Carestream

User Guide for the Lux HD 43 Detector

Publication No. AP3375

2024-08-27

Supersedes:

2024-08-03

Notices and Conventions

Notices and Conventions

The information herein is based on the experience and knowledge relating to the subject matter gained by Carestream Health, Inc. prior to publication. No patent license is granted by this information.

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.

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.

Contents

1 Safety and Regulatory Information

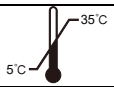
CAUTION:

- For continued safe use of this equipment, follow the instructions contained in this operating manual.
- Study this manual carefully before using the equipment and keep it at hand for quick reference.
- The manufacturer assumes no liability from problems that occur when you do not follow the cautions in this manual.

Safety Symbols

The following symbols may be used for marking on this equipment:

Symbol	Explanation
	This side up
	Fragile, handle with care
	Keep dry
	Stacking limit by number
	Temperature limits
	Humidity limits
	Keep away from direct sunlight
	Manufacturer: this symbol is accompanied by the name and address of the manufacturer
EC REP	Manufacturer's authorized representative in the European community
MD	Indicates this product is a medical device
UDI	Unique Device Identification

Symbol	Explanation
	Caution! Consult accompanying documents
	Consult instructions for use
	This symbol indicates that this device must be sent to separate collection facilities for recovery and recycling at the end of its service life
	Non-ionized electromagnetic radiation
	Indicates the degrees of protection provided by enclosure (IP Code) against solid objects or liquids is equivalent to IP67
	Indicates the Federal Communications Commission certificate
Rx only	For prescription use only
	Indicates the country (CN refers to China) where the product is manufactured
	Model Number: Indicates the model number of the product.
	Handle with care
	Indicates the maximum allowed weight over a 4cm diameter circular area
	Operating temperature limits
	Type B applied part
	Signifies that the user manual must be read
	Direct current

Abbreviations

Abbreviation	Explanation	Abbreviation	Explanation
AC	Alternating Current	LED	Light Emitting Diode
AED	Automatic Exposure Detection	PC	Personal Computer
AP	Access Point	ROI	Range of Interest
a-Si	Amorphous Silicon	RF	Radio Frequency
CsI	Cesium Iodide	SDK	Software Development Kit

Abbreviation	Explanation	Abbreviation	Explanation
DC	Direct Current	SN	Serial Number
DQE	Detective Quantum Efficiency	SID	Source Image Distance
DR	Digital radiography	SNR	Signal to Noise Ratio
EMC	Electro Magnetic Compatibility	MTF	Modulation Transfer Function
EMI	Electromagnetic Interference	SSID	Service Set Identifier
GigE	Gigabit Ethernet	TFT	Thin Film Transistor
FPD	Flat Panel Detector	UI	User Interface
IP	Internet Protocol	UPS	Uninterrupted Power Supply
HVG	High Voltage Generator	WL	Window Level
LAN	Local Area Network	WW	Window Width

Medical Equipment Classification

Lux HD 35 Detector

Important:

This device is a patient contact equipment and is a Type B applied part.

Type of protection against electrical shock:	Internally powered
Degree of protection against electrical shock:	Type B applied part
Degree of protection against ingress of foreign material:	**IP67** (Detector only without battery) For improved cleaning performance, the detector provides an IP67 rating. Refer to the Procedure to Clean the Detector and the Procedure to Clean the Battery Well. The Detector IP67 rating does not apply when the battery is installed.
Mode of operation:	Continuous operation
Data transmission	Wired and Wireless transmission
Flammable anesthetics:	Not suitable for use in the presence of flammable anesthetics or a mixture of flammable anesthetics with air or oxygen or nitrous oxide.

Product Safety Standards

ANSI/AAMI/IEC 60601-1-2:2014/A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-2:2014/AMD1:2020	
ES60601-1:2005/AMD2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1:2005/AMD2:2020	
IEC 60601-2-54:2022	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
IEC TS 60601-4-2:2024	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
ANSI C63.27-2021	American National Standard For Evaluation Of Wireless Coexistence
IEC 62133-2:2017	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 - 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.6/Amend.1 Section 38.3

Precautions

WARNING:

To avoid electromagnetic interference do not operate the device in close proximity to other electronic devices.

WARNING:

Use of accessories, transducers and cables other that those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Technical Description of the Lux HD 43 Detector

The Lux HD 43 detector is considered group 1, Class A for conducted and radiated emissions according to CISPR 11.

Note:

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals. If it is used in a residential environment (for which CISPR class B is normally required) this equipment might not offer adequate protection to radio-frequent communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Basic safety must be maintained by keeping cabinetry and shielding intact as delivered and following the safety and EMC instructions in this guide.

FCC Notice (United States)

This equipment complies with part 15 of the FCC Rules. Operation of the device is subject to the following two conditions:

1. This equipment may not cause harmful interference.
2. This equipment 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 A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy. If it is not installed and used in accordance with the instruction manual, it may cause harmful interference to radio communications.

Operation of this equipment in a residential area is likely to cause harmful interference, in which case the users will be required to correct the interference at their own expense.

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

 **CAUTION:**

This is a Class A product. In a domestic environment, this product may cause radio interference, in which case the user may be required to take adequate measures.

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 incompliance 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.

ISED Notice

This device complies with Innovation, Science and Economic Development 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.

5150-5250MHz is in door use only.

ISED 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 IEC/IEEE 62209-1528: 2020. 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 unfonctionnement non souhaité.
Cet appareil de classe B est conforme à la norme canadienne ICES-003.
5150-5250MHz est dans l’usage de porte seulement.

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 IEC/IEEE 62209-1528: 2020.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.

Indications for Use/Intended Use

Lux HD 43 Detector and Lux HD 35 Detector 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. Lux HD 43 Detector and Lux HD 43 Detector are not intended for mammography or dental applications.

Intended User

The intended users are properly trained doctors, radiographers, or radiologic technologists.

Contraindications

None known.

Intended Target Groups

All patients who require DR X-ray scanning.

Intended medical conditions:

This device is intended for use on patients who require DR X-ray scanning.

Essential Performance

According to its intended use and results of risk management, essential performance is identified and described as:

In case the detector has no response to orders or loss of communication, the detector can be in normal operation state by software re-connection.

Guidance and Manufacturer's Declaration for EMC

Important Information Regarding Electromagnetic Compatibility (EMC)

Lux HD 43 needs special precautions regarding EMC and needs to be installed only by Carestream or authorization engineers and put into service according to the EMC information provided in the user manual.

This equipment 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 use of accessories and cables other than those specified by Carestream, with the exception of accessories and cables sold by Carestream of Lux HD 43 as replacement parts for internal components, may result in increased emissions or decreased immunity of the detector.

Lux HD 43 should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the detector should be observed to verify normal operation in the configuration in which it will be used.

Electromagnetic Emissions

The equipment is intended for use in the electromagnetic environment specified

below. The customer or user of the equipment should ensure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment-Guide
Conducted and radiated RF emissions CISPR 11	Group 1 Class A	The equipment is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic distortion IEC 61000-3-2	Compliant	
Voltage fluctuations/flicker IEC 61000-3-3	Compliant	

EMS Compliance Table

Enclosure Port

Phenomenon	Basic EMC Standard	Immunity Test Levels
		Professional Healthcare Facility Environment
Electrostatic Discharge	IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table “Proximity Fields from RF Wireless Communications Equipment”
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Proximity Fields from RF Wireless Communications Equipment

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

Proximity Magnetic Fields

Test Frequency	Modulation	Immunity Test Level (A/m)
30 kHz	CW	8
134.2 kHz	Pulse modulation 2.1 kHz	65
13.56 MHz	Pulse modulation 50 kHz	7.5

Input A.C. Power Port

Phenomenon	Basic EMC Standard	Immunity Test Levels
		Professional Healthcare Facility Environment
Electrical fast transients/burst	IEC 61000-4-4	±2kV 100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±0.5kV, ±1kV
Surges Line-to-ground	IEC 61000-4-5	±0.5kV, ±1kV, ±2kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V 0.15MHz - 80MHz 6V in ISM bands between 0.15MHz and 80MHz 80% AM at 1kHz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle At 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º
		0% U_T; 1 cycle 70% U_T; 25/30 cycles Single phase: at 0º
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 cycles

Signal Input/Output Parts Port

Phenomenon	Basic EMC Standard	Immunity Test Levels
		Professional Healthcare Facility Environment
Electrostatic discharge	IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Electrical fast transients/bursts	IEC 61000-4-4	±1kV 100kHz repetition frequency

Phenomenon	Basic EMC Standard	Immunity Test Levels
		Professional Healthcare Facility Environment
Surges Line-to-ground	IEC 61000-4-5	±2kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V 0.15MHz - 80MHz 6V in ISM bands between 0.15MHz and 80MHz 80% AM at 1kHz

Cable Information Provided Against EMC

Cable	Recommended Cable Length	Shielded/unshielded	Qty.	Classification
DC power cable	3m	Shielded	1pc.	DC power

Radio Frequency (RF) Compliance Information

Nation	Standard
U.S.A	47 CFR part 15, subpart B 47 CFR part 15, subpart C 15.247 47 CFR part 15, subpart E 15.407 KDB447498 D01 v06 General Exposure Guidance

Interference may occur in the vicinity of equipment marked with the following symbol:

2 Detector Operation

A detector can be used with analog or digital systems to capture images digitally.

The detector translates into a digital format the X-ray energy absorbed during an X-ray exposure.

Software corrects the digital image for display on the Console.

CAUTION:

Patient movement could impact image acquisition while the detector is in Beam Detect Mode. Perform all patient positioning and wait for the patient to stabilize before activating beam detect on the detector.

Features

- **Portable X-ray receptor**—Used on a table, behind a patient in a bed or wheelchair, in a table, or a wall-mounted Bucky
- **Wireless or Tethered transmission**—These detectors transmit images wirelessly, powered by a battery, or via an optional tether
- **Removable Battery**

General Product Information

Lux HD 43 detectors absorb, measure, and translate into digital electronic format the X- ray energy imparted on internal sensors during the course of an X-ray exposure.

Lux HD 43 detectors are patient contact equipment and are a Type B applied part. Detector communications may be wireless via internal radio or it may be wired via a tether interface device. Control and image processing software resides in a separately approved detector interface/support device. Communication with the detector is via above described wireless or tether. Examples of detector interface/support devices include, but are not limited to: DRX-1 System, DRX-Revolution and DRX-Evolution.

Patient Contact Considerations

Detectors do not transfer energy to the patient. There is no patient circuit. However, radiographers may wish to place the detector indirect patient physical contact to minimize image artifacts in certain exams. Lux HD 43 detectors may be used as applied parts when internally powered or when receiving supplemental power only from a tether device with the round, plastic tether interface connector.

 **CAUTION:**

To reduce the effects of backscatter, employ proper collimation techniques and utilize a radiation barrier placed behind the detector.

Lifetime

The Lux HD 43 detector has an expected life of 10 years based on an average usage of

56000 exposures per year.

Recommended Separation Distance

 **WARNING:**

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30.0 cm (12.0 in.) to any part of the Lux HD 43 detector including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment may occur.

Cautions

CAUTION:

Product Disposal

This symbol indicates that this product and its battery should not be disposed of with your domestic or commercial waste. Disposal of this product in an unlawful manner may have a negative impact on health and the environment.

When disposing of the product, be sure to follow the procedure that conforms to the laws and regulations in your area.

Disposal of Biomedical Waste

Dispose of medical waste (disinfection wipes, disposable medical gloves, etc.) following the normal medical waste treatment procedures for biomedical waste. Improper disposal of those can lead to the spread of illness and disease.

- 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 enclosure.
- Do not expose the equipment to liquid.
- Perform periodic maintenance to ensure continued safe use of the equipment.
- Refer to the *IMAGEVIEW System Software Online Help* for procedures on detector calibration.
- The equipment must be repaired only by authorized Service personnel.
- The detector must be handled with care. Dropping the detector may damage internal
- components impacting image quality. If there is any indication of reduced image quality, perform a detector calibration.
- Any attempt to open the detector by unauthorized personnel will void the warranty.

- When a detector is used outside of the Bucky, it should be placed in a protective sleeve or bag which is disposed of after each patient exam.
- Change the detector battery outside the patient vicinity.
- If the device fails to achieve its intended use, please contact Carestream service. Images can be extracted through maintenance procedures.

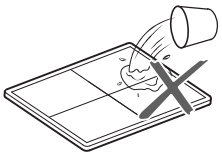
Installation Precautions

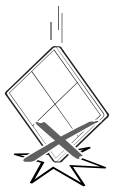
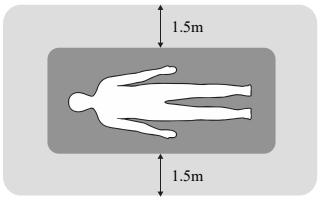
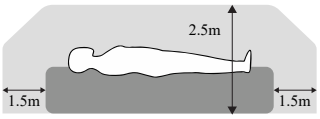
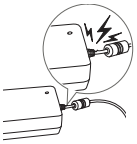
Safety Standards Reference

The safety standards listed below apply to the product and its accessories.

	• **Integration of this system should be conducted by trained and authorized personnel.**
	• **After the system integration, it is necessary to verify that the system is installed correctly as described in this manual, and then implement the clinical test of the whole system to ensure the safety and optimal use of the system.**
	• **All X-ray sources and controls, shielding, personal safety monitoring, personnel safety precautions, and training involved in the use of the device are the responsibility of the system integrator and/or the end user.**
	• **Do not install the device in or around flammable gases, gas mixtures, liquids, chemicals, or other substances.** Otherwise, it may cause explosion, fire, or electric shock, resulting in serious product damage, personal injury, or death.
	• **Do not install the system in any of the locations listed below:** 1) Close to facilities where water is used 2) Where it will be exposed to direct sunlight 3) In a poorly ventilated space 4) Close to a heat source such as a heater 5) Where the power supply is unstable 6) In a location exposed to strong magnetic fields 7) In an oxygen-rich environment 8) In a dusty environment 9) In a saline or sulfurous environment 10)Where temperature or humidity exceeds the prescribed operating environment 11)In an environment prone to freezing or condensation 12)On an unstable or vibrating surface 13)In an area with an altitude of over 3,000 meters
	• **To ensure optimal image quality, it is recommended that you avoid placing the product or its cables near devices that could produce electromagnetic interference (EMI).** All wireless devices, whether they comply with the EMC standard or not, may emit electro-magnetic interferences and cause the system to malfunction when they are used nearby.
	• **Install the device in an environment with good ventilation to ensure efficient and long-term system performance.** Overheating can cause fire or damage to the device.

Electrical Safety

CAUTION	• **The device must be used only in rooms or areas that comply with all laws and regulations for electrical safety in medical premises, where provisions for safety ground connections are present.**
CAUTION	• **Use only power sources (AC 100V~240V) specified in the detector label for use with the device.**
CAUTION	• **No modification of this device is allowed.** Ignoring this warning may result in an explosion, fire, or electric shock, which may result in personal injury, death, or substantial product damage.
CAUTION	• **Personnel not authorized by Carestream are prohibited from opening the device enclosure.**
CAUTION	• **If the ambient temperature changes drastically (rapid heating or cooling or during transportation), condensation may occur inside the device and the device must be allowed to stand at room temperature for at least 4 hours before powering on.** Otherwise, if the system is turned on with dew condensation on the detector, electric shock or device damage may occur.
CAUTION	• **To avoid the risk of electric shock, the device must be only connected to a supply mains with protective earth. Verify that all system devices are properly grounded.**
CAUTION	• **The supplied power adapter must not be used to power other devices.**
CAUTION	• **Do not connect the device to any component or accessory other than original accessories or third-party accessories expressly approved by Carestream.** Use of accessories other than those provided or approved could result in serious product damage, electric shock, or personal injury.
CAUTION	• **To protect against short-circuit and electrical shock, no liquid or metal should be allowed to leak inside this device. Do not spill liquid or chemicals onto the device.** 
CAUTION	• **Keep the device away from patient's blood, body fluids, water, etc.**
CAUTION	• **Do not use the device in a location where metal particles could come into the device.** This may cause an electrical shock.
CAUTION	• **Do not handle the device with wet hands.** Otherwise, electrical shock may occur, resulting in serious injury or death. 
	• **Before connecting the power supply, make sure that the surfaces of the device and the plug are dry.**

CAUTION	
CAUTION	• **Take special care to move the device and do not subject it to strong shocks or vibrations.** The device may be damaged due to strong shock or vibration, and continued use of the system without repair may cause fire or electric shock. 
CAUTION	• **Non-medical devices such as battery chargers, wireless routers, and infrared devices cannot be used in the patient's environment.**  Patient's vicinity 
CAUTION	• **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 of the device.
CAUTION	• **Never use the power adapter or the cables are damaged, frayed, exposed, or have broken or bent pins.** Otherwise, electrical shock may occur, resulting in serious injury or death. 
CAUTION	• **Always turn OFF the power to each piece of the device before connecting or disconnecting cables and accessories.**
CAUTION	• **Securely plug the three-core AC plug into the AC outlet to avoid a contact failure.** If contact failure occurs, or if dust or metal objects come into contact with the exposed metal prongs of the plug, fire or electrical shock may occur.
CAUTION	• **Do not connect multiple portable socket outlets or extension cords to the system.**
CAUTION	• **Do not supply power to more than one piece of device using the same AC outlet.**
CAUTION	• **For safety, the power cable should be unplugged from the AC outlet and the battery pack should be removed when the device is not in use for an extended time.**
CAUTION	• **Do not modify a cable or subject the cable to external stress or damage. Avoid placing anything heavy on the cable, stepping on the cable, pulling the cable, or subjecting the cable to excessive bending or bundling.**

 CAUTION	• **Disconnect the cable by pulling on the connector or the plug, not the cable itself.**
 CAUTION	• **To prevent possible electric shock, do not attempt to insert fingers or other foreign objects into the interfaces of the detector.**
 CAUTION	• **To make it easy to disconnect the AC plug at any time in an emergency, keep the power socket where the power cable is connected unobstructed.** Otherwise, it may not be possible to disconnect the plug in an emergency.
 NOTE	• **To prevent a sudden power failure and ensure the reliability of the power supply to the system, use of an external UPS is highly recommended.** Otherwise, data loss may occur if the external power supply is unstable or suddenly interrupted during system operation.

EMC safety

 CAUTION	**This equipment should only be used in conjunction with equipment that meets all requirements in the "Product Safety Standards" section to avoid unintended interference affecting the realization of the IFU/intended use**
 CAUTION	**This device can store images internally, if the images are not transferred to the computer due to unexpected interference after X-ray exposure, please contact service engineer to assist in completing the manual export of the images.** **Do not repeat X-ray exposure.**

Radiation Safety

 CAUTION	• **The detector is not designed to control X-ray doses. The system integrator is responsible for controlling the X-ray radiation.**
 CAUTION	• **Full use must be made of all radiation protection devices, and procedures available to protect the patient and operator from X-ray radiation.**

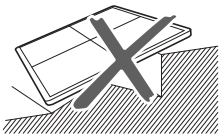
Cybersecurity

 CAUTION	• **Take special care of the following:** 1) Connection of the device to an IT network that includes other equipment could result in previously unidentified risks to patients, operators, or third parties 2) The system manufacturer should identify, analyze, evaluate, and control these risks 3) Subsequent changes to the Network could introduce new risks and require additional analysis

 CAUTION	• **When the setting of the network to which the device is connected has been changed, check that the change does not affect the system operation and take measures if necessary. The setting change may include the following:** 1) Changes in the IT-network configuration; 2) Connection of additional items to the IT-NETWORK 3) Disconnecting items from the IT-NETWORK 4) Update of equipment connected to the IT-NETWORK 5) Upgrade of equipment connected to the IT-NETWORK
 CAUTION	• **Hazardous situations resulting from the failure of the IT network:** 1) Unable to complete basic performance operations 2) Unable to complete product configuration 3) The operating system is not compatible 4) Failed to change or upgrade the software 5) Interface communication abnormal 6) Failed to respond to commands 7) Loss of data 8) Data transfer failed
 CAUTION	• **To maximize the wireless transmission performance, attention should be paid to the following aspects:** 1) Do not block the wireless module of the detector 2) Reduce the barrier between the detector and the external AP (router) 3) Select channels with less equipment connection 4) Keep the detector and router as far away as possible from strong signal interference sources such as motors and transformers 5) Place the external AP as high as possible above the detector
 CAUTION	• **Use of multiple pieces of WLAN devices that use the same channel may interfere with each wireless communication and cause a decline in transmission speed.**
 NOTE	• **It is recommended to use a dedicated computer for the system. This computer should be used only as a work tool and any software programs that are not needed should be uninstalled.**
 NOTE	• **Minimize the number of running programs before image acquisition to ensure the necessary operating system resources for the process.**
 NOTE	• **The installation of new programs on the PC and the update of the operating system may interfere with the image acquisition software. After installing new programs in the computer or updating the operating system, be sure to check the system operation before attempting to use it on a patient.**

NOTE	• **We recommend having a qualified IT security professional build up and maintain a secure network environment for proper protection against viruses, malware, and intrusions (e.g. firewall, anti-virus software).** Failure to maintain cybersecurity can result in compromised device functionality, loss of data, or exposure of other connected devices or networks to security threats.

Handling Precautions

CAUTION	• **Only doctors or legally qualified operators are allowed to use this product.**
CAUTION	• **The system must be used for the purposes and applications for which it is intended.**
CAUTION	• **All the cables must be plugged and secured during clinical use.**
CAUTION	• **When the detector is placed vertically or in any tilted position, it must be securely fastened to a support structure to prevent the product from tipping or flipping over. When placed horizontally, the surface should be flat and stable to prevent the device from bending and doing damage to the internal sensor.** Otherwise, the device may fall and/or be damaged due to unstable placement, resulting in personal injury. 
CAUTION	• **Do not expose the backside of the device with X-rays. X-ray exposure should be limited only to the active imaging area in order not to cause damage to the electronic components of the device, and cover the whole active area in order not to obtain an image with artifact.**
CAUTION	• **If the detector is not used in a Bucky, it must be enclosed in a protective plastic bag that is disposed of after each patient exam.**
CAUTION	• **Do not let the patient or object heavier than the load limit be on the detector.** Otherwise, the internal sensor may be damaged and the image quality may be degraded.
CAUTION	• **Do not unscrew or loosen the screws on the detector since all the screws are secured properly at the time of shipment.** Otherwise, it may result in poor image quality or damage to the device.
CAUTION	• **Be sure to monitor the internal temperature related to the patient's contact area to avoid any adverse effects on the patient.**
CAUTION	• **As the supplied cables are long, be careful not to entangle the cables during use, and not to be tripped over the cables.**

	• **Care should be taken when inserting and unplugging, as misinsertion, plugging at an angle, or unplugging with excessive force can lead to interface damage or even device failure.**
	• **In AED mode, exposure should result in a dose greater than 900nGy/s @80KV+90mmAl reaching the detector surface.**

Battery Pack Instructions

	• **Do not use the specific battery pack as a power source for devices other than this device.**
	• **Charge the battery pack only with the designated battery charger or power adapter.**
	• **Do not try to open the battery pack or change its internal structure. Do not insert any object into or pry open the battery pack.** Attempting to open the battery can release toxic and hazardous substances, resulting in electric shock, burns, or fire.
	• **Do not attempt to use a battery pack or battery charger that has deteriorated or expired.**
	• **If you notice an unusual odor, heat, discoloration, deformation, or other abnormality during use, charging, or storage, remove the battery from the device or battery charger, and stop using it.**
	• **To avoid short circuits of the battery:** 1）Do not place the battery pack and metal objects together 2）Do not expose the terminals to dirt or let them come into contact with metal objects. 3）Do not allow the battery pack to come into contact with water and other liquids
	• **Do not subject the battery pack and battery charger to excessive heat or severe shock.**
	• **When the detector is only powered by the battery pack, do not remove the battery directly during data transmission.**
	• **Do not subject the battery pack to strong impact or pressure.**
	• **To avoid damaging the battery connector port, special care should be taken when inserting and removing the battery pack.**
	• **Charge the battery pack in time when the battery level is less than 20% (power LED flashes orange), and stop charging when it is fully charged. Over-discharging and over-charging can shorten battery life.**
	• **The battery charger only supports the charging of a single battery pack. The battery charger will stop working when multiple batteries are inserted at the same time.**

CAUTION	• **Prior to clinical use, be sure to keep the battery pack fully locked in place after inserting it into the detector battery compartment.** Otherwise, accidental dropping of the battery may cause injury to personnel, damage to the battery, and the product not functioning as intended.
NOTE	• **If this device is not in use for a long period of time (more than 5 days), store it with the battery pack moved. Make sure to recharge it to 30%~50% every 3 months, and 50%~70% every 6 months to maintain its best performance.**
NOTE	• **The battery comes partially charged. We recommend you fully charge the battery prior to its initial use to ensure its optimal performance and longevity.**
NOTE	• **It takes approximately three hours to fully charge a battery pack. The specific charging time may vary depending on the temperature, the remaining battery level, the charging method (battery charger or power adapter), and the device status.**
NOTE	• **As a consumable part, the battery pack may have expired if it is consumed quickly after being fully charged. In this case, contact Carestream's after-sales technicians to replace the battery.**
NOTE	• **The device and charger may heat up during charging. This does not affect the device's service life or performance.**
NOTE	• **Two or more batteries cannot be charged at the same time. Charging will automatically stop if more than one battery pack is inserted.**

Calibration Precautions

CAUTION	• **To ensure optimal performance of the system, it is important to verify that the system is calibrated successfully. Do not try to use the system if the system calibration is not performed.**
CAUTION	• **The calibration result can be different by the use environment. If the calibration result is not satisfactory, contact the after-sales technicians of Carestream.**
CAUTION	• **The user is responsible for ensuring that the calibration files are created or updated when:** 1) Create offset, gain, and defect templates after system installation is completed 2) Update offset, gain, and defect templates when major changes occur in system settings hardware configuration 3) Update gain and defect templates when the X-ray source is replaced 4) Update gain and defect templates when the relative position of the detector and X-ray source changes (if the detector is dropped) 5) Update gain and defect templates at least every six(6) months

 CAUTION	• **To acquire an optimal image, before template generation, be sure that:** 1) The device is in thermal equilibrium (the cold-start device has been warmed up for about 20 minutes) 2) The active imaging area of the detector can be covered by X-rays and centered in regards to the X-ray beam 3) No object is in the field (except filter)
 CAUTION	• **Take note of the following when creating templates:** 1) There should be no detector motion 2) Keep the power supply connected 3) X-rays are required when generating the Offset template 4) No X-rays should be exposed when generating Gain and Defect templates

Handling of Device Failures and Serious Incidents

 CAUTION	• **Always be alert when operating this device. Turn off the device, unplug the adapter power cable immediately or remove the battery, and contact Carestream After-Sales Service Center or local Carestream distributor if any of the following occurs:** 1) When there is smoke, odd smell, or abnormal sound 2) When liquid has been spilled into the device or a metal object has entered the device 3) When the device has been dropped and is damaged 4) When the power plug or power cable is damaged 5) When the device cannot work properly
 CAUTION	• **Always be sure to keep checking the condition of the system and the patient to ensure they are normal during the use of the device. Any serious incident that has occurred concerning the use of the device should be reported to the local authority and the manufacturer.**

Cleaning Instructions

 CAUTION	• **Before performing the cleaning procedure, the device must always be disconnected from the power supply.**
 CAUTION	• **It is mandatory to carefully follow the disinfecting steps specified in this manual using the recommended disinfectants, in order not to damage the device.**
 CAUTION	• **Clean the plug of the power cable periodically by unplugging it from the AC outlet and remove dust and dirt from the plug, its periphery, and the AC outlet with a dry cloth.** Otherwise, accumulation of dust or dirt can lead to electric shock or reduced insulation, resulting in plug overheating or fire.

Inspection & Repair Precautions

 CAUTION	• **In the interest of the safety and health of patients, users, and other persons, inspections must be performed at scheduled intervals to ensure the operational reliability and functional safety of the device**

	• **Any repair must be performed exclusively by authorized service personnel.**
	• **Do not perform maintenance and inspection during clinical use. Be sure to turn off the power when performing the inspections indicated in this manual to avoid electrical shock.**
	• **It is recommended to perform the image quality analysis and testing on a regular basis. Contact your local distributor or Carestream if the image remains unsatisfactory after troubleshooting the possible causes.**

Pediatric Considerations

In order to help ensure that pediatric patients receive the minimum necessary amount of radiation while producing diagnostic quality images, the Lux HD 43 detector

supports pediatric imaging with IMAGEVIEW software.

When the Pediatric Support Option is enabled, a wide range of views for pediatric

imaging is supported. Pediatric imaging involves the same body parts as adults. These views provide custom technique settings based on weight and/or age using pediatric

patient sub-populations for the purpose of minimizing pediatric dose. Additionally, the system software provides detector dependent (varies based on detector type (GOS or

CsI)) exposure indicators for all views to be used by radiographers as a means of monitoring and tracking exposure levels.

Search the system Online Help system, Pediatric Support Option and IEC Exposure Indicators Overview for more information.

Further information regarding special considerations for pediatrics can be found at the following websites:

- Image Gently Campaign: http://www.imagegently.org/
- FDA's Pediatric X-ray Imaging: http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm
- Carestream's solutions for Pediatrics: http://www.carestream.com/medical/solutions/ pediatric-imaging.html

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) http://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

Change Battery

You can change the detector battery without causing the detector to reboot or lose wireless connection.

Remove the battery and replace it within 12 seconds and the detector will continue to run. If the battery is removed for more than 12 seconds, the detector will shutdown.

Note:

If left undisturbed, the detector will remain active until the battery runs out.

CAUTION:

Physically damaged batteries or battery contacts can cause the detector to overheat and should not be used. Always inspect batteries and battery contacts for physical damage prior to use.

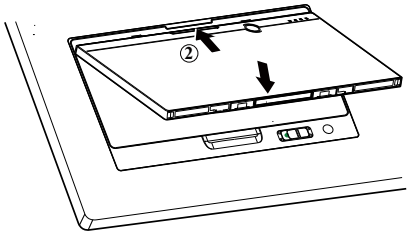
Use only compatible Carestream detector batteries and chargers.

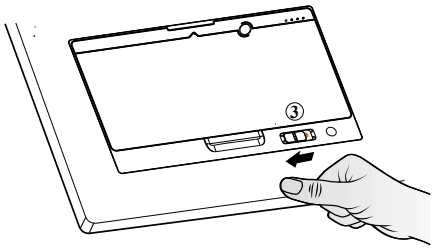
Insert the Battery Into the Detector

①. Place a fully charged battery in the battery footprint in the detector so that the contacts on the back edge of the battery are inserted first. The battery fits into the detector only one way.

②. Make sure that connectors on the battery pack are pointed to the opening in the battery compartment.

③. Slide the battery lock lever.

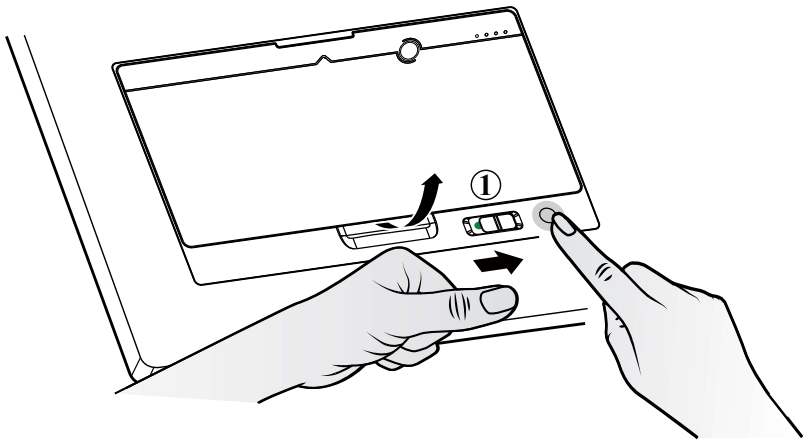




Battery Unlatch Procedure

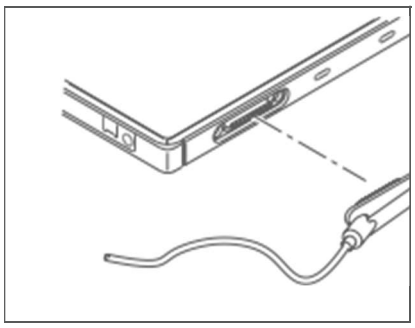
Battery unlatch procedure for the detector battery:

- Place the detector on a flat surface.
- Press button to unlock tab
- Slide the battery lock to unlock

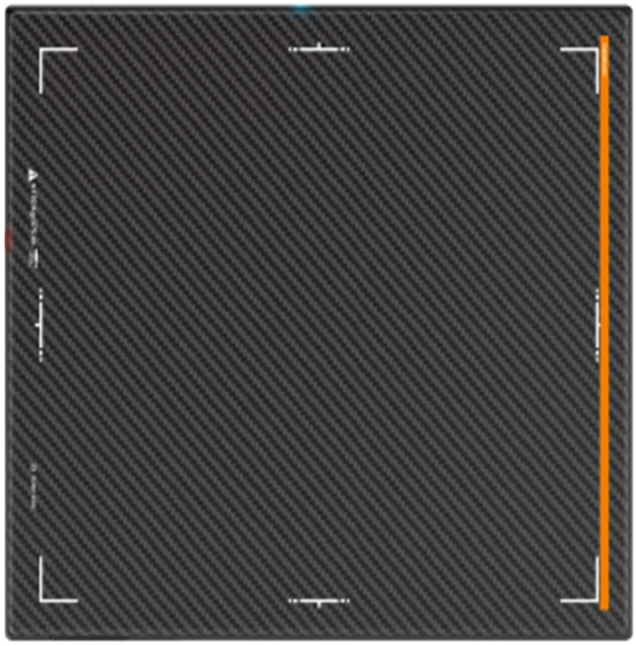


Connect a Tether to the Detector

Place the metal end of the tether on the magnetic bar on the side of the detector.



Detector Status LED(s)



The Lux HD 43 detector has a single LED that will change color and flash depending on the following conditions.

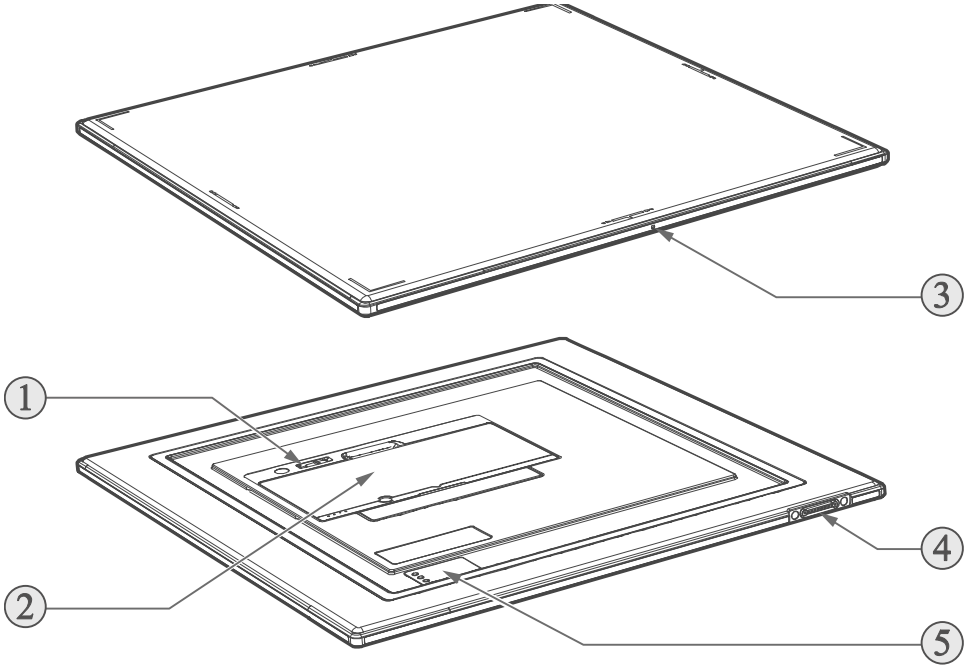
LED	Detector Status
No color	The detector is in sleep mode or off
White (flashing)	The detector is awake, but no network connection
White (solid)	The detector is awake and connected
Blue (solid)	The detector is selected
Green (solid)	The detector is in the Ready state

LED	Detector Status
Red (solid)	An error has occurred. The error can be cleared. 1. Connect to the console. 2. Remove and re-insert the battery.
Red (flashing)	An error has occurred and cannot be cleared. 1. Look up the fault code on the detector GUI display. 2. Remove and re-insert the detector battery to reboot the detector. Check fault status. 3. Call service with the fault code information.

3 Detector Overview

Component Description

Lux HD 43

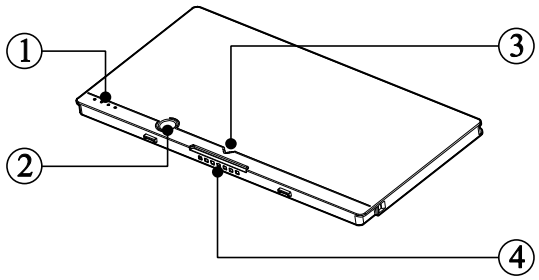


①	Battery latch
②	Battery pack
③	LED indicators
④	Power interface
⑤	User Interface

Tether Box

No.	Name	Description
①	DC connector	Connects to the DC power cable
②	AC jack	Connects the AC power cable

Battery Pack



No.	Name	Description	
①	Battery LEDs	● ○ ○ ○	Battery remaining 0%~25%
		● ● ○ ○	Battery remaining 25%~50%
		● ● ● ○	Battery remaining 50%~75%
		● ● ● ●	Battery remaining 75%~100%
②	Touch button	Touches to display the remaining battery level	
③	Battery connector port	Connects to the detector or the battery charger	
④	Insertion direction indication mark	Indicates the insertion direction of the battery pack	

Detector Connection Methods

Wired Connection

Using the wired connection, the detector transmits image data to the PC via tether cable. Compared to the wireless connection, the wired connection supplies a constant power supply and features a faster data communication rate.

Wireless Connection

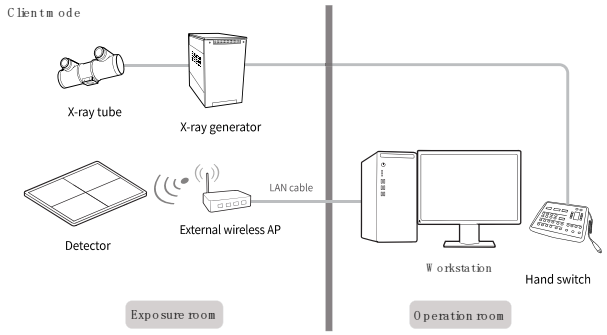
In the wireless mode, the detector and workstation transmit data and config. information through a wireless network, which is more flexible and easy to operate than a wired connection.

NOTE

In wireless modes, a fully charged battery pack must be installed to power the detector. However, if you connect a power adapter, the detector will preferentially receive power from the adapter and charge the battery pack.

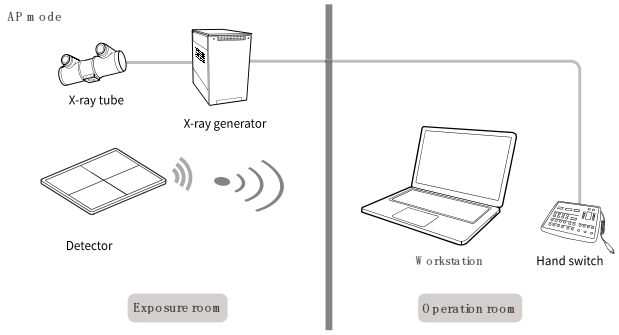
Client Mode

In this mode, an external device (such as a router) acts as an AP (wireless access point), and the connection is established between the detector (Lux HD 43) and the workstation (PC) through the wireless network of the external AP.



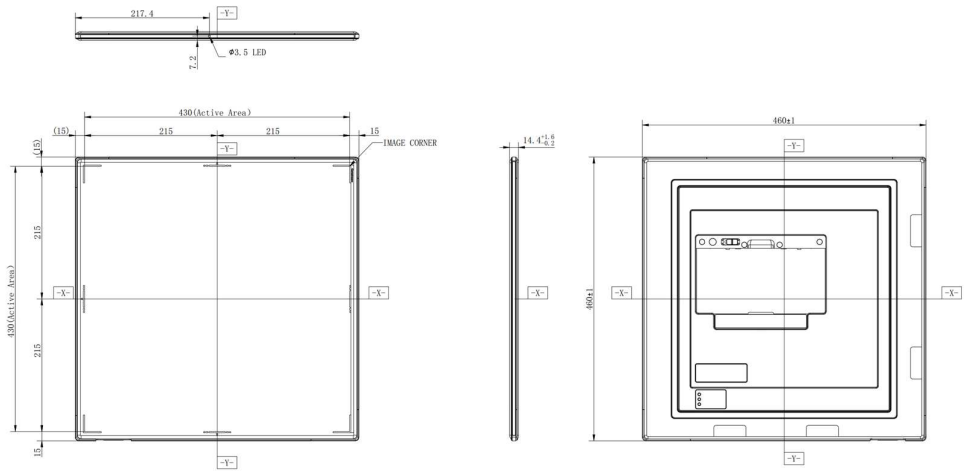
AP Mode

In this mode, the detector (Lux HD 35) itself acts as an AP transmitting a wireless hotspot, and the connection is established between the detector (Lux HD 35) and the workstation (PC) through the wireless network of the detector AP.



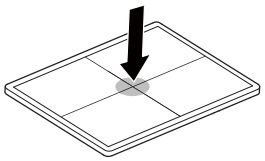
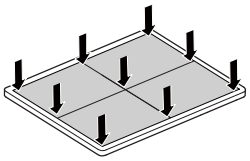
Specifications

Drawing



Specifications

Item	Specification
Model	Lux HD 43
Application	General radiography / Tomosynthesis / Fluoroscopy
Scintillator	CsI
Sensor type	a-Si TFT
Pixel pitch	100μm
Active area	426.7mm×426.7mm
Effective pixel matrix	4267×4267 pixels
A/D conversion	16 bits
Preview image time	＜2s (exposure window time not included)
Full image time	＜5.5s (exposure window time not included)
Cycle time	＜8s
Spatial Resolution	＞4.3 lp/mm
Trigger mode	Software/AED
Battery autonomy	6.7 hours (image acquisition every 48 seconds)
Wireless communications	IEEE802.11a/b/g/n/ac/ax(2.5GHz/5GHz) protocol
Communication interface	GbE/Wi-Fi
Network ports	Used for Ethernet communication and data transfer (28000/28001/27999)
Internal image storage	500 full images

Item	Specification
Wireless mode	AP/Client
Data transmission rate	802.11b: 1, 2, 5.5 and 11Mbps 802.11a/g: 6, 9, 12, 18, 24, 36, 48 and 54 Mbps 802.11n: MCS0~15, up to 300Mbps 802.11ac: MCS0~9, Nss=2, BW=80MHz up to 866.7Mbps 802.11ax: MCS0~11, Nss=2, BW=40MHz up to 573.5Mbps 802.11ax: MCS0~11, Nss=2, BW=80MHz up to 1201Mbps
Load limit	 **Local load**: 150kg@ ϕ 40mm  **Uniform load:** 300kg @active area overall
Rated power supply	External power supply (adapter): 18V (DC), 1.75A Internal power supply (battery): 11.55V (DC), 1.8A
Ingress Protection	IP67
Dimensions (W×H×D)	460mm×460mm×14.4mm
Weight	2.6kg (without battery)

Recommended Environmental Conditions

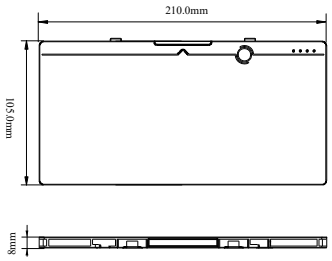
The device must be transported, stored, and operated in permissible environmental conditions, as stated below:

Item	Operation	Storage & Transportation
Ambient temperature	5~35℃	-10℃~60℃
Relative humidity	5%~90%RH (non-condensing)	10%~95%RH (non-condensing)
Atmospheric pressure	700~1060mbar	700~1060mbar
Altitude	Max. altitude 3000m	/

Power Adapter

Item	Specification
Model	DRX-TPC1
Input	100~240V 50Hz/60Hz AC input
Output	18V single output, 18W

Battery Pack

Item	Specification
Model	Battery-KX
Rated capacity	Typ.4900mAh @ Discharge 0.2C
Nominal voltage	11.55V
Nominal voltage	13.2V
Discharged end voltage	9V
Charging method	CC-CV
Operation temperature	Charge 0℃~60℃ Discharge -10℃~60℃
Storage temperature	-20℃~45℃ (less than 3 months) -20℃~35℃ (less than 6 months)
Operation humidity	5%~90%RH
Storage humidity	5%~95%RH
Dimensions (W×H×D)	210.0mm×105.0mm×8mm 
Weight	0.28kg

Wireless Connection

Item	Specification
Wireless standard	IEEE 802.11a/b/g/n/ac/ax
Frequency range	2.400 GHz ~ 2.497 GHz (2.4 GHz) 5.1 GHz~5.9 GHz (5 GHz)
Data transmission rate	802.11b: 1, 2, 5.5 and 11Mbps 802.11a/g: 6, 9, 12, 18, 24, 36, 48 and 54 Mbps 802.11n: MCS0~15, up to 300Mbps 802.11ac: MCS0~9, Nss=2, BW=80MHz up to 866.7Mbps 802.11ax: MCS0~11, Nss=2, BW=40MHz up to 573.5Mbps 802.11ax: MCS0~11, Nss=2, BW=80MHz up to 1201Mbps
Modulation	802.11a/g: DQPSK, DBPSK, CCK 802.11b: OFDM /64QAM,16QAM, QPSK, BPSK 802.11n HT20: BPSK, QPSK, 16QAM, 64QAM and OFDM 802.11n HT40: BPSK, QPSK, 16QAM, 64QAM and OFDM 802.11ac：BPSK, QPSK, 16QAM, 64QAM ,256QAM and OFDM

Item	Specification
	802.11ax：BPSK, QPSK, 16QAM, 64QAM, 256QAM, 1024QAM and OFDM
Transmission power	802.11b /11Mbps: 17dBm(50mW) 802.11a/g /54Mbps: 15dBm(32mW) 802.11n HT20 /MCS7: 16dBm(40mW) 802.11n HT40 /MCS7: 16dBm(40mW) 802.11n AC80 /MCS9: 16dBm(40mW) 802.11n AX80 /MCS11: 14dBm(26mW)
Security	WPA, WPA-PSK, WPA2, WPA2-PSK, WPA3-PSK, WEP 64bit & 128bit
Antenna	Dual-band antennas (2pcs)

IT Network

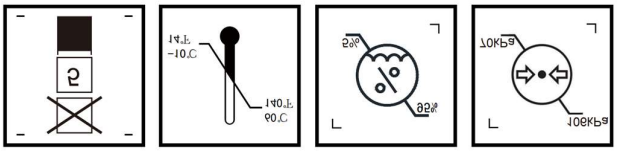
Item	Description
Purpose for IT-network	Transmits image data, commands, and status commands between detector and workstation
Required characteristics	Follows IEEE 802.11a/b/g/n/ac/ax protocol when connecting wirelessly Supports 2.4GHz and 5GHz (recommended)
Required configuration	The wireless NIC and the detector must work on the same IP segment such as 10.0.1.XXX, and support IEEE 802.11a/b/g/n/ac/ax protocol
Intended information flow	The detector sends the acquired image data to the workstation, and the workstation sends the user's commands to the detector
Wireless standard	IEEE 802.11a/b/g/n/ac/ax
Frequency range	2.400 GHz ~ 2.497 GHz (2.4 GHz) 5.1 GHz~5.9 GHz (5 GHz)
Data transmission rate	802.11b: 1, 2, 5.5 and 11Mbps 802.11a/g: 6, 9, 12, 18, 24, 36, 48 and 54 Mbps 802.11n: MCS0~15, up to 300Mbps 802.11ac: MCS0~9, Nss=2, BW=80MHz up to 866.7Mbps 802.11ax: MCS0~11, Nss=2, BW=40MHz up to 573.5Mbps 802.11ax: MCS0~11, Nss=2, BW=80MHz up to 1201Mbps
Modulation	802.11a/g: DQPSK, DBPSK, CCK 802.11b: OFDM /64QAM,16QAM, QPSK, BPSK 802.11n HT20: BPSK, QPSK, 16QAM, 64QAM and OFDM 802.11n HT40: BPSK, QPSK, 16QAM, 64QAM and OFDM 802.11ac：BPSK, QPSK, 16QAM, 64QAM ,256QAM and OFDM 802.11ax：BPSK, QPSK, 16QAM, 64QAM, 256QAM, 1024QAM and OFDM
Occupied bandwidth	2.4GHz≤40MHz; 5.1GHz≤80MHz; 5.8GHz≤80MHz
Transmission power	802.11b /11Mbps: 17dBm(50mW) 802.11a/g /54Mbps: 15dBm(32mW) 802.11n HT20 /MCS7: 16dBm(40mW)

Item	Description
	802.11n HT40 /MCS7: 16dBm(40mW) 802.11n AC80 /MCS9: 16dBm(40mW) 802.11n AX80 /MCS11: 14dBm(26mW)
Security	WPA, WPA-PSK, WPA2, WPA2-PSK, WPA3-PSK, WEP 64bit & 128bit

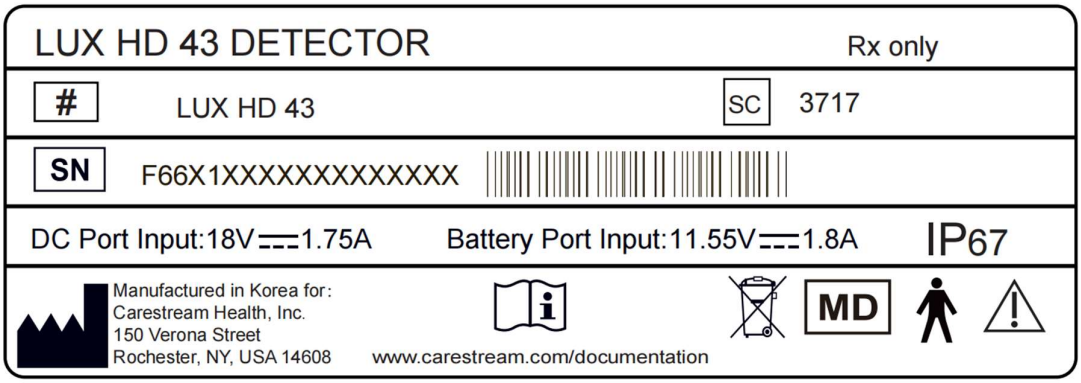
Label Description

All labels shown below are for description and explanation only. The actual labels may vary due to product enhancement.

Packaging Box



Lux HD 43



Battery Pack

NOTE

Take special care not to stain, damage, or remove the labels attached to the device and its accessories, as this may affect the warranty service.

4 Service Information

This chapter presents the service information, including service life, a checklist of the periodic inspection and maintenance, as well as the contact information of the Carestream after-sales service department.

Service Life

The service life of the Lux HD 35 is expected to be up to 10 years under proper regular inspection and maintenance.

NOTE

Refer to the physical labels for the specific date of manufacture and use-by date.

The whole product life cycle is subject to that of the detector. For other replaceable parts, their replacement will not affect the whole product life, even if their service life is shorter than that of the detector.

The main parts required to maintain the functioning of this product will be stocked for 5 years after the termination of production to prepare materials for repair.

Regular Inspection and Maintenance

- Lithium coin batteries on the PCB in the detector intended to be changed only by service personnel
- Not serviced or maintained while in use with the patient
- In order to ensure the safety of patients, operating personnel, and third parties, and to maintain the performance of the device, be sure to perform the regular inspection as listed below:

Stage	Check Item	Operation
Before startup	Detector	Ensure the detector is not damaged, screws are not loose, the surface is clean and dry, and no dust and impurities are attached to the interfaces
	Cables	Ensure cables are not damaged or torn
		Ensure all cable connectors and interfaces are securely connected
	Battery	Ensure the battery pack is not damaged or swollen, and no dust and impurities are attached to the battery pins
		Ensure the battery is fully charged
		Ensure the battery lever is fully locked after insertion
During operation	LEDs	Ensure the LEDs light up properly
	Preheating	Ensure that the device is in thermal balance before making the calibration templates or performing acquisition (preheat for at least 20 minutes)
	Connection	Check the Link and Mode LEDs to ensure that the current wired or wireless communication is normal
	Temperature	Monitor the internal temperature related to the patient's contact area
	Power supply	Check the power LED to ensure that the battery is sufficient or an external power supply is stable

Stage	Check Item	Operation
After shutdown	LEDs	Ensure the device is turned off normally and all LEDs are off
	Cleaning and dis-infection	Ensure the patient's contact surfaces are properly clean and disinfected
Monthly	Exposure conditions	Ensure the exposure conditions (ray source, high voltage generator, SID, etc.) are normal
	Cleaning	Ensure there is no dust accumulated on the plugs, interfaces, or connectors
	Resolution	Performs a performance test using a resolution test card or resolution map
Yearly	Battery	Check the battery life. If the battery consumes too fast, replace the battery in time
	Bad points Dark state noise Image uniformity	Uses system checker
	Linear	Examines the image gray value to evaluate linear
Irregular	Calibration	The detector must be calibrated for its initial use, every following six-month interval or when the exposure conditions change

Cleaning

After the device is used, perform the following steps to clean it:

① Put on single-use PPE gloves;

② Open the package lid, pull out a wipe through an opening, and close the lid to retain moisture;

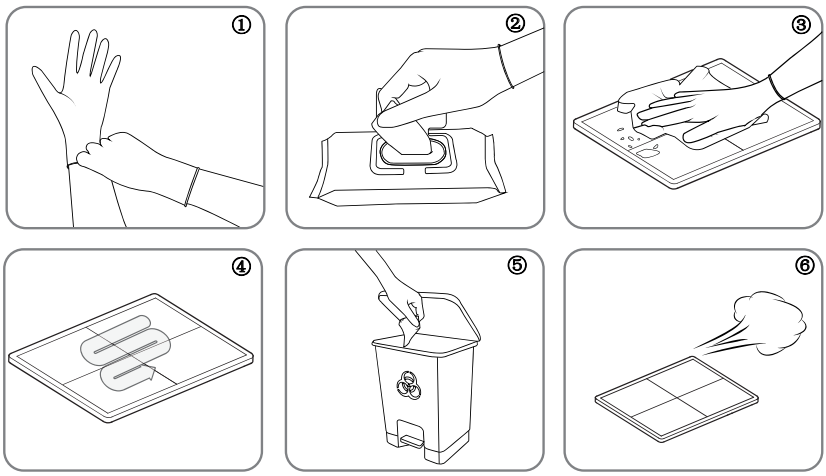
③ If present, remove visible soil prior to cleaning;

④ Clean all sides of the patient's contact surface from top to bottom in an “S” shaped pattern using as many wipes as needed, and keep the surface wet for two minutes. If needed, place a wipe over a plastic card to clean grooves or gaps that may not easily be accessed;

⑤ After cleaning, dispose of the used wipes and gloves into the medical waste bin;

⑥ Let the surface air dry.

⑦ Once the flat surface is free of visible dust and stains, you can conclude the cleaning process.



CAUTION	Before cleaning, ensure that the device is powered off, all cables and battery packs are removed.

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

CARESTREAM is a trademark of Carestream Health. Pub. No. TBD

Rev. A

" Rx only"