	Recommended Cable Length	Shielded or Unshielded	Number	Cable Classification
AC Power Cable	3 m	Unshielded	1 pcs	AC Power
DC Power Cable	3.5 m	Unshielded	1 pcs	DC Power
LAN Cable (configuration mode)	3 m	Shielded	1 pcs	Signal

Important Information Regarding Electromagnetic Compatibility (EMC)

TRIMAX 43C requires special precautions regarding EMC and needs to be installed only by Carestream or authorized personnel and put into service according to EMC information provided in the user manual.

TRIMAX 43C in use may be susceptible to electromagnetic interference from portable and mobile RF communications such as mobile (cellular) telephones. Electromagnetic interference may result in incorrect operation of the system and create a potentially unsafe situation. The minimum distance between the panel and other equipment should be larger than 12 inch.

TRIMAX 43C conforms to this EN60601-1-2:2015 standard for both immunity and emissions. Nevertheless, special precautions need to be observed.

The use of accessories, transmitters, and cables other than those specified by this user manual, with the exception of accessories and cables sold by Carestream as TRIMAX 43C replacement parts for inner components, may result in increased emission or decreased immunity.

Radio Frequency Compliance

Country	Item
U.S.A	FCC Code CFR47 Part15B (2018) ANSI C63.4(2014) FCC CFR47 Part 15C (2018)Radio Frequency Devices ANSI C63.10(2013) KDB 558074 D01 15.247 Meas Guidance v05r02 FCC CFR47 Part 15E (2018) Unlicensed National information infrastructure devices ANSI C63.10(2013) KDB 789033 D02 General UNII Test Procedures New Rules v02r01 KDB 662911 D01 Multiple Transmitter Output v02r01 248227 D01 802.11 Wi-Fi SAR v02r02 447498 D01 General RF Exposure Guidance v06 648474 D04 Handset SAR v01r03 865664 D01 SAR measurement 100MHz to 6GHz v01r04 865664 D02 RF Exposure Reporting v01r02 941225 D06 Hotspot Mode v02r01 616217 D04 SAR for laptop and tablets v01r02

Country	Item
European Union	ETSI EN 300 328 V2.1.1 ETSI EN 301 893 V2.1.1 ETSI EN 300 440 V2.1.1 ETSI EN 301 489-3 V2.1.1 Draft ETSI EN 301 489-1 V2.2.1 Draft ETSI EN 301 489-17 V3.2.0 EN 55032: 2015 EN 55035: 2017 EN 61000-3-2: 2014 EN 61000-3-3: 2013 EN 50566: 2017 EN 62209-2: 2010 EN 62479: 2010

FCC Compliance

- The panel has been tested to comply with limits for a Class B digital device, pursuant to part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.
- Operation is subject to the following two conditions.

  The panel may not cause harmful interference.

  The panel must accept any interference received, including interference that may cause undesired operation.
- The panel generates, uses, and radiates radio frequency energy and, if not installed and used in accordance with the instruction, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If the panel does cause harmful interference to radio or television reception, which can be determined by turning the panel off and on, the user is encouraged to correct the interference by one or more of the following measure.
  - Reorient or relocate the antenna.
  - Increase the separation between the panel and receiver.
  - Connect the panel into an outlet different from the receiver is connected.
  - Consult the distributor or an experienced radio/TV technician for help.

Correction and Calibration Template Generation

Correction and calibration should be performed after installation and every six months. The new correction and calibration should be performed after any major change on the system settings and hardware configuration.

Battery Safety Standards

Standards	Description
CAN/CSA E62133:13 1st Ed. Rev.	Secondary cells and batteries containing alkaline or other non-acid electrolytes — Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications First Edition
UL 62133, 1st Ed. Rev.	Secondary cells and batteries containing alkaline or other non-acid electrolytes — Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications First Edition
UL 2054	Household and commercial batteries
IEC 62133-2:2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes — Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications — Part 2: Lithium systems
UN38.3	United Nations Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria ST/SG/AC.10/11/Rev.5/Amend.1 and Amend.2

Intended Use and Essential Performance

Intended Use

These devices are indicated for digital imaging solutions designed to provide general radiographic diagnosis for human anatomy including both adult and pediatric patients. They are intended to replace film/screen systems in all general-purpose diagnostic procedures. This device is not intended for mammography or dental applications.

Essential Performance

For TRIMAX 43C, the intended use and the result of risk management, getting imaging and function of data transmission is defined as essential performance.

Getting qualified dark image proves that essential performance does not influence the intended use. For the method of getting dark image, see the Installation and Operation sections.

Application Specification

Patient Population

- Adult and pediatric patients
- Weight: not relevant
- Health: not relevant
- Nationality: multiple
- Patient state: patient is not user
- Gender: except for pregnant women

Pediatric Use: Guidance & Considerations

Special care should be exercised when imaging patients outside the typical adult size range, especially smaller pediatric patients whose size does not overlap the adult size range (e.g.less than 50 kg (110 lb) in weight and 150 cm (59 in) in height, measurements which approximately correspond to that of an average 12 year old.

The following ranges of pediatric subpopulations are to be used as a guide for manufacturers in developing medical devices:

Pediatric Subgroup	Approximate Age Range
Newborn (Neonate)	From birth to 1 month of age
Infant	Greater than 1 month to 2 years of age
Child	Greater than 2 to 12 years of age
Adolescent	Greater than 12 through 21 years of age

Exposure to ionizing radiation is of particular concern in pediatric patients because:

1. For certain organs and tumor types, younger patients are more radio sensitive than adults (the cancer risk per unit dose of ionizing radiation is higher for younger patients);
2. Use of equipment and exposure settings designed for adults of average size can result in excessive and unnecessary radiation exposure of smaller patients;
3. Younger patients have a longer expected lifetime putting them at higher risk of cancer from the effects of radiation exposure.

To help reduce the risk of excessive radiation exposure, you should follow the ALARA (As Low As Reasonably Achievable) principle and seek to reduce radiation dose to only the amount necessary to obtain images that are adequate clinically.

Additional guidance and recommendation are provided by the Alliance for Radiation Safety in Pediatric Imaging (Image Gently Alliance) https://www.imagegently.org/

Table 1: Techniques for Typical Body Parts

Body Parts	Patient Size	kVp	mAs	SID	Grid
Abdomen AP/PA	Very Low Birth Weight (Less than 1.5 Kg)	55	1	1m	no
	Low Birth Weight (Between 1.5 and 2.5 Kg)	55	1.6	1m	no
	Newborn (Age is less than 1 month and Weight above than 2.5 Kg)	70	1.6	1m	no
	Infant (Age is between 1 month and 2 years)	73	2	1m	no
	Child (Age is between 2 years and 12 years)	75	7.1	1m	yes
	Preadolescent (Age is between 12 years and 13 years)	75	14	1m	yes
	Adolescent (Age is between 12 years and 21 years)	75	20	1m	yes
	Adult Small	75	18	1m	yes
	Adult Medium	80	22	1m	yes
	Adult Large	85	32	1m	yes

Body Parts	Patient Size	kVp	mAs	SID	Grid
Chest PA/AP	Very Low Birth Weight	50	1	1m	no
	Low Birth Weight	55	1	1m	no
	Newborn	65	1	1m	no
	Infant	70	1.6	1m	no
	Child	70	1.6	1m	no
	Preadolescent	90	2	1m	yes
	Adolescent	90	2	1m	yes
	Adult Small	110	1.8	1.8m	yes
	Adult Medium	110	2.8	1.8m	yes
	Adult Large	120	4	1.8m	yes
Extremities AP/PA	Very Low Birth Weight	50	1	1m	no
	Low Birth Weight	55	1	1m	no
	Newborn	57	1	1m	no
	Infant	57	1.2	1m	no
	Child	58	1.2	1m	no
	Preadolescent	62	1.6	1m	no
	Adolescent	62	2	1m	no
	Adult	Regarding adult details techniques of Extremities, please refer to the table of "Techniques for Adult Extremities"			no

Table 2: Techniques for Adult Extremities

Adult Extremities List	kVp	mAs	SID	Grid
Ankle - AP	58	4	1	no
Ankle - Lateral	58	4	1	no

Adult Extremities List	kVp	mAs	SID	Grid
Femur - AP	70	16	1	yes
Femur - Lateral	70	10	1	yes
Hand - PA	53	1.8	1	no
Hand - oblique	53	1.8	1	no
Humerus - AP	75	7.1	1	yes
Humerus - Lateral	70	3.2	1	yes
Knee - AP	65	10	1	yes
Knee - Lateral	65	10	1	yes
Wrist - PA	55	1.8	1	no
Wrist - Lateral	55	1.8	1	no

Intended Operator

All procedures should be carried out by an operator who has completed the professional training offered by the company's customer service staff.

Life Time

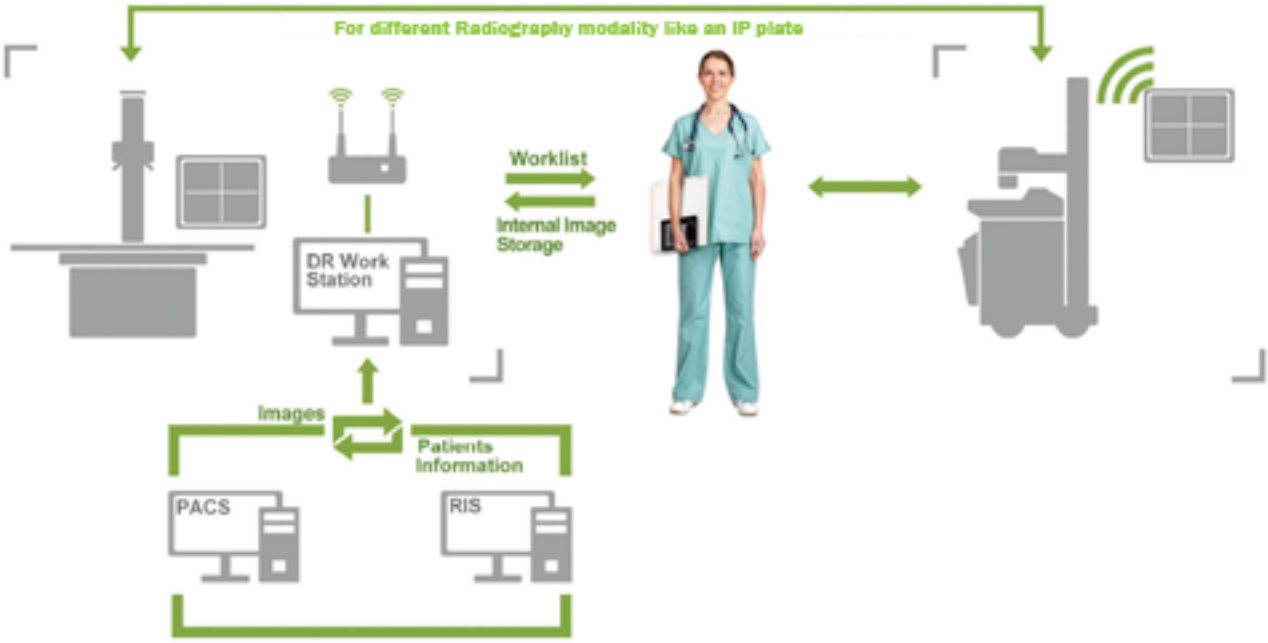
Lifetime: 7 years without frequency limit

2 Overview

The TRIMAX 43C Detector is a cassette-size, wireless x-ray flat panel detector based on amorphous silicon thin-film transistor technologies. It is developed to provide the highest quality of radiographic images with an active matrix of 3072×3072 with 139 um pixel pitch. The detector supports wireless communication between the panel and the workstation and is powered by an internal battery.

Scope

This manual contains information about the TRIMAX 43C. Information in the manual, including the illustrations, is based on a prototype. If your system configuration does not have features described in this manual, the information does not apply to your detector.



Features

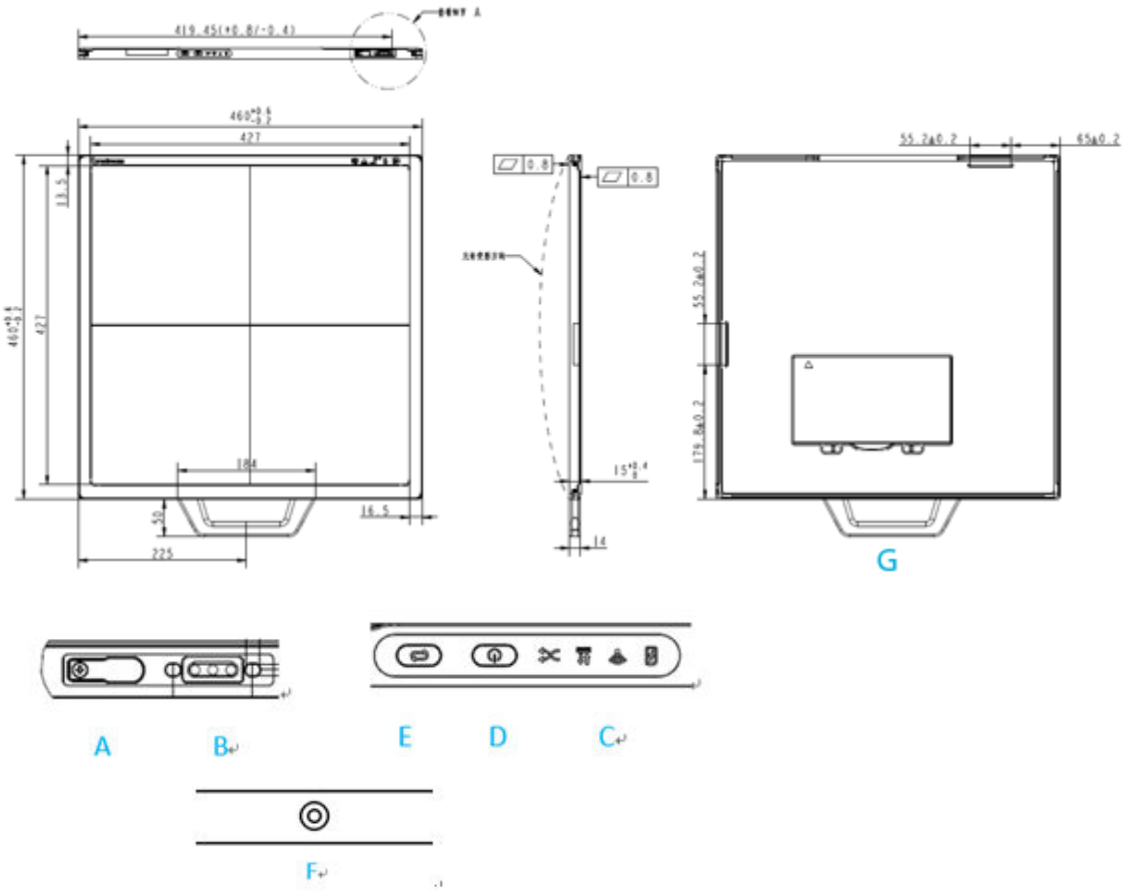
- Wireless static flat panel detector used for general radiography
- Cassette-size
- Sync-shot exposure trigger
- CsI scintillation screen
- Easy-to-change cable and easy-to-update firmware
- Battery recycling

Components and Specifications

Product Components

Component Description

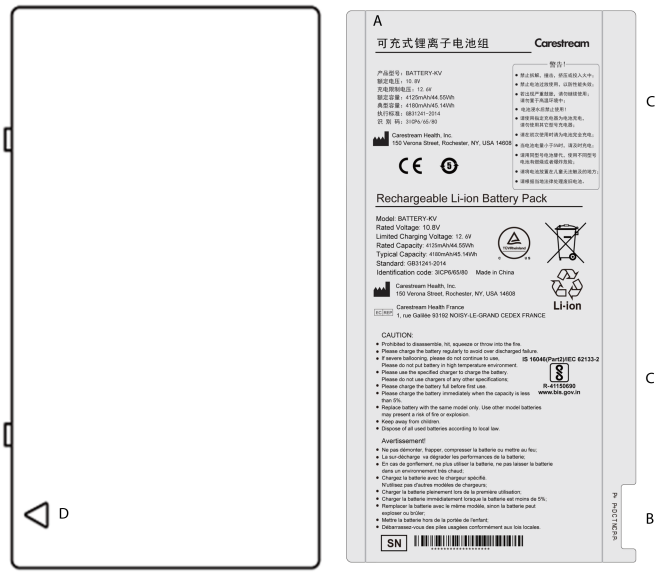
Detector



Item	Description	Notes
B	DC jack	For optional power input
A	Ethernet port	For service
C	Detector indicator	Detector indicator of control panel
D	Power button	Power button of control panel
E	Mode button	Mode switch

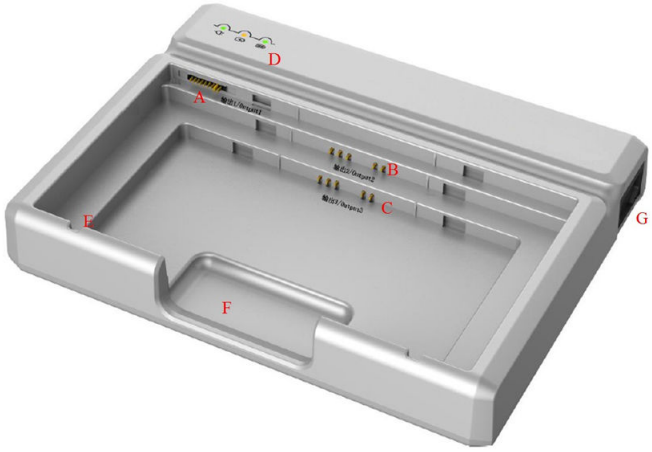
Item	Description	Notes
F	Power indicator	The other Power indicator
G	Handle	Optional

Battery



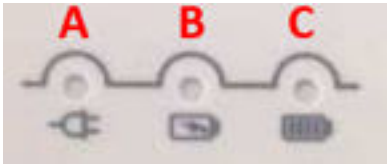
Item	Description	Notes
A	Battery label	
B	Battery interface	8 pin battery connector
C	Pilot pin	
D	Indicator	Installation direction indicator

Battery Charger

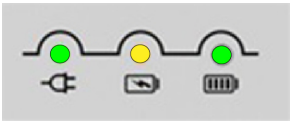
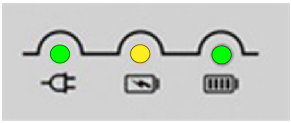


Item	Description	Notes
A	Battery Interface A	8 pin battery connector
B	Battery Interface B	Not used
C	Battery Interface C	Not used
D	Indicator	The indicator definition is as follow
E	The limit ball plug	/
F	Hand Pull Position	/
G	AC Jack	220V (ac) input

Battery Charger Indicator



Item	Name
A	Power Indicator
B	Charging Indicator
C	Charge Full Indicator

X Indicator		Operating Status
All off		No power input
A indicator on		• AC power input • Multiple batteries inserted
A indicator on B and C alternately blink 2 times		Battery insertion self test
A and B indicator on		Battery charging
A and C indicator on		Battery capacity full, charging stops
A indicator on B and C alternately blinking		Battery is not charging properly

Two or more batteries charging cannot be charged at the same time. Charging will automatically stop if more than one battery is inserted.

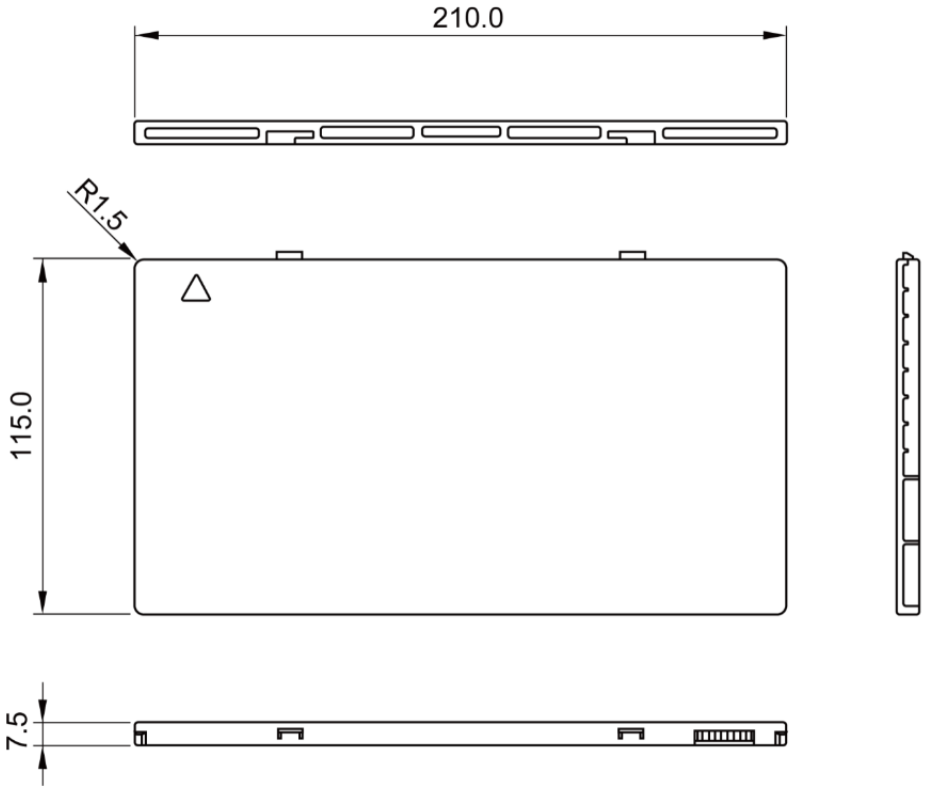
Product Specifications

Detector

Item	Specifications
Model	TRIMAX 43C
Image Sensor	a-Si (amorphous silicon) TFT
Pixel Size	139 µm
Active Array	3072 x 3072
Active Area (H x V)	427.0 x 427.0 mm (16.8 x 16.8 in.)
Gray Scales	16 bit
Spatial Resolution	3.6 Lp/mm
Cycle Time	Min. 8.5 sec.
Power Consumption	Max. 20 W
Dimension (L × W × H)	460.0 x 460.0 x 15.0 mm (18.1 x 18.1 x 0.6 in.)
Weight (with one battery)	4.68 kg (10.32 lb)
Image Transfer	Wireless: IEEE802.11a/b/g/n/ac

Item	Specifications
Data Transmission Rate (Wireless)	802.11b: Max. 11 Mbps 802.11a/g: Max. 54 Mbps 802.11n: Max. 300 Mbps (MIMO 2 x 2) 802.11ac: Max. 867 Mbps(MIMO 2 x 2)

Battery



Item	Specifications
Model	Battery-KV
Rated capacity	Typ. 4180 mAh @ Discharge 0.2C
Nominal voltage	10.8 V
Charge voltage	12.6 ± 0.05 V
Discharged end voltage	9 V
Charging method	CC-CV

Item	Specifications
Operating temperature	Charge 0–60 °C (32–140 °F) Discharge 0–60 °C (32–140 °F)
Storage temperature	≤3 month -20 °- +45 ° (-4–113 °F) ≤6 month -20°- +35 ° (-4–95 °F)
Relative humidity	5 %~95 %
Dimension (L × W × H)	210.0 x 115 x 7.5 mm (8.3 x 4.5 x 0.30in.)
Weight	0.28 kg (0.62 lb)

Battery Charger

Item	Specifications
Model	Charger-Combo
Simultaneous Charging	1 Battery Pack
Full Charging Time	≤ 3 hr
Rated Power Supply	90~264 V (ac)
Dimension (L × W × H)	240.0 x 184.0 x 38.0 mm (9.4 x 7.2 x 1.52 in.)
Weight	0.55 kg (1.2 lb)

Power Supply

Item	Specifications
DC Power (Optional)	24V (dc), 0.8A
Battery Package	10.8V (dc), 1.78A

CAUTION:
The charging cable can only be used in areas not are accessible to the patient, such as in the Bucky.

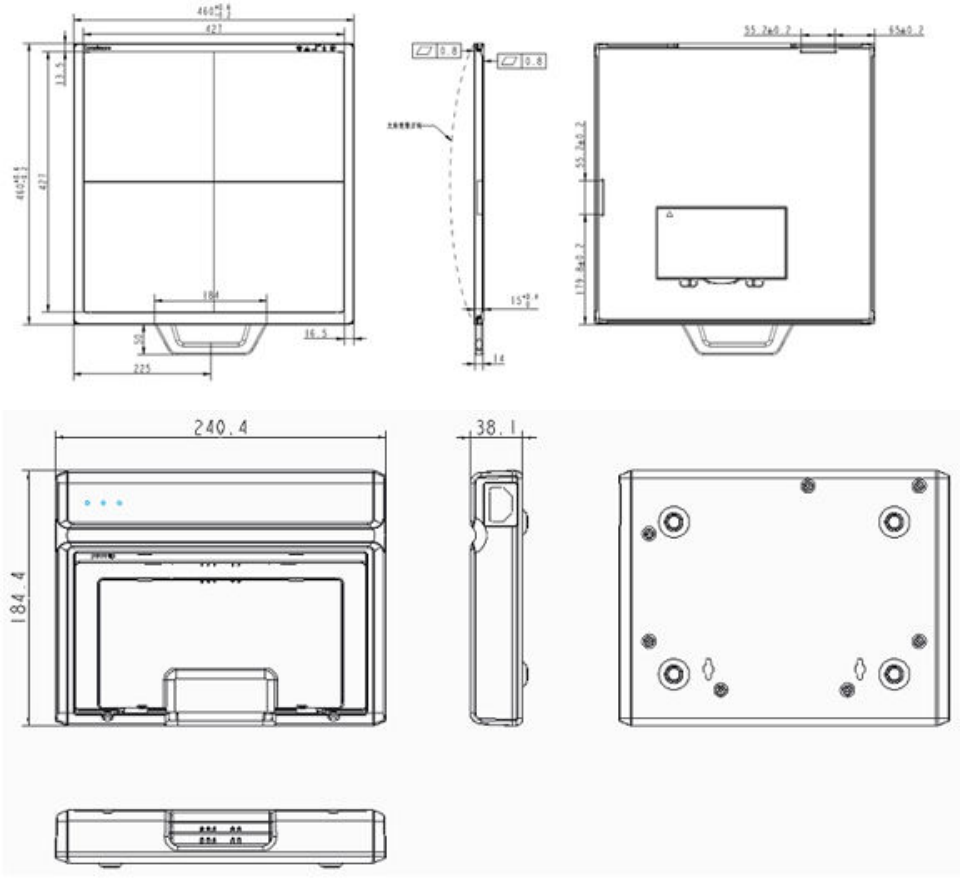
The product must be used with the approved adapter and CB certificate number SG PSB-MD-00191.

Wireless Communication

Item	Specifications
Wireless Standard	IEEE 802.11 a/b/g/n/ac
Frequency Range	2.412~2.472 GHz: ch1~ch13 5.18~5.24 GHz: ch36~ch48 5.745~5.85 GHz: ch149~ch165
Data Transmission Rate	802.11b: Max. 11 Mbps 802.11a/g: Max. 54 Mbps 802.11n: Max. 300 Mbps (MIMO 2x2) 802.11ac: Max. 867 Mbps(MIMO 2x2)
Modulation	802.11b: CCK, DQPSK, DBPSK 802.11a/g/n: 64 QAM, 16 QAM, QPSK, BPSK 802.11ac: 256 QAM, 64 QAM, 16 QAM, QPSK, BPSK
Transmission Power	Max.17 dBm

Item	Specifications
Security	WPA, WPA-PSK, WPA2, WPA2-PSK, WEP 64 bit & 128 bit
Antenna	2 dual band inner antenna

Mechanical Outlines



Use Environment

	Temperature	Temperature Change	Humidity	Atmospheric Pressure	Pressure Change
Operating	5–35 °C (41–95 °F)	< 1k/min	10 %–90 % RH	700–1060 hPa	<10 kp/min (1 kp=1.0197E-5Pa)
Storage	-20–55 °C (-4–131 °F)	< 1k/min	5 %–95 % RH	700–1060 hPa	<10 kp/min (1 kp=1.0197E-5Pa)

Temperature	Temperature Change	Humidity	Atmospheric Pressure	Pressure Change
TRIMAX 43 detectors shall operate at a specified altitude of not more than 3000.0 m (9842.5 ft). The environment specific is only for the detector.				

IT Network

Purpose for IT-network

Transmission of image data and command/status communication between the detector and the workstation.

Required Features

Wireless communication follows IEEE 802.11a/b/g/n/ac protocol. It works on 2.4 GHz and 5 GHz.

It supports at least 2 routers.

Hazardous Situations from Failure of the IT Network

- Incompatibility of the operating system is not compatible
- Inability to update or change software
- Incompatibility of the interface
- Inconsistency of interface or format leads to data distortion
- Data transfer protocol error
- Data output failure

Required Configuration

The wireless card and the detector must work on the same IP segment such as 192.168.8.XXX.

They must support IEEE 802.11a/b/g/n/ac.

Technical Specifications

Item	Specifications
Wireless Standard	IEEE 802.11a/b/g/n/ac
Frequency Range	2.412-2.472 GHz: ch1-ch13 5.18-5.24 GHz: ch36-ch48 5.745-5.85 GHz: ch149-ch165

Item	Specifications
Data Transmission Rate	802.11b: Max. 11 Mbps 802.11a/g: Max. 54 Mbps 802.11n: Max. 300 Mbps (MIMO 2x2) 802.11ac: Max. 867 Mbps (MIMO 2x2)
Modulation	802.11b: CCK, DQPSK, DBPSK 802.11a/g/n: 64 QAM, 16 QAM, QPSK, BPSK 802.11ac: 256 QAM, 64 QAM, 16 QAM, QPSK, BPSK
Security	WPA, WPA-PSK, WPA2, WPA2-PSK, WEP 64 bit, and 128 bit

Intended Information Flow

The detector sends the acquired image data to the workstation. The workstation sends the user's commands to the detector. Please refer to the operation manual of the console for detail.

Hazardous Situations Resulting From Failure of the IT-network

- Failure of completing essential performance
- Failure of finishing configuration of product
- Incompatibility of operating system
- Failure of change or update to software
- Compatibility of interface
- Data transfer protocol error
- Inconsistency of interface or format leads to data distortion
- Data output failed

Warning

Connection of the main unit to an IT network that includes other equipment could result in previously unidentified risks.

The manufacturer of the x-ray machine should identify, analyze, evaluate, and control these risks; subsequent changes to the IT-network could introduce new risks and require additional analysis.

Changes to the IT-Network

- Changes in the IT-network configuration
- Connection of additional items to the IT-network
- Disconnecting of items from the IT-network
- Update of equipment connected to the IT-network

Service Information

Product Lifespan

The estimated product lifetime is up to 7 years under appropriate regular inspection and maintenance (battery 5 years).

Regular Inspection and Maintenance

In order to ensure the safety of patients and operator, and to maintain the performance and reliability of the panel, be sure to perform regular inspections at least once a year. If necessary, clean the panel, make adjustments, or replace consumables such as fuses etc. There may be cases where an overhaul is recommended depending on conditions. Contact Carestream service or your local dealer for regular inspection or maintenance.

Repair

If the problem cannot be solved, contact Carestream service or your local dealer for repairs. Please refer to the label and provide the following information:

Product Name:

Series Number:

Description of Problem: (as clearly as possible)

Replacement Parts Support

Main parts (those required to maintain the function of the product) needed to repair the product will be stocked for 5 years after discontinuance of production.

Disposal

CAUTION:

Do not dispose of this product with your residential or commercial waste. Improper handling of this type of waste could have a negative impact on health and on the environment. Some countries or regions, such as the European Union, have set up systems to collect and recycle electrical or electronic waste. Contact your local authorities for information about dropping off waste products for recycling. If collection systems are not available, call Carestream Customer Service for assistance.

In the European Union, this symbol indicates that when the last user wishes to discard this product, it must be sent to appropriate facilities for recovery and recycling. See http://recycle.carestreamhealth.com for additional information on the collection and recovery programs available for this product.

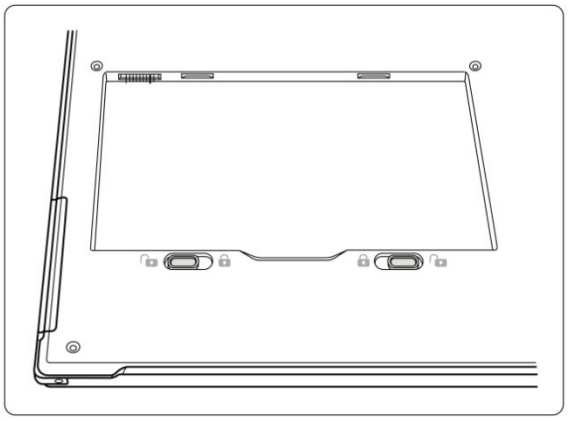
3 Installation

Panel Installation

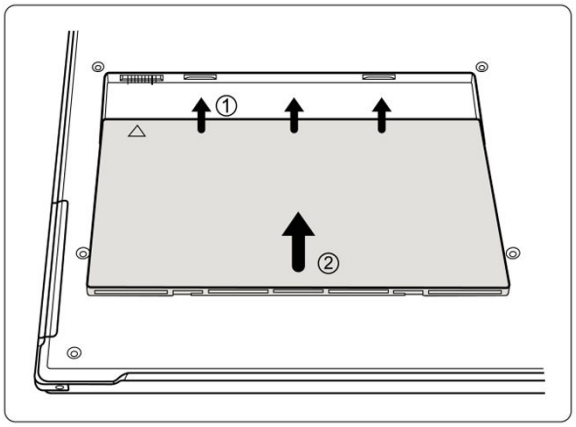
Install the Detector Battery

The detector can be powered by the battery package or DC power. The detector will be activated as soon as power is supplied and will power off as soon as power is removed.

1. Make sure that the connectors for the battery and battery compartment are aligned.

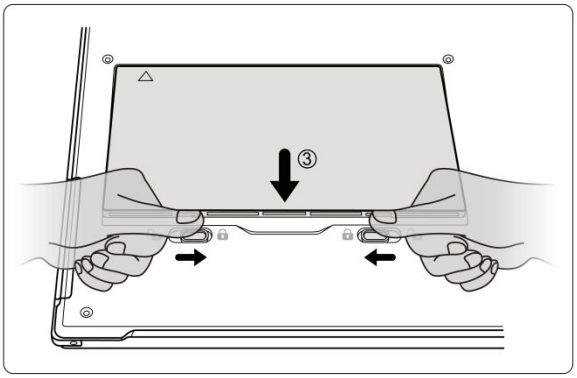


2. Slide the battery into the battery compartment.



Note:
Make sure the battery level is >10 % of full capacity.

3. Slide the two battery lock levers toward the center of the detector..



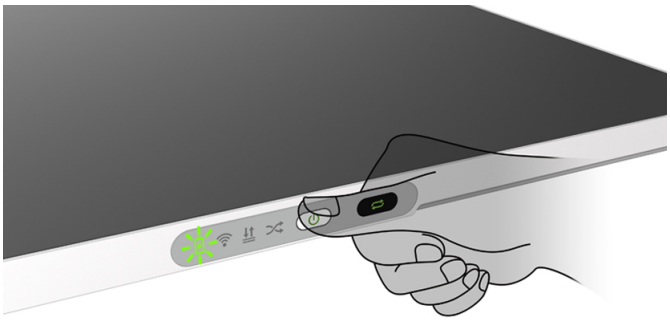
Power on the Detector

On the control panel, the power button is used to power the detector on and off.

To power on the detector, press and hold the power button for 4 seconds. The detector must either have a battery installed with >10 % charge or have the DC power connected.

To power off the detector, press and hold the power button for 4 seconds.

To reset the detector, press and hold the power button for 8 seconds.



Power Indicator

After booting up, the user can check the status LED indicator.

Power Indicator	Lighting Status	Operating Status		
		Operating	Battery Capacity	DC Input
OFF		Power OFF	--	--
Orange ON		Power ON	≤20%	No
Green ON		Power ON	• Battery capacity ≥20 %, no DC input • DC input (Optional)	
Orange Blinking		Power OFF	<20 %	Yes
Green and Orange Blinking		Power OFF	≥20 % and <95 %	Yes

Power Indicator	Lighting Status	Operating Status		
		Operating	Battery Capacity	DC Input
Green Fast Blinking		Power OFF	≥95 % and <100 %	Yes
OFF		Power OFF	=100 %	Yes

Link Indicator

Power Indicator	Lighting Status	Description
Off		• Shut down • Wired connection broken and wireless connection not ready
Green On		Wired connection is built
Blue On		• Client mode, wireless connection is built • AP mode, wireless AP is ready (Not used)
Blue Blinking		Client mode, no connection is built
Green and Blue Blinking		Initialization

Status Indicator

Power Indicator	Lighting Status	Description
Off		• Shut down • Exposure prohibit

Power Indicator	Lighting Status	Description
Green On		Exposure enable
Green Blinking		Image transmission
Orange On		Error
Orange Blinking		Safety mode

Mode Indicator

Power Indicator	Lighting Status	Description
Off		• Shut down • Wired connection is built
Green On		AP mode, wireless AP is ready (Not used)
Blue On		Client mode, wireless client is ready
Blue and Green Blinking		Initialization

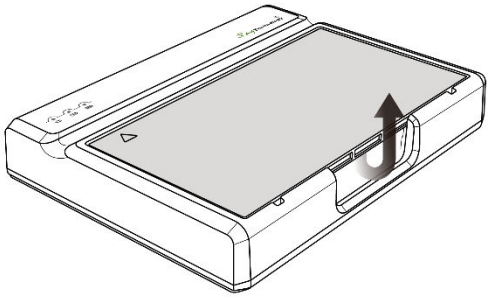
Button Function

Action	FPD Status	Power	Mode	Note
				
Power ON	Power OFF	Short hold	No action	Hold for 4 seconds
Forced restart		Long hold	No action	Hold for more than 7 seconds. Release the power button when the power indicator is ON.
Exit the battery from ship mode		Press 3 times	No action	Release after two short presses (interval < 1second).
Enter safety mode		Short hold	Long hold	Power button: hold for 4 seconds Mode button: hold for 7 seconds
Forced restart	Power ON	Long hold	No action	Hold for more than 7 seconds, when the Power indicator is OFF and then ON, release Power button.
Enter/exit sleep mode		Double click	No action	Release after two short presses (interval <1second)
Power OFF		Short hold	No action	Hold for 4 seconds, Release the Power button when the power indicator is OFF.
Restore default configuration		Triple check Short hold	Long hold	1. Hold the Mode button hold for 7 seconds. 2. Press the Power button 3 times. 3. Short hold the Power button for 4 seconds.

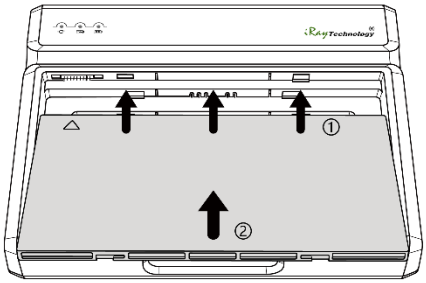
Action	FPD Status	Power	Mode	Note
				
Wireless ConnectionMode Switch	Power ON	No action	Long hold and then short click	1. Hold the Mode button hold for 7 seconds. 2. Release the Mode button after Mode indicator starts blinking, and then press again in 5 seconds. The mode starts switching. 3. Press the Mode button to switch modes. The Mode indicator blinks at the corresponding color. 4. Wait at intended mode, the Mode indicator will switch color after several seconds. • Blue = client • Green = AP (Not used)

Install the Detector Battery Charger

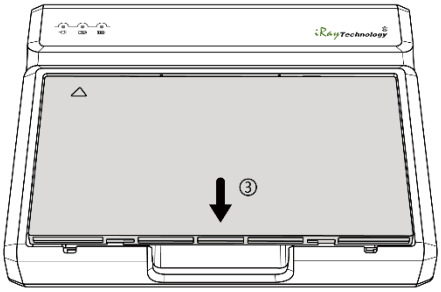
1. Remove the battery from the battery charger.



2. Insert battery into battery charger in the orientation shown below.



3. Press the battery down into the battery compartment.



Detector Battery Lock and Activation

To ensure the safety of the battery during transportation or storage, the battery can be set to ship mode where it is locked and will not provide any voltage output.

Enter Ship Mode

Method	Steps
Factory configuration	
Web write in	1. Connect the adapter to the detector and power it on. 2. Connect the other end of the adapter to the PC. 3. Insert the battery into the detector. 4. Open a web browser and enter the following address: **http://10.0.1.150/cgi-bin/shipmode.cgi?action=on** The battery is placed in ship mode.

Exit Ship Mode

Method	Steps
Web exit	1. Connect the adapter to the detector and power it on. 2. Connect the other end of the adapter to the PC. 3. Insert the battery into the detector. 4. Open a web browser and enter the following address: **http://10.0.1.150/cgi-bin/shipmode.cgi?action=off** The detector exits ship mode.
Adapter + FPD	1. Connect the adapter to the detector and power it on. 2. Insert the battery into the detector. 3. Press the power button for approximately 4 seconds to shut down the detector. 4. In the shutdown state, press the power button 3 times to exit ship mode.

Method	Steps
Charger	1. Power on the charger. 2. Insert the battery into the charger for 3 to 5 seconds to exit ship mode.

4 Operation

Notes for Using

Do the following to ensure that the detector functions correctly.

Before Exposure

Inspect the detector daily and confirm it is working properly.

Check that there is no condensation on the any of the surfaces of the detector. Condensation can be caused by the sudden heating of the room in cold areas. If this occurs, wait until the condensation evaporates before performing an exposure or problems may occur with the quality of captured images. When changing the temperature in an air-conditioner environment, be sure to raise or lower the temperature gradually.

The product should be warmed up for 15 minutes before exposure or updating the gain map and defect map.

Make sure exposure rate is over 900 nGy/s @70 KV.

Make sure the wave form of the energy going to the x-ray tube is square and not pulse.

Check if the patient has recently been injected with a radio isotope; this may cause the detector to transmit an image without performing an x-ray.

During Exposure

Important:
To prevent image noise, artifacts, or incorrect images, do not use the product near equipment generating a strong magnetic field.:

After Usage

Remove the battery from the detector if the detector will not be used for more than 5 days. If the battery is stored for an extended time, it should be charged (30 % to 50 %) every 3 months or charged (50 % to 70 %) every 6 months.

Cleaning, Disinfection, and Sterilization of Patient Contact Surfaces

To prevent the risk of infection, wipe the patient contact surfaces after every examination with a nonflammable disinfectant, such as benzalkonium chloride or benzalkonium bromide. For details on how to sterilize, consult a specialist.

CAUTION:

Do not spray disinfectants or detergents directly onto the detector.

To prevent damage to the surface of the detector, wipe with a cloth slightly dampened with a neutral detergent. Do not use solvents such as benzene and acid.

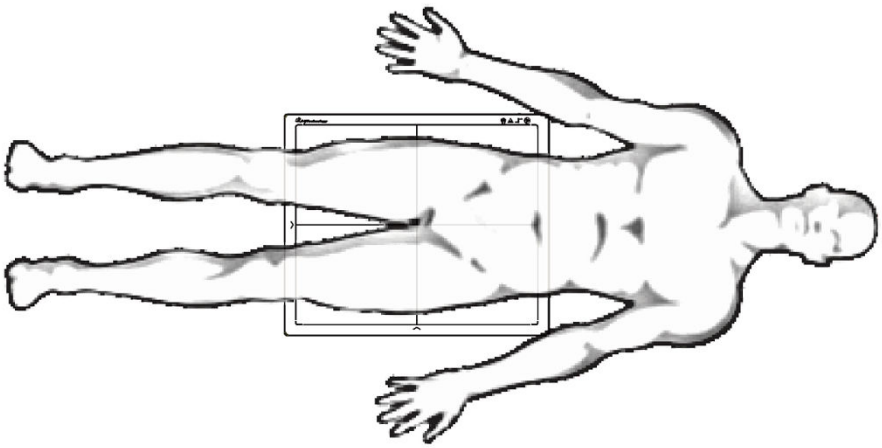
It is recommended to use a waterproof non-woven cover as the isolated layer between the detector and a patient who is bleeding.

Applied Part

The front and back of the detector is an application part.

Detector Position

To prevent abnormal light lines, place the detector behind the patient in the orientation shown below.



Appendix (For Service Personnel Only)

Software and Settings

Main Interface

Button	Function
Home	Home page, shows the list of the detectors
Acquire	Acquire images, free for use after connecting the detector
SDK	Configure UI for SDK, free for use after connecting the detector
Detector	Configure UI for detector, free for use after connecting the detector
Calibrate	Calibrate UI, for generation and management of the calibration template
Local File	Image management, free for use at any time
Connect	Connect the detector
Close	Disconnect the detector
Syncbox	Manage the syncbox

Message Box

Status Box

Tab	Description
SN	Serial number of the detector
Status	Status of the detector, busy or ready
Task	The task that is currently being executed
Message	Information

Tab	Description
	Remaining power of the battery, shown as a percentage

Progress Bar

If the progress bar

- Is green while taking an x-ray, the image quality is acceptable
- Is not green while taking an x-ray, the image quality will be degraded

General Settings

Parameter	Description	Can be Modified
Product No.	Type number of the detector	No
Sub Product No.	Sub-type of the detector	No
Serial No.	Serial number of the panel	No
Main Version	Version of the firmware of Main FPGA	No
Main MB CPU Version	Version of the MB CPU of Main FPGA	No
MCU Version	Version of the firmware of MCU	No
Arm Version	Version of the App of ARM	No
Kernel Version	Version of the Kernel of ARM	No
Inner Subflow	Sub work-flow	Yes
Prep CapMode	Reserved	No
Self CapEnable	Reserved	Yes
Self Cap Span Time	Should not be modified; keep the original value	Yes
Trigger Mode	Trigger mode	Yes
Sequence Interval Time	Should not be modified; keep the original value	Yes
Set Delay Time	Exposure window for Freesync mode	Yes
Exp Window Time	Exposure Window for Software/Inner mode, the value should not be larger than 10s	Yes
Acquire Delay Time	Reserved	Yes

Parameter	Description	Can be Modified
Integrate Time	Should not be modified; keep the original value	Yes
Src Port	Port number for detector	No
Src IP	IP address for detector	No
Src MAC	MAC address for detector	Yes
Dest Port	Port number for PC	No
Dest IP	IP address for detector	No
Self Clear Enable	Related to Prep CapMode, the value should be configured as On if Prep CapMode is configured as PrepCapMode_ClearAcq. Otherwise, the value should be Off If the Trigger Mode is Software/Inner, the value should be On	Yes
Self Clear Span Time	Should not be modified; keep the original value	Yes
Hvg Prep On	Reserved	Yes
Hvg XRay Enable	Reserved	Yes
Hvg XRay On	Reserved	Yes
Tube Ready Time	Reserved	Yes
Image Pkg Gap Time	Reserved	Yes
Out Mode Cap Trigger	Reserved	Yes

SDK Settings

Parameter	Description	Can be Modified
Host IP	IP Address of local workstation	Yes
Host Port	Port of local workstation	Yes
Ftp Download Host IP	FTP download server IP; keep the same as Host IP	Yes
Ftp Download Host Port	FTP download server Port; keep the same as Host Port	Yes

Parameter	Description	Can be Modified
Ftp Upload Host IP	FTP upload server IP; keep the same as Host IP	Yes
Ftp Upload Host Port	FTP upload server Port; keep the same as Host Port	Yes

Network Settings

Button	Description
Add	Add the information of SSID and the AP Key
Del	Delete the information of SSID and the AP Key
Up	Move up the AP information
Down	Move down the AP information
Select	Select the AP
Read Config	Read the parameters of the AP information when the detector is set as AP
Write Config	Write the parameters of the AP information when the detector is set as AP
Read Wifi Status	Read the WIFI status of the current detector
Scan from FPD	Scan the AP

Operating Modes

Software Mode

Block Diagram

Software mode is the basic way to acquire an x-ray image.

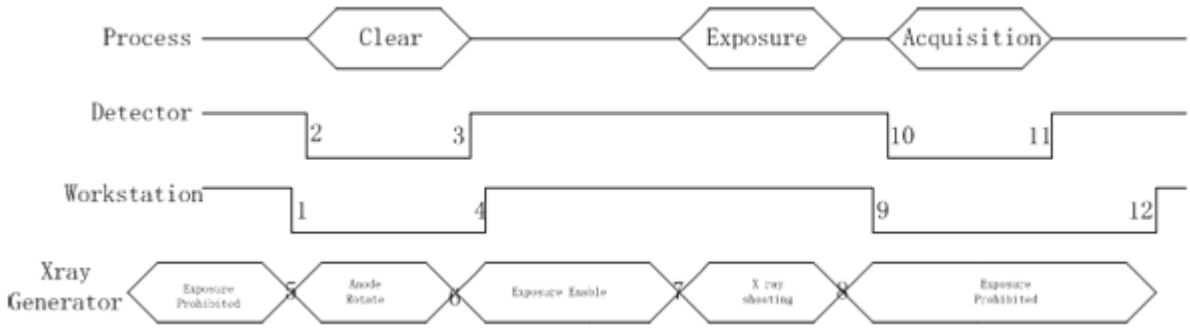
The workstation is a host device installed with iDetector and SDK. Installation describes how to establish connections between the panel and workstation. In software mode, the workstation does not control the x-ray generator. Users decide when to take x-rays.

Work Flow

1. Workstation receives **prep** request and sends **clear** command to the panel.
2. Panel receives **clear** from the workstation and starts clearing leakage from the panel. Meanwhile, the panel sends an **Exposure Prohibited** message to the workstation.
3. Panel finishes **clear** and sends an **Exposure Enable** message to the workstation.
4. Workstation shows **Exposure Enable** on the iDetector's message bar to tell the user to take the x-ray now.
5. User triggers the x-ray generator to initialize and do an anode rotation to prepare for taking x-rays.
6. X-ray generator finishes preparation for taking x-rays and reminds the user to take the x-ray.
7. X-ray generator starts releasing the x-ray.
8. X-ray generator finishes taking the x-ray.
9. Workstation receives **acquire** request and sends **Data Acquisition** command to the panel.
10. Panel receives **Data Acquisition** from the workstation and starts data acquisition operation.
11. Panel completes image acquisition and begins to send data to the workstation.
12. Workstation receives all image data from the panel after calibration if hardware calibration is on.

Time Setting

To set a clear scenario for programming, see the diagram below.



Inner2 Mode

Block Diagram

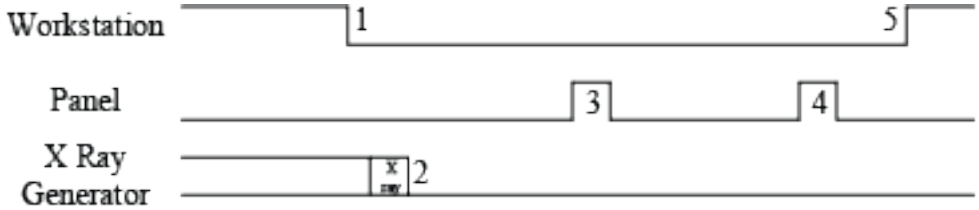
The workstation is a host PC device installed with iDetector and SDK. Installation describes how to establish connections between the panel and workstation. In inner2 mode, the workstation does not control the x-ray generator. Users decide when to take x-rays.

Work Flow

1. Workstation receives **prep** request.
2. X-ray generator is ready to take x-rays and starts releasing the x-ray.
3. Panel starts uploading a Pre-dark image and a Light image to the workstation for preview. If hardware offset is selected, panel first performs an offset and then uploads the preview image.
4. Panel starts uploading Post-dark image to the workstation. If hardware offset is selected, panel first performs correction and calibration and then uploads the processed image to the workstation.
5. Workstation enters exposure prohibit state.

Time Setting

To set a clear scenario for program, see the diagram below.



Freesync Mode

Block Diagram

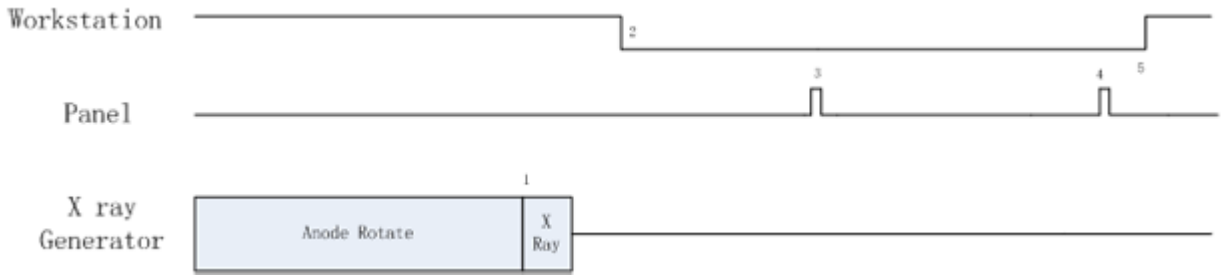
The workstation is a host PC device installed with iDetector and SDK. Installation describes how to establish connections between the panel and workstation. In FreeSync

mode, the user does not interact with the workstation. After taking x-rays, images immediately appear on the screen.

Work Flow

1. X-ray generator is ready to take x-rays and starts releasing the x-ray.
2. Workstation receives **Exposure Prohibited** from the panel.
3. Panel starts uploading a Pre-dark image and a Light image to the workstation for preview. If hardware offset is selected, panel first performs an offset and then uploads the preview image.
4. Panel starts uploading Post-dark image to the workstation. If hardware offset is selected, panel first performs correction and calibration and then uploads the processed image to the workstation.
5. Workstation receives **Exposure Enable** from the panel.

Time Setting



Software Installation

Do the following if the iDetector application is not working:

1. Install MICROSOFT .NET Framework 4.5.
2. Install vcredist_x86_2013 (or vcredist_x64_vs2013).

Important:

The iDetector application should not be used for a hospital terminal.

Set the Connection Mode

The detector supports the following two connection modes and should be configured per site requirements.

Wireless Client Mode

1. Connect one end of the Gigabit Ethernet cable to the workstation.
2. Connect another end to the LAN port of external wireless AP.
3. From the workstation, open the **Control Panel** and then the **Network and Sharing Center**.
4. In the **Connections:** field, click on **Local Network**.
5. Open the IPV4 settings.
6. For the IP and network mask setting, select **Obtain an IP address automatically**.
7. Open the browser and type **10.0.1.1** and log into external wireless AP.
8. Do the wireless setup.
9. Configure 2.4 GHz wireless network.
    - SSID: NETGEAR_BIG_24
    - Security: WPA2-PSK
    - Password: 12345678
    - Channel: Check the current Wi-Fi environment, and choose a relatively clean channel.
10. Configure 5G Hz wireless network.
    - SSID: NETGEAR_BIG_50
    - Security: WPA2-PSK
    - Password: 12345678
    - Channel: Check the current Wi-Fi environment, and choose a relatively clean channel.
11. Configure LAN IP address.
    - IP address: 10.0.1.1
    - Subnet Mask: 255.255.255.0
12. Do an external wireless AP reboot: Apply the above settings and reboot your wireless router.
13. Recover the local network IPV4 setting.
    - IP setting—IP address: 10.0.1.251
    - Network mask setting—Subnet mask: 255.255.255.0
14. Connect the panel to the workstation with the Ethernet cable.

15. Select:
    - Detector
    - Wifi
    - Read Config
    - Client
16. Select **Add** and enter the **SSID** and **Password**. Select **Apply**.
17. Choose **SSID** and select the one with a check mark. Select **Write Config** to save the parameters.
18. Turn on the wireless router.
    a. Make sure there is a wired connection between the outer, work station, and IP 10.0.1.251.
    b. Select **Read Wifi Status** to check wireless transmission status, numerical value occurred means the link is up and available.

    The detector will connect to the wireless AP the next time it is powered on.

Wireless AP Mode

A wired cable can also be used to configure detector in wireless client mode. The wired connection should only be used by the service operator.To start configuration with wired cable, it is necessary to complete this procedure.

1. Connect the panel to the workstation with the Ethernet cable.
2. Select the **Detector** tab and then **Wifi**.
3. In the **Mode** field, select **AP**.
4. Select **Read Config** to display the default settings.
5. Change the settings for **SSID** and **password**.

   Important:
   Make sure that the SSID is different from others already used.
6. In the **Frequency** field, click on the arrow and select a value from the drop-down list..
7. In the **Country** field, click on the arrow and select a country from the drop-down list.
8. In the **Channel** field, click on the arrow and select a clean frequency and channel.
9. Select **Write Config** to save the settings.

   Note:
   Do not remove the wired cable until the FPD status is **Ready**.

The detector will connect to the wireless AP the next time it is powered on.

10. Configure the external wireless card.
    a. Open the local wireless signal list.
    b. Select the SSID that belongs to the detectors. Enter the password and select **OK**.
    c. Open the wireless card configuration.
    d. Open the IPV4 setting and set the following values:.
        - IP setting—IP address: 10.0.1.251
        - Network mask setting—Subnet mask: 255.255.255.0
    e. Open SDK and select the detector.
    f. Select **Connect**.

Shortcuts

Shortcut	Result
Double-click the window using the left mouse button.	The image is centered and displayed at the maximum size.
Double-click the window using the right mouse button.	The window level and width are adjusted to WL: 32767/WW: 65535.
Drag the left mouse button to move the displayed image.	
Drag the right mouse button horizontally to adjust the window width, and drag the right mouse button vertically to adjust the window level.	
F3 key	Quickly adjust the image window width and window level.

Establish a Connection with the Detector

1. Open SDK, select the detector, and select **Connect**.
2. Confirm that the values for **IP address** and **Port** are the same as the values in **config.ini**.

   Note:
   The value for **Cfg_HostPort** should be the default of **28000**.

   Note:
   When the connection is changed to a different network card, the user must reconnect the detector using a different IP address.

   The rule of Multi-Share control is based on the IP address. The second terminal with a different IP address is not allowed to operate a detector after the first one is connected. If there is no command transmission between the detector and workstation after 5 minutes, the detector releases access authority.

Configure the Detector

1. From the iDetector menu, select the **Acquire** tab.
2. Acquire the module related setting, such as loading correction and calibration template, acquiring images.
3. See the SDK module-related settings, such as IP address.
4. See the Detector module related settings, such as trigger module, wireless signal.
5. Calibrate the module related setting, such as making correction and calibration template. The template in the panel could be uploaded to a workstation, and the template in a workstation could also be downloaded to panel.
6. See the Local File module related setting, such as import a Raw or DCM image.

Correction and Calibration Template Generation

Correction and calibration should be performed after installation and every six months. The new correction and calibration should be performed after any major change on the system settings and hardware configuration.

Pre-offset Template Generation

If panel is configured to do Pre-offset correction, Pre-offset Template is necessary.

1. Select **Calibrate**.
2. Select **Start Generate Templates**.
3. Select **Create Offset**.
4. Select **Start create offset template file**.
   The screen will display **Offset Map Generating**.
5. When complete, the screen will display **Offset MAP Generated!**

Gain Calibration Template Generation

Before doing this procedure, make sure SID1.2m, no copper is required.

Actual screens may be different from those shown in this procedure.

Note:
Use software post offset correction.

1. On the gain template generating page, five images need to be created.
2. Select **Start**.
3. Select **PREP** and start the exposure.
4. When completed, select **Acquire** to get the light image.
5. If the value meets the expected value, select **Accept**, and then acquire the other four images.
   If the value does not meet the expected value, do not click **Accept**. Adjust the exposure dose, and then click **PREP** to acquire the light image again.
6. When all five images are created, select **Generate** to generate the gain template.

Defect Correction Template Generation

Before doing this procedure, make sure SID1.2m, no copper is required.

Actual screens may be different from those shown in this procedure.

Note:
Use software post offset mode.

1. On the **Defect Calibration** page, start the exposure. Eight images need to be captured.
2. Select **Start**.
3. Select **PREP** and start the exposure.
4. When completed, select **Acquire** to get the light image.
5. If the value meets the expected value, select **Accept**, and then acquire the other seven images.

   If the value does not meet the expected value, do not select **Acquire**. Adjust the exposure dose, then select **PREP** to acquire the light image again.
6. When all eight images are created, select **Generate** to generate the gain template.

   Note:

   Make sure your x-ray dose is correct. If your dose is out of the range, iDetector will remind you to adjust the dose. Then you can select **start creating** and try again.

   If users operate with two panels, SDK has a probability of automatically quitting.

Image Check and Upload

OPEN provides two features for image check and uploading: Local Image Check and Panel Image Upload. Local Image Check is used to check images saved in the workstation. Panel Image Upload is used to upload images stored in the panel.

Local Image Check

1. From the **Local File** tab, select **Load File**. Choose the specified file.
2. Choose the images stored in the workstation. The screen will display the images.

Panel Image Upload

Prerequisites:

Make sure the firewall is closed.

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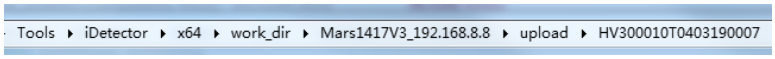
1. Select the **Images** tab from the **Detector** interface.
2. Select **Query Images**.
   The images stored on the detector will be listed.
3. Select **Upload Images** and choose the specified image. Select **OK**.
   When the state changes to **Success**, the image has been uploaded.

   The upload process can be canceled by selecting **Stop Upload**.

   The uploaded images are saved in the path of the detector serial number.



Defect Template Check and Modification

The iDetector software provides the ability to check the defect template. If the template has updates, the user can add and delete pixels or defective lines by modifying the opened defect template.

Defect Template Check

1. From the **Local File** page, select **Load File**.
2. Select the specified defect template, and select **Open**.
   The defect template will be displayed.

Defect Template Modification

1. Open the specified defect template.
   The defect management dialog box will be displayed.
2. Locate the pixel that needs to be managed, type the coordinates of the pixel, and select **Add**. The information will be added to the template.

   Note:
   If **Delete** is selected, the information will be removed from the template.
3. Select **Save**.
4. It is similar to manage the defect pixel. If the user needs to add the defect line, type the coordinates of the line, and select **Add**. If the information needs to be deleted, select **Delete**.

Correction and Calibration Management

Correction and Calibration Template Synchronization

The detector supports correction and calibration template storage. Templates in the detector can be uploaded to a workstation, and templates in a workstation can be downloaded to a detector.

1. After generating the offset, gain, and defect templates, select the templates and select **Download to FPD**.
2. Select **Download**.
3. Select **Read Status**.
4. If the **Activity** column shows **disable**, select the row and select **Active** to enable it.

Correction and Calibration Management

The detector supports the following ways to do correction and calibration:

- In software correction and calibration, the workstation completes all correction and calibration.
- In hardware correction and calibration, the panel completes all correction and calibration.

1. User can set the calibration method on the **Detector** page.

   Note:
   The hardware-based calibration is on.

2. Select:

   - **HWPostOffset**
   - **HWGain**
   - **HWDefect**

   Note:
   The hardware-based calibration is on.

3. Select:

   - **SWPostOffset**
   - **SWGain**
   - **SWDefect**

   Note:
   The software-based calibration is on.

Update the Firmware

The Internet can be used to upgrade the detector firmware.

This procedure applies to MCU, FPGA, and ARM.

1. Connect the panel to a PC.
2. Open a browser, type **detector IP** in the search bar, and then press **Enter**.
3. Enter the following and select **login**.
   - User name: **admin**
   - Password: **admin**
4. Click on the three squares located on the left side of the screen.
5. Select **Upgrade** and then **Browse**.
6. Select one the firmware files from the list and select **Open**.
   - 1717V3TISA07_IMAGE_MCU_xxxx_xx_13.ifm
   - 1717V3TISA07_FPGA_xxxx_xx_13.ifm
   - 1717V3TISA07_IMAGE_ARM_xxxx_xx_13.ifm

   Important:
   Selecting 1717V3TISA07_IMAGE_ALL_xxxx_xx_13.ifm will allow all three versions of firmware to be updated at the same time.
7. When the selected file name is displayed on the interface, select **Upgrade**.
8. Select **Close** when the **Notice** box is displayed.
   The progress bar will be displayed.
9. If the upgrade is successful, the following interface screen will be displayed.

   Note:
   If the screen is not displayed, the upgrade has failed.

Publication History

Version	Date	Changes
A	2020-02-10	Initial release

Carestream Health, Inc.
150 Verona Street
Rochester, NY, USA 14608

Made in China for Carestream Health, Inc.

Pub. No. AJ4312
Rev A.

CE 2797

“Rx only”

FCC Regulations:

Contains module's FCC ID：2ACHK-01070189

- 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.
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential 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 radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

  —Reorient or relocate the receiving antenna.

  —Increase the separation between the equipment and receiver.

  —Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

  —Consult the dealer or an experienced radio/ TV technician for help.
- Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.
- W52/UNII I is in door use only

Radio Frequency (RF) Energy

This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the United States.

During SAR testing, this device was set to transmit at its highest certified power level in all tested frequency bands, and placed in positions that simulate RF exposure in usage against the body with no separation. Although the SAR is determined at the highest certified power level, the actual SAR level of the device while operating can be well below

the maximum value.

This is because the device is designed to operate at multiple power levels so as to use only the power required to reach the network. In general, the closer you are to a wireless Base station antenna, the lower the power output.

The exposure standard for wireless devices employing a unit of measurement is known as the Specific Absorption Rate, or SAR. The SAR limit recommended by the ICNIRP used by the general public is 2.0W/kg averaged over ten grams of tissue and, is 1,6W/kg Averaged over one gram of tissue by IEEE Std 1528.

The FCC has granted an Equipment Authorization for this product with all reported SAR Levels evaluated as in compliance with the FCC RF exposure guidelines.

For this device, the highest FCC reported SAR value for usage is 0.042W/kg.

While there may be differences between the SAR levels of various product and at various positions, they all meet the government requirements.

SAR compliance for body-worn operation is based on a separation distance of 0 mm between the unit and the human body. Carry this device at least 0 mm away from your body to ensure RF exposure level compliant or lower to the reported level. To support body-worn operation, choose the belt clips or holsters, which do not contain metallic components, to maintain a separation of 0 mm between this device and your body.

RF exposure compliance with any body-worn accessory, which contains metal, was not tested and certified, and using such body-worn accessory should be avoided.

IC Notice

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.

This Class B digital apparatus complies with Canadian ICES-003.

IC:25116-01070189

IC Radiation Exposure Statement

This EUT is in compliance with SAR for general population/uncontrolled exposure limits in IC RSS-102 and had been tested in accordance with the measurement

methods and procedures specified in IEEE 1528 and IEC 62209. This equipment should be installed and operated with minimum distance of 0 cm between the radiator and your body. This device and its antenna(s) must not be co-located or operating in conjunction with any other antenna or transmitter.

Cet appareil est conforme aux Normes RSS d'Industy Canada. Son utilisation est soumise à deux conditions:

(1) Ce dispositif ne peut pas provoquer d'interférences, et

(2) Ce dispositif doit accepter toutes les interférences reçues, y compris les interférences susceptibles de provoquer un fonctionnement non souhaité.

Cet appareil de classe B est conforme à la norme canadienne ICES-003.

IC:25116-01070189

Déclaration d'exposition IC

Cet EUT est conforme aux valeurs SAR à la norme SAR pour le grand public ainsi qu'aux limites d'exposition non règlementée IC RSS-102 et a été testé selon les méthodes et procédures spécifiées par les Normes IEEE 1528 et IEC 62209. Cet appareil devrait être installé et utilisé en respectant une distance minimale de 0 cm avec votre corps. Cet appareil et son (ses) antenne (s) ne doivent pas être situés à proximité l'un de l'autre et ne doivent pas fonctionner en même temps qu'une autre antenne ou qu'un autre émetteur.

- UNII I is in door use only
- Les dispositifs RL- EL sont restreints à une utilisation à l’intérieur seulement dans la ba nde de 5 150 à 5 250 MHz.

Cet appareil est conçu et fabriqué de façon à ne pas dépasser les limites d'émission pour l'exposition à l'énergie de radiofréquence (RF) fixées par la Federal Communications Commission des États-Unis et Industrie Canada.

Au cours des essais SAR, cet appareil est configuré pour transmettre des données à son niveau de puissance le plus élevé à toutes les bandes de fréquences testées et placées dans l'ensemble des positions simulant l'exposition aux radiofréquences contre la tête et près du corps, avec une séparation de 0 mm. Bien que le DAS soit déterminé par le niveau de puissance le plus élevé, le niveau SAR réel de l'appareil en fonctionnement peut être bien inférieur à la valeur maximale indiquée. Cela est dû au fait que l'appareil est conçu pour fonctionner à plusieurs niveaux d'alimentation, pour s'adapter aux capacités des différents réseaux électriques. De manière général, plus vous vous trouverez pès d'une station sans fil, plus la fréquence de transmission sera basse.

La norme d'exposition pour les dispositifs sans fil employant une unité de mesure est connue sous le nom de taux d'absorption spécifique (SAR). La limite SAR fixée par la FCC est de 1,6 W / kg et de 1,6 W / kg par Industry Canada.

Cet appareil est conforme à la norme SAR pour le grand public ainsi qu'aux limites d'exposition non règlementées ANSI / IEEE C95.1-1992 et Canada RSS 102, et a été testé conformément aux méthodes et procédures spécifiées par les Normes IEEE1528 et Canada RSS 102. Ce dispositif a été testé et respecte les directives FCC et IC sur

l'exposition aux radiofréquences lorsqu'il est testé en contact direct avec le corps.
Pour cet appareil, la valeur SAR la plus élevée pour une utilisation près du corps est de 0.042 W/kg.
Bien qu'il puisse exister des différences entre les niveaux de SAR selon les dispositifs et les emplacements où ils sont utilisés, tous répondent aux exigences Gouvernementales.
La valeur SAR déclarée conforme est une distance de 0 mm entre l'unité et le corps humain. Eloignez cet appareil à une distance d'au moins 0 mm de votre corps pour vous assurer que le niveau d'exposition aux RF est conforme ou inférieur au niveau indiqué. Vous pouvez également opter pour un étui ne contenant aucun composant métallique, pour maintenir une séparation de 0 mm entre cet appareil et votre corps.
Pour tout appareil contenant du métal, la conformité de l'exposition aux radiofréquences n'a pas encore été testée / certifiée de manière précise.