Carestream

User Manual for the Focus HD 43 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 European Representative

EC REP

Carestream Health France SAS

207, Rue de Bercy

75012 Paris

France

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.
- Carestream shall not be liable for any damage or loss arising from the use of any options or consumable products other than those dedicated as original products by Carestream.
- 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

Contents

1 Safety and Regulatory Information

Medical Equipment Classification

Type of protection against electrical shock	Internal electrical power source equipment (battery)
Degree of protection against electrical shock	Type-B applied part
Degree of protection against ingress of water	IP56
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

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 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 Focus HD 43 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 Focus HD 43Detector 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, ±5 kHz 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
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV
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–80 MHz 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 ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transients/burst	IEC 61000-4-4	±1 kV 100 kHz repetition frequency
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
LAN Cable (configuration mode)	3.5 m	Shielded	1 pcs	Signal

Important Information Regarding Electromagnetic Compatibility (EMC)

Focus HD 43 should be used in the hospital environment except for near active HF surgical equipment and the RF shielded room of a medical equipment system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.

Use of Focus HD 43 adjacent or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify correct operation.

Focus HD 43 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.

CAUTION:
Portable and RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in.) to any part of the Focus HD 43, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Focus HD 43 conforms to this IEC60601-1-2:2014/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 Focus HD 43 replacement parts for inner components, may result in increased emission or decreased immunity.

Battery Safety Standards

Standards	Description
IEC 62133:2012	Secondary cells and batteries containing alkaline or other non-acid electrolytes
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

Radio Frequency Compliance

Country	Item
U.S.A	FCC CFR47 Part 15C (2019) Radio Frequency Devices ANSI C63.10 (2013) FCC Code CFR47 Part15B (2020) ANSI C63.4 (2014) FCC CFR47 Part 15E (2019) IEEE 1528- 2013 IEEE C95.1: 1991 IEEE C95.1: 1992
European Union	ETSI EN300 328 V2.2.2 ETSI EN301 893 V2.1.1 ETSI EN300 440 V2.1.1 ETSI EN 301 489-1 V2.2.3 ETSI EN 301 489-17 V3.2.4 ETSI EN 301 489-3 V2.1.1 EN 55032:2015+A11:2020 EN 55035:2017+A11:2020 EN 50566:2017 EN 62209-2:2010+A1:2019 EN 62479:2010

FCC Regulations

- 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.
- Contains module's FCC ID：2ACHK-01070189

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.

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 general public 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.

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.

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.
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.

Contains 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. The SAR limit is 1.6 W/kg by Industry Canada. 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.

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.

Refer to the *IMAGEVIEW System Software Online Help* for procedures on detector calibration.

Intended Use

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.

Application Specification

Patient Population

- Adult and pediatric patients

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 (for example, 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 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 and Disinfection of Patient Contact Surfaces

After every examination, wipe the patient contact surfaces of the detector using disinfectants such as ethanol, to prevent the risk of infection. 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 alcohol, thinner, benzene, acid and base.

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

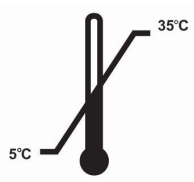
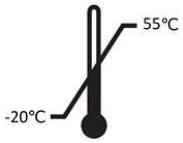
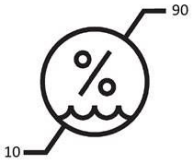
The front of the detector is an applied part.

Symbols

Symbols and Conventions

Labels and Markings on the Equipment

	This indicates the name and address of the manufacturer.
	This indicates the name and address of a Carestream authorized representative in the European-Union.
	Follow the instructions for use.
	Handle with care.

	This indicates operational temperature limits.
	This indicates storage temperature limits.
	This indicates FCC compliance.
	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.
Rx only	Device is for prescription use only.
IP56	Degree of protection against water (IEC 60529).
	Type B Applied Part (IEC 60601).
	This indicates consulting the user guide for general information.
MD	Medical Device: Any serious incident that may occur in relation to this device should be reported to the manufacturer and the national competent authority.

Cautions

Environment for Installation and Use

CAUTION:

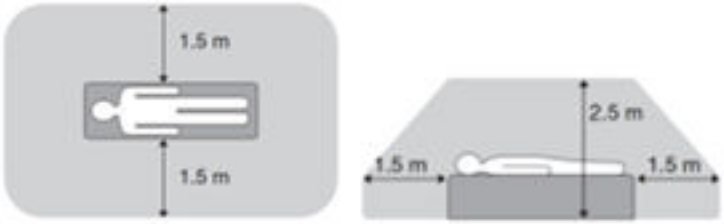
- Follow all safety labels on the equipment.
- For continued safe use of this equipment, follow the instructions contained in this operator's manual.
- Study this manual carefully before using the equipment and keep it at hand for quick reference.
- The equipment must be used only by qualified personnel and only after training in the specific operations. It is the operator's responsibility to ensure the patient's safety while the equipment operates by visual observation, proper patient positioning, and use of the protective devices provided.
- Do not submerge the equipment in liquid.
- Perform periodic maintenance to ensure continued safe use of the equipment.
- The equipment must be repaired only by authorized Service personnel.
- The detector is fragile and contains glass. Handle with care! Dropping or handling the detector roughly could result in damage and may void the warranty. If the detector is dropped or handled roughly , or if there is any indication of reduced image quality, perform a calibration.
- Any attempt to open the detector by unauthorized personnel will void the warranty.
- If a detector is not used in a Bucky, it must be enclosed in a protective plastic bag that is disposed of after each patient exam.
- Change the detector battery outside the patient vicinity.

CAUTION:

Do not install the product in any of the locations listed below.

- Where there is exposure to direct sunlight
- Close to a heat source

CAUTION:
Non-medical equipment such as battery charger, access point and PoE device cannot be used in the vicinity of a patient.



Power Supply

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

Avoid damage to the cords.

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

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.

Handling

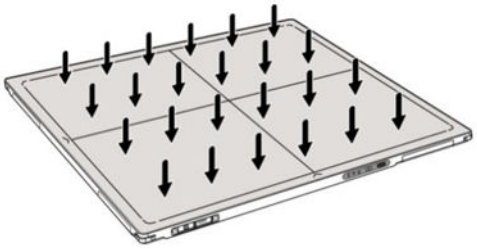
CAUTION:
No modification is allowed.

CAUTION:
Do not spill liquid or chemicals onto the equipment.

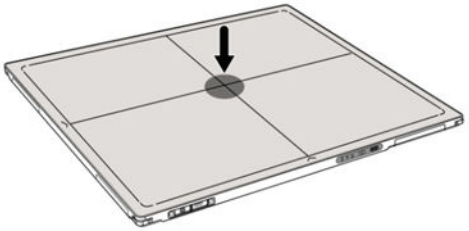
CAUTION:
Do not place excessive weight on the panel to avoid damage to the internal image sensor and an incorrect image.

Load Limit

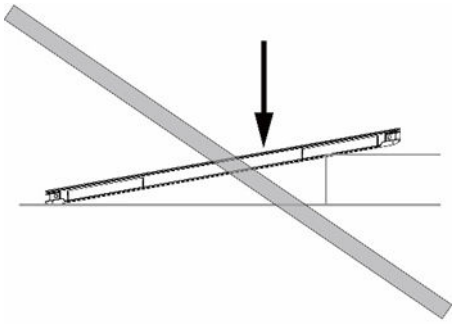
Uniform load: 300 kg over the whole area of the surface



Local load: 100 kg on an area 4 cm diameter



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.



CAUTION:

- Do not invert the positive and negative poles.
- 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.
- Only use the charger provided to charge the battery.
- Do not replace the battery provided with one from another company.
- Only qualified personnel may replace the battery inside the main unit.
- Do not remove the battery when the detector is powered on.
- Only use the DC power cable provided by the manufacturer.

Maintenance and Inspection

CAUTION:

- Remove the power of the product before cleaning.
- Never use alcohol, ether, and other flammable cleaning agent. Never use methanol, benzene, and acid to avoid corrosion on the equipment.

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

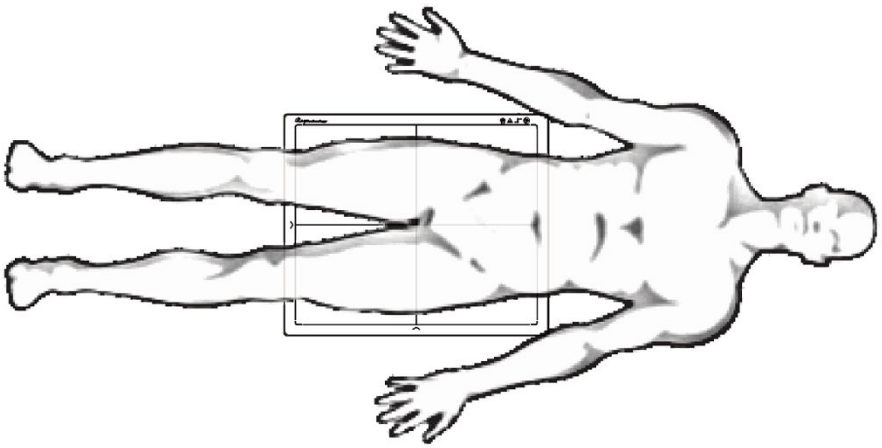
When a Problem Occurs

CAUTION:
If any one of the following occurs, immediately disconnect the power, 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

Detector Position

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

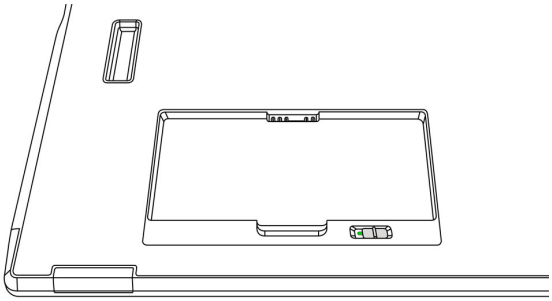


Panel Installation

Install the Detector Battery

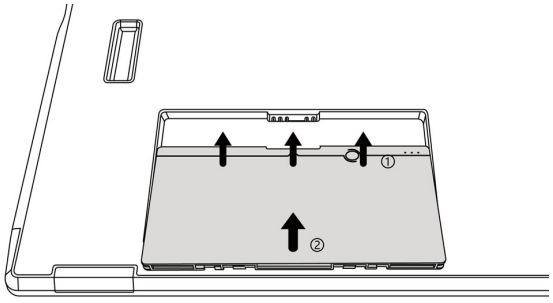
The detector can be powered by the battery package or DC power. The detector will be activated as soon as power is supplied and will power off as soon as power is removed.

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



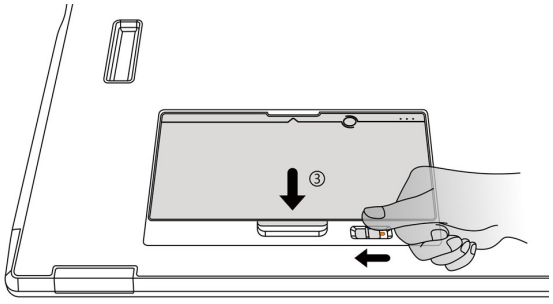
aligned.

2. Slide the battery into the battery compartment.



Note:
Make sure the battery level is more than 15 % of full capacity.

3. Slide the battery lock lever toward the center of the detector.

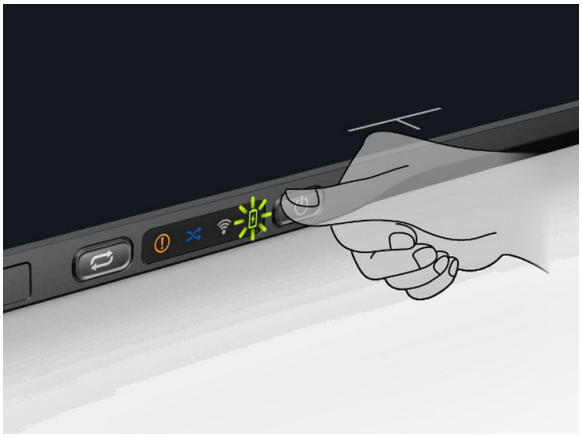


Power on the Detector

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

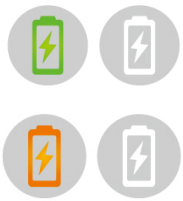
To power on the detector, press and hold the power button for 2 seconds. The detector must either have a battery installed with > 15 % charge or have the DC power connected.

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



Power Indicator

Power Indicator	Lighting Status	Status		
		Battery Capacity	DC Input	Description
OFF		N/A	N/A	Detector is OFF
Green ON		N/A	Yes	Detector is ON
Green ON		> 10%	No	Detector is ON
Orange Blinking		> 6% and ≤10%	No	Detector is ON

Power Indicator	Lighting Status	Status		
		Battery Capacity	DC Input	Description
Green Blinking		≥ 95 %	Yes	Detector is OFF
Green and Orange Blinking		< 95 %	Yes	Detector is OFF

Link Indicator

Power Indicator	Lighting Status	Description
Off		• Power OFF • Wired connection broken and wireless connection not ready
Green On		Wired connection is built (Service mode)
Blue On		• Client mode, wireless connection is built • AP mode, wireless AP is ready (Not used)
Blue Blinking		Client mode, connection is not built

Status Indicator

Power Indicator	Lighting Status	Description
Off		Detector is OFF
Green ON		Exposure is allowed
Green Blinking		Detector is in WIFI mode switch status
Orange On		Error

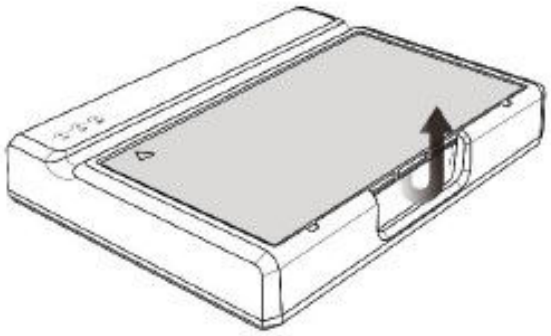
Mode Indicator

Power Indicator	Lighting Status	Description
Blue On		Client mode is enabled
Blue Blinking		1. Press and hold the Mode button for approximately seven seconds. When the status LED indicator starts to blink, release the button. The Mode LED indicator blinks blue indicating that the detector is in Client mode. 2. Press and release the Mode button. The Mode LED indicator will blink from blue to green, indicating that WIFI mode has switched from Client to AP. 3. The setting will be valid if the Mode button is not pressed again for seven seconds.
Green On		AP mode is enabled

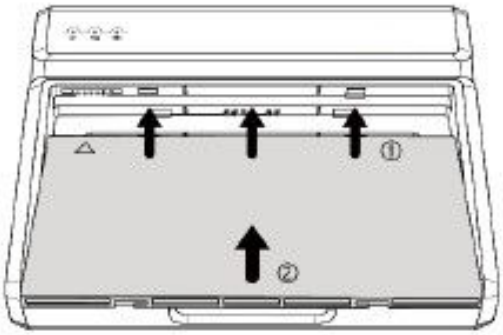
Power Indicator	Lighting Status	Description
Green Blinking		1. Press and hold the Mode button for approximately seven seconds. When the status LED indicator starts to blink, release the button. The Mode LED indicator blinks green indicating that the detector is in AP mode. 2. Press and release the Mode button. The Mode LED indicator will blink from green to blue, indicating that WIFI mode has switched from AP to Client. 3. The setting will be valid if the Mode button is not pressed again for seven seconds.
Off		• Detector is OFF • Client connection is not built

Install the Detector Battery Charger

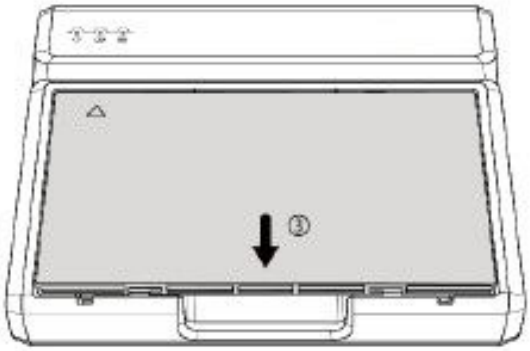
1. Remove the battery from the battery charger.



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



3. Press the battery down into the battery compartment.



Detector Battery Activation

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

Exit Ship Mode

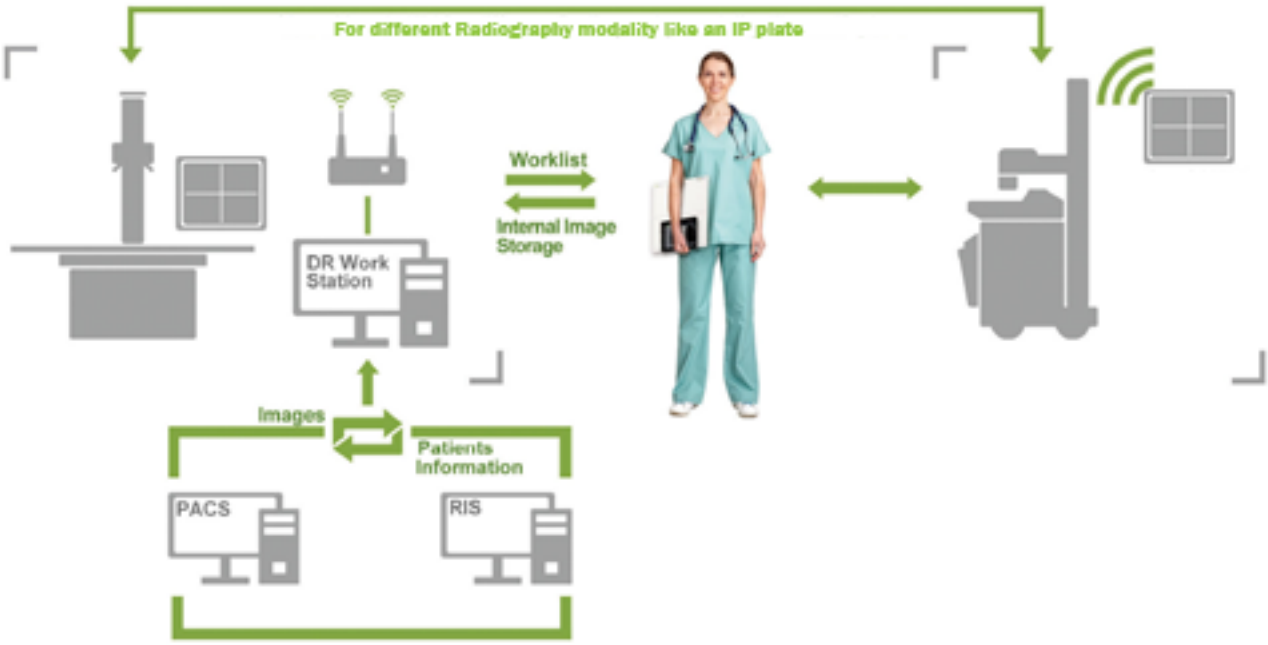
Method	Steps
Charger	1. Power on the charger. 2. Insert the battery into the charger for 3 to 5 seconds to exit ship mode.

3 Overview

The Focus HD 43 is a cassette-size, wireless, digital, X-ray flat panel detector based on amorphous silicon thin-film transistor technologies. It is developed to provide the good quality of radiographic image, which contains an active matrix of 4267 × 4267 with 100 µm pixel pitch. The scintillator of Focus HD 43 is CsI (Caesium Iodide) which is direct deposit.

Scope

This manual contains information about the Focus HD 43. 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

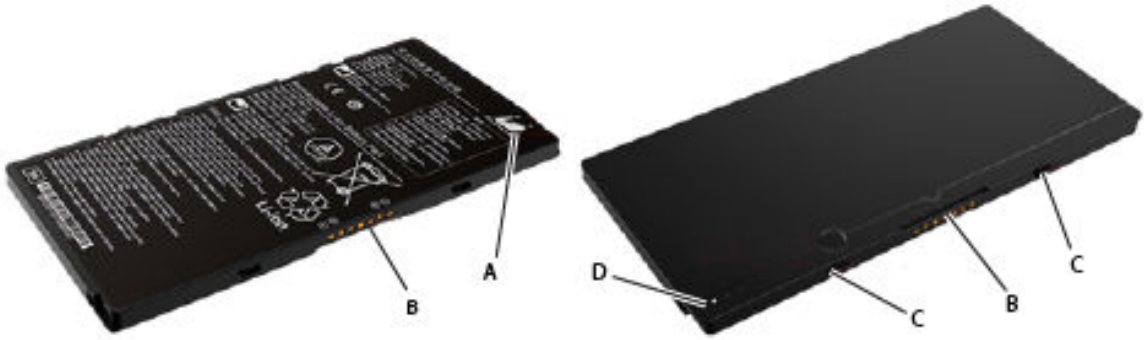
Product Components

Component Description

Detector

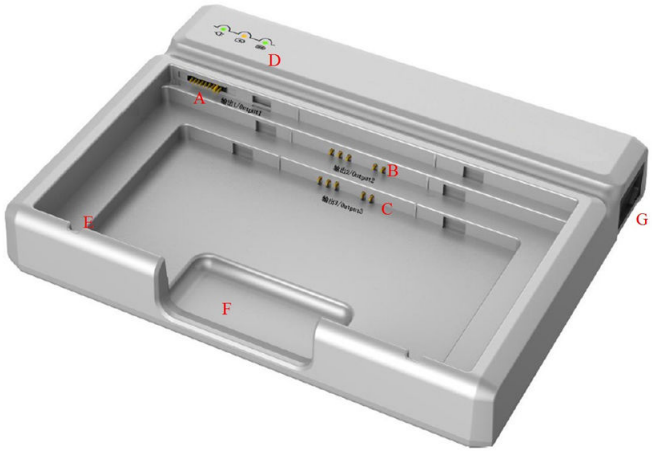
Item	Description	Notes
1	DC input interface	
2	Mode button	
3	Detector status indicator	
4	Mode indicator	
5	Link indicator	
6	Power level indicator	
7	Power button	

Battery



Item	Description
A	Battery label
B	Battery interface
C	Guide block
D	Touch display

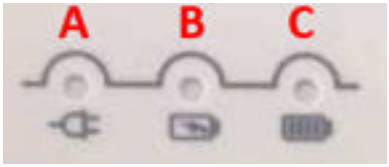
Battery Charger



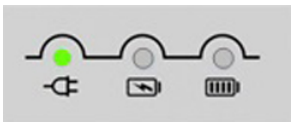
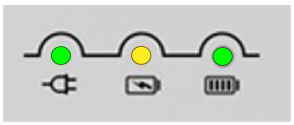
Item	Description	Notes
A	Battery Interface A	8 pin battery connector for Focus 43C
B	Battery Interface B	7 pin battery connector for Focus HD 43

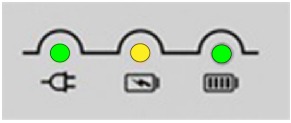
Item	Description	Notes
C	Battery Interface C	Not used
D	Indicator	The indicator definition is as follow
E	The limit ball plug	/
F	Hand Pull Position	/
G	AC Jack	220 V (ac) input

Battery Charger Indicator



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

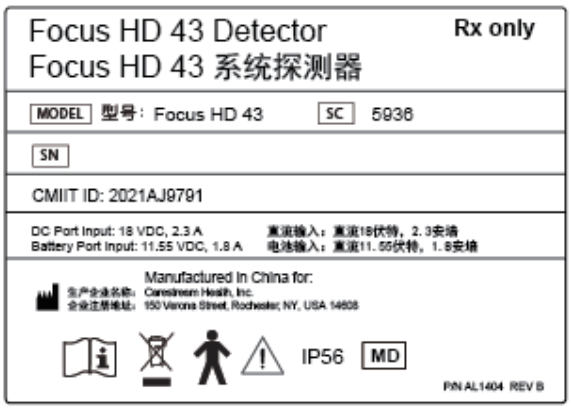
X Indicator		Operating Status
All off		No power input
A indicator on		• AC power input • Multiple batteries inserted
A indicator on B and C alternately blink 2 times		Battery insertion self test
A and B indicator on		Battery charging

X Indicator		Operating Status
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

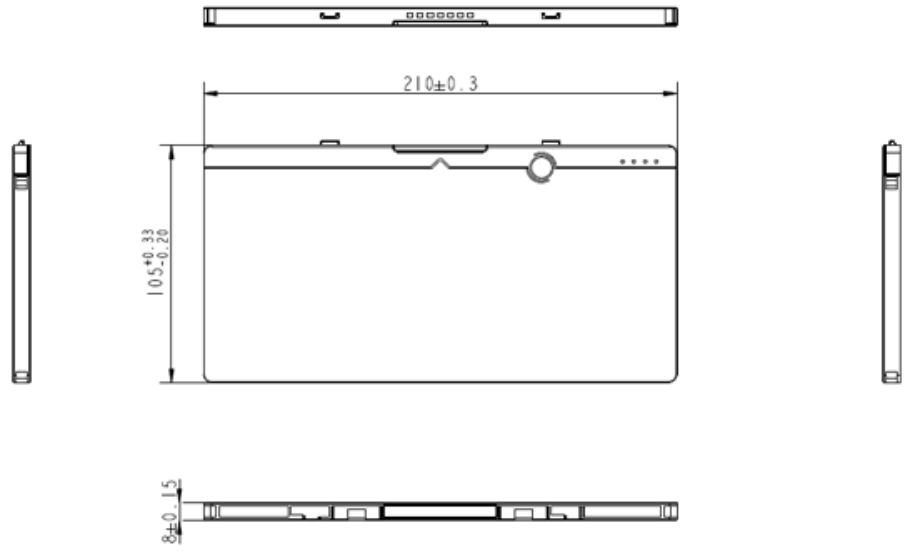
Detector



Item	Specifications
Model	Focus HD 43
Image Sensor	a-Si (amorphous silicon) TFT
Scintillator	Csi
Pixel Size	100 µm
Fill Factor	60%
Active Array	4267 x 4267
Active Area (H x V)	426.7 x 426.7 mm (16.8 x 16.8 in.)

Item	Specifications
Image Transfer	WiFi Wireless : IEEE802.11 a/b/g/n/ac
Power Consumption	Max. 42 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)	3.5 kg (7.7 lb)
Panel Protection	IP56
Trigger Mode	Software/AED

Battery



Item	Specifications
Model	Battery-KX
Rated capacity	Min. 4700mAh, Typ. 4900mAh @ Discharge 0.2C
Nominal voltage	11.55 V
Charge voltage	13.2 V
Discharged end voltage	9 V

Item	Specifications
Charging method	CC-CV
Operating temperature	Charge 0–60 °C (32–140 °F) Discharge -10–60 °C (14–140 °F)
Storage temperature	1 month -20 °- +50 ° (-4–122 °F) ≤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 105.0 x 8.0 mm (8.3 x 4.1 x 0.30 in.)
Weight	0.28 kg (0.62 lb)

Battery Charger

Item	Specifications
Model	Charger-Combo
Simultaneous Charging	1 Battery Pack
Full Charging Time	≤ 4 hr
Rated Power Supply	90~264 V (ac)
Dimension (L × W × H)	240.0 x 184.0 x 41.5 mm (9.4 x 7.2 x 1.6 in.)
Weight	0.55 kg (1.2 lb)

Power Supply

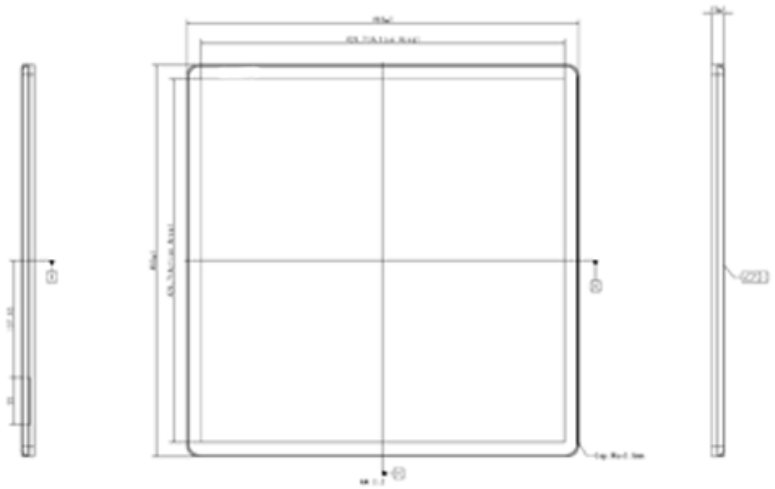
Item	Specifications
DC Power	18V (dc), 2.3A
Battery Package	11.55V (dc), 1.8A

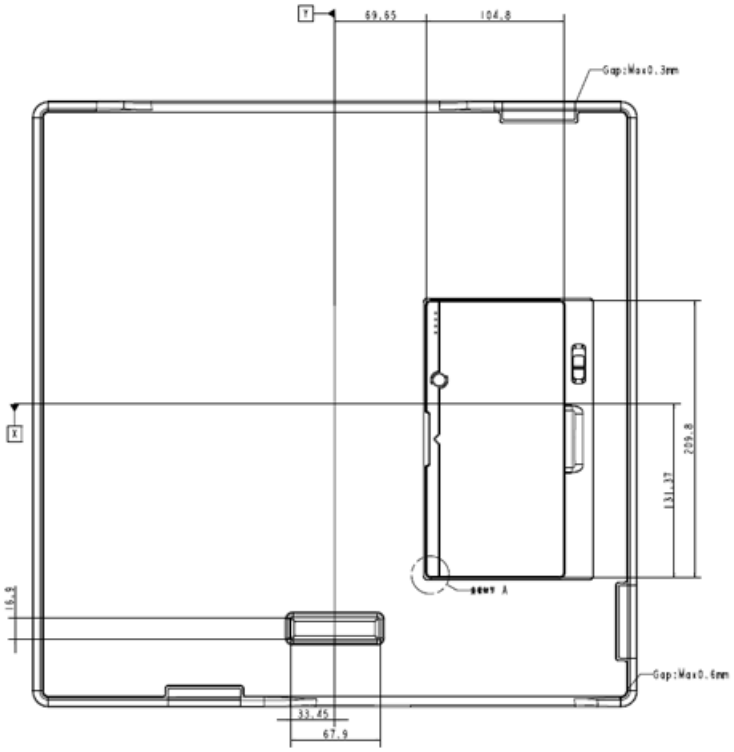
CAUTION:
The charging cable can only be used in areas not are accessible to the patient, such as in the Bucky.

Wireless Communication

Item	Specifications
Wireless Frequency Range	2.412~2.472GHz, 5.18~5.22GHz; 5.745~5.85GHz
Data Transmission Power	• 13dBm (Typ.) @802.11a • 16dBm (Typ.) @802.11b • 14dBm (Typ.) @802.11g • 13dBm (Typ.) @802.11n HT20 • 11dBm (Typ.) @802.11n HT40 • 16dBm@2.4GHz • 13dBm@5.8GHz
Wireless Modulation	• 802.11b: CCK, DQPSK, DBPSK • 802.11a/g/n: 64QAM, 16QAM, QPSK, BPSK • 802.11ac: 256QAM, 64QAM, 16QAM, QPSK, BPSK
Wireless Band	• 2.4 GHz ≤ 40 MHz • 5.1 GHz ≤ 80 MHz • 5.8 GHz ≤ 80 MHz
Data Transmission Rate (Wireless)	• 802.11b: max. 11 Mbps • 802.11a/g: Max. 54 Mbps • 802.11n: Max. 300 Mbps (MMO 2 x 2) • 802.11ac: Max. 867 Mbps (MMO 2 x 2)
X-ray Energy	40 - 150 kV
Panel Protection	IP56
SID	90.0 - 180.0 cm (35.4 - 80.0 in.)

Mechanical Outlines





Use Environment

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

Focus HD 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.

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.

FCC Regulations:

Contains 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.

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.

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 general public 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.

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.

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.

Contains 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. The SAR limit is 1.6 W/kg by Industry

Canada. This equipment should be installed and operated with minimum distance of 0 mm

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.

Remarque IC

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.

Contient 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.La limite DAS est de

1,6W/kg par Industrie Canada. Cet appareil devrait être installé et utilisé en respectant une distance minimale de 0 mm 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.

Publication History

Version	Date	Changes
A	2021-07-08	First release
B	2021-09-21	Updated: • Medical Equipment Classification • Radio Frequency Compliance • Cautions • Product Specifications

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Made in China for Carestream Health, Inc.

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"Rx only"