Carestream

CARESTREAM DRX-1 System User Guide

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CARESTREAM DRX-1 System

Publication Number AA5219

Revision A

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Document Conventions

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 procedures that you must follow precisely to avoid damage to the system or any of its components, yourself or others, loss of data, or corruption of files in software applications.

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Contents

1 Safety and Regulatory Information

This document applies to the CARESTREAM DRX-1 System. Unless otherwise specified, this product will be referred to as the System from this point forward.

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.

Note

For technical information on the safety, regulatory, hardware, and operation of the products not discussed in this manual, see the following publications:

- *CARESTREAM DRX-1 System Battery and DRX Detector Battery User Guide*
- *CARESTREAM DRX-1 System Battery Charger User Guide*
- *CARESTREAM DRX-1 System Detector/CARESTREAM DRX-1C System Detector/CARESTREAM DRX 2530 Detector Model DRX 2530-01 User Guide*
- *CARESTREAM DRX-1 System Online Help*

Indications for Use

CARESTREAM DRX-1 System

The device is intended to capture for display radiographic images of human anatomy including both pediatric and adult patients. The device is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. Excluded from the indications for use are mammography, fluoroscopy, and angiography applications.

Caution

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

System Components

The DRX-1 System may contain the following CARESTREAM products:

Detector (one or more)	DRX-1 System Detector DRX-1C System Detector DRX 2530C Detector Model DRX 2530-01
Battery (any quantity)	DRX-1 System Battery DRX Detector Battery
Battery Charger	DRX-1 System Battery Charger
Console	DRX-1 System Console DRX-1 System Console Model C
Tether Interface	DRX-1 System Tether Interface DRX-1 System Tether Interface Model DRX-TPC1
Wireless Access Point	DRX-1 System Wireless Access Point

Medical Equipment Classification

Table 1: CARESTREAM DRX-1 System Medical Electrical Equipment Classification

Type of protection against electrical shock	Internally powered equipment Class I Equipment
Degree of protection against electrical shock	Type B Applied Part
Degree of protection against ingress of water	Ordinary protection
Mode of operation	Continuous operation
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.

Table 2: CARESTREAM DRX-1 System Tether Interface Medical Electrical Equipment Classification

Type of protection against electrical shock	Class I Equipment
Degree of protection against electrical shock	Type B
Degree of protection against ingress of water	Ordinary protection
Mode of operation	Continuous operation
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.

Table 3: CARESTREAM DRX-1 System Tether Interface Model DRX-TPC1 Medical Electrical Equipment Classification

Type of protection against electrical shock	Class II Equipment
Degree of protection against electrical shock	Type B
Degree of protection against ingress of water	Ordinary protection
Mode of operation	Continuous operation
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.

Safety

Product Safety Standards

These Product Safety Standards apply to a DRX-1 System with the following CARESTREAM products:

Detector (one or more)	DRX-1 System Detector DRX-1C System Detector DRX 2530C Detector Model DRX 2530-01
Battery (any quantity)	DRX-1 System Battery DRX Detector Battery
Battery Charger	DRX-1 System Battery Charger
Console	DRX-1 System Console DRX-1 System Console Model C
Tether Interface	DRX-1 System Tether Interface DRX-1 System Tether Interface Model DRX-TPC1
Wireless Access Point	DRX-1 System Wireless Access Point

USA	UL 60601–1:2003—Medical Electrical Equipment, 1st Edition
	ANSI/AAMI ES60601–1: 2005—Medical Electrical Equipment—Part 1: General requirements for safety and essential performance
Canada	CAN/CSA–C22.2 No. 601.1–M90 (R2005)—Medical Electrical Equipment
	CAN/CSA–C22.2 No. 601.1S1–94 (R1999)—Supplement No. 1–94 to CAN/CSA–C22.2 No. 601.1–M90
	CAN/CSA–C22.2 No. 601.1B–90 (R2006)—Amendment 2 to CAN/CSA–C22.2 No. 601.1–M90
	CAN/CSA C22.2 No. 60601–1–02 (R2006)—Medical Electrical Systems
	CAN/CSA C22.2 No. 60601–1–08—Medical Electrical Equipment—Part 1: General requirements for safety and essential performance

Europe	EN 60601–1: 2006—Medical Electrical Equipment — Part 1: General requirements for safety and essential performance
	EN 60601–1–6: 2010—Medical Electrical Equipment—Part 1: General requirements for safety and essential performance—Collateral Standard: Usability
	EN 60601–1: 1990 + Amendment 1: 1993 + Amendment 2: 1995—Medical Electrical Equipment
	EN 60601–1–1: 2001—Medical Electrical Systems
	EN 60601–1–4: 1996 + Amendment 1: 1999—Programmable Electrical Medical Systems
International	IEC 60601–1: 2005—Medical Electrical Equipment—Part 1: General requirements for safety and essential performance
	IEC 60601–1–6: 2010—Medical Electrical Equipment—Part 1: General requirements for safety and essential performance—Collateral Standard: Usability—3rd Edition
	IEC 60601–1: 1988 + Amendment 1: 1991 + Amendment 2: 1995—Medical Electrical Equipment
	IEC 60601–1–1: 2000—Medical Electrical Systems
	IEC 60601–1–4: 1996 + Amendment 1: 1999—Programmable Electrical Medical Systems

Product Safety Standards

These Product Safety Standards apply to the following CARESTREAM products:

Battery Charger	DRX-1 System Battery Charger
Console	DRX-1 System Console DRX-1 System Console Model C
Wireless Access Point	DRX-1 System Wireless Access Point

USA	UL 60950–1, 2nd Edition—Information Technology Equipment—Safety—Part 1: General Requirements
Canada	CAN/CSA C22.2 No. 60950-1–07, Information Technology Equipment—Safety—Part 1: General Requirements
Europe	EN 60950–1: 2006, with latest amendments—Information Technology Equipment—Safety—Part 1: General Requirements
International	IEC 60950–1: 2005, with latest amendments—Information Technology Equipment—Safety —Part 1: General Requirements

DRX-1 System EMC Standards

IEC 60601–1–2:2007 includes EMC requirements and tests, Medical Electrical Equipment including CISPR 11:2009 + A 1:2010, Group 1, Class A.

Precautions

Electromagnetic Compatibility Precautions

Medical electrical equipment requires special precautions regarding Electromagnetic Compatibility (EMC). Medical equipment must be installed and put into service according to the EMC information provided in this document.

Communications Equipment

Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment EMC performance.

The wireless version of the detector operates with the 802.11n protocol in the 5 GHz frequency band. The radio output power is 50 mW (nominal).

Replacement of Cables, Accessories, or Transducers

The use of cables, accessories, or transducers, other than those specified in this document, with the exception of transducers or cables sold by the manufacturer of the equipment as replacement parts for internal components, may result in increased emissions or decreased immunity of the medical equipment.

Other Equipment

The detector should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the detector should be observed to verify normal operation in the configuration in which it will be used.

Shielded Locations

The typical location of the detector will be in a shielded room only because the detector functions with sources of X-ray energy. The detector is fully compliant with the requirements of IEC 60601–1–2:2007 without being located in a shielded room.

FCC Notice (United States)

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

1. This device may not cause harmful interference.
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 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.

Recommended EMC Environment

Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment—Guidance
RF Emissions CISPR 11	Group 1	The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The System 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.
Harmonics Emissions IEC 61000–3–2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000–3–3	Complies	

Electromagnetic Immunity for Equipment and Detectors Fully Compliant with IEC 60601–1–2:2007

The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment—Guidance**
Electrostatic Discharge (ESD) IEC 61000–4–2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000–4–4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000–4–5	± 1 kV line to line ± 2 kV line to earth	± 1 kV line to line ± 2 kV line to earth	
Voltage dips, short interruptions, and voltage variations on power supply lines IEC 61000–4–11	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 sec	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 sec	
Power frequency (50/60 Hz) magnetic field IEC 61000–4–8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note

U_T is the Mains (ac) voltage prior to application of the test level.

Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the System.

The System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the detector as recommended below, according to the maximum output of the communications equipment.

Rated Maximum Output Power of Transmitter	**Separation Distance According to Frequency of Transmitter**		
Watts	**Meters**		
	150 kHz–80 MHz $d = 1.17 \sqrt{P}$	80 MHz–800 MHz $d = 1.17 \sqrt{P}$	800 MHz–2.5 GHz $d = 2.33 \sqrt{P}$
0.01	0.117	0.117	0.233
0.10	0.37	0.37	0.737
1	1.17	1.17	2.33
10	3.70	3.70	7.36
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Wireless Declaration

Radio Frequency Exposure Declarations

The System is a portable wireless devices according to FCC regulation 2.1093 (b). The System has been shown to be compliant for localized specific absorption rate (SAR) for uncontrolled environment/general exposure limits specified in ANSI/IEEE standard C95.1–1999. The maximum SAR measurement (averaged over 1 gram of tissue) is 0.992 W/kg. The measured value is well under the spatial peak SAR of 1.6 W/kg specified in FCC regulation 2.1093 d (2) for uncontrolled environment/general exposure conditions.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada.

To reduce potential radio interference to other users, the antenna type and gain should be so chosen that the Equivalent Isotropically Radiated Power (E.I.R.P) is not more than that necessary for successful communication.

Conformément à la réglementation d'Industrie Canada, le présent emétteru radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada.

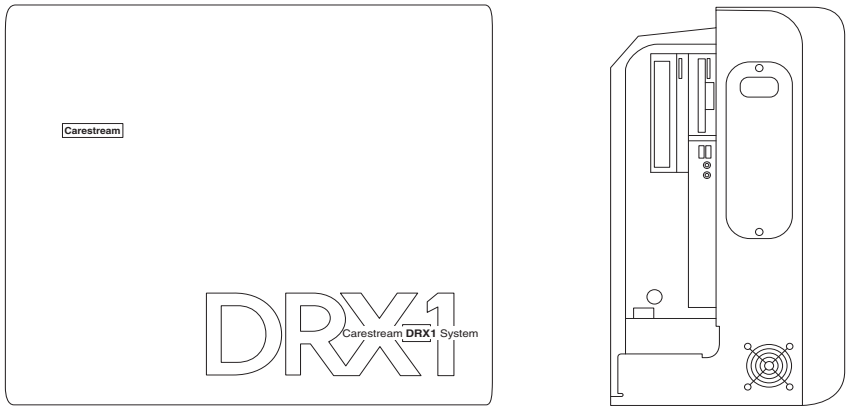
DRX-1 System Product Information

DRX-1 System Console

Caution

The System Console is not medical electrical equipment and should not be placed in the patient vicinity.

Figure 1: CARESTREAM DRX-1 System Console



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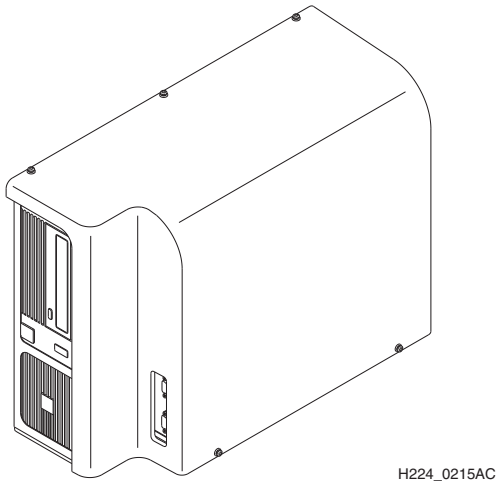
Size	57 x 50 x 28 cm (22 x 20 x 11 in.)
Weight	41 kg (90 lb)
Electrical Ratings	100 V (ac), 50/60 Hz 4 A Max 110–127 V (ac), 50/60 Hz 4 A Max 220–230 V (ac) 50/60 Hz 4 A Max

DRX-1 System Console (Model C)

Caution

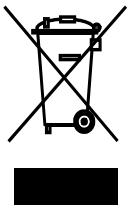
The System Console Model C is not medical electrical equipment and should not be placed in the patient vicinity.

Figure 2: CARESTREAM DRX-1 System Console Model C



Size	50.0 x 37.5 x 21.5 cm (20 x 15 x 8.5 in.)
Weight	20.4 kg (45.0 lb)
Electrical Ratings	100–240 V (ac), 50/60 Hz 2 A

Disposal Information



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. Contact your local representative or refer to *http://recycle.carestreamhealth.com* for additional information on the collection and recovery programs available for this product.

Note

For disposal information for the CARESTREAM DRX-1 System Battery Charger or CARESTREAM DRX-1 System Battery, see the *CARESTREAM DRX-1 System Battery Charger User Guide* or the *CARESTREAM DRX-1 System Battery/CARESTREAM Detector Battery User Guide*.

Transport and Storage Environment

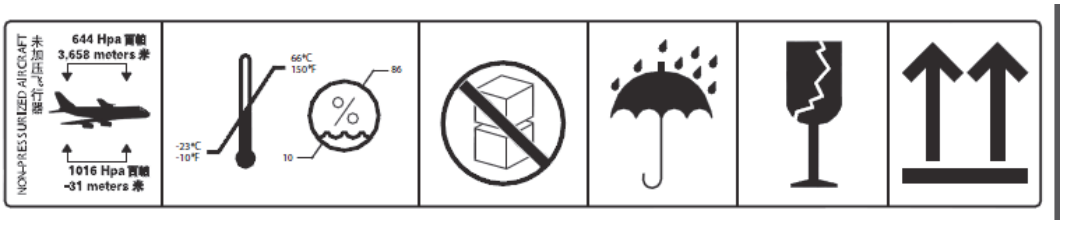
System Environmental	–23 to 66 °C (–10 to 150 °F), 10 to 86 % RH, maximum altitude 3658 m (12000 ft)
Battery Charger Environmental	Storage: –20 to 70 °C (–4 to158 °F)

Note

The following graphic is applied to the shipping package, and describes the conditions that should be met while the package is in transit and storage.

Note

The following graphic is shown for reference only. The actual shipping label may vary slightly.



Operating Environment

Caution

Do not operate this equipment outside of its operating environment limits. Doing this may cause the equipment to malfunction. The operating environment limits are as follows:

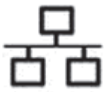
System Environmental	15 to 30 °C (59 to 86 °F), 10 to 86 % RH, maximum altitude 3000 m (9843 ft)
Battery Charger Environmental	Operating: 0 to 30 °C (32 to 86 °F)

Note

If your location is more than 3000 meters (9843 ft) above sea level, a Mains isolation transformer may be required. Contact Carestream Health for guidance.

Safety Labels

Safety Symbols

	Refer to the instruction manual or booklet		Generator Cable
	Exposure Switch		Ethernet Cable
	Tether Cable		USB Connection
	Equipotentially		DC Power Unit
	Remote Sensor Cable		Refer to the instruction manual or booklet
	Consult instructions for use		

2 Hardware and Operation

Overview

The CARESTREAM DRX-1 System lets you connect a digital DR detector to an analog system and capture images digitally. Use the existing analog console to set up the exam and determine the technique. Then, expose the subject with the System, view the image, and manipulate the image on the computer using Image Viewing Acquisition Software. You can send the image to destinations such as workstations via an Ethernet connection.

The System lets you change a traditional film or Computed Radiography (CR) system to a Digital Radiography (DR) system with minimal changes to hardware. The CARESTREAM DRX-1 System Detector fits existing Buckys, just as cassettes do. A new Console connects to HIS/RIS and PACS. You can continue to use film or CR in your system as desired.

At the Console, the user can download patient data from the RIS (or input from the Console) and initiate prep and expose functions.

The battery-powered detector absorbs, measures, and translates into digital format the X-ray energy absorbed during an X-ray exposure. Software corrects the digital image and generates a preview and full-resolution image on the Console.

The detector operates in a wireless state, using a battery for power, and allowing wireless communication for control and data transmission. The detector may optionally be used with a tether. The tether provides power and communications to the detector.

On the Console, the radiographer:

- Views or prepares the patient data and acquisition procedures for the examination.
- Acquires radiographic images using the detector.
- Sends radiographic images and associated patient data from the detector to an output device, such as hard copy, soft copy, or archive devices.

Note

For technical information on the safety, regulatory, hardware, and operation of the products not discussed in this manual, see the following publications:

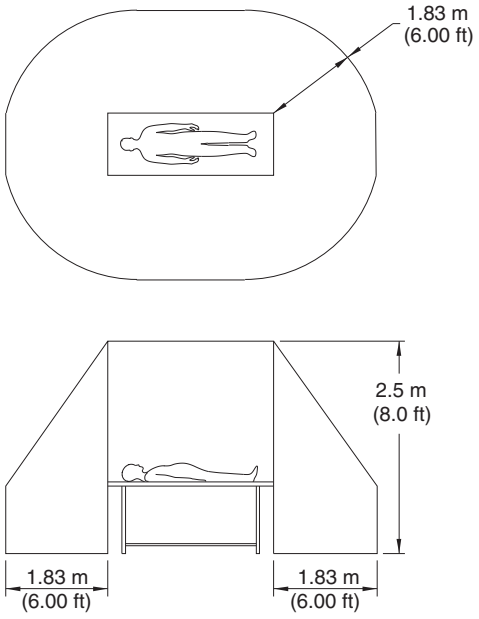
- *CARESTREAM DRX-1 System Battery and DRX Detector Battery User Guide*
- *CARESTREAM DRX-1 System Battery Charger User Guide*
- *CARESTREAM DRX-1 System Detector/CARESTREAM DRX-1C System Detector/CARESTREAM DRX 2530 Detector Model DRX 2530-01 User Guide*
- *CARESTREAM DRX-1 System Online Help*

Cautions

Caution

- Follow all safety labels on 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 System 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 operation, proper patient positioning, and use of the protective devices provided.
- The detector is fragile and contains glass. Handle with care! Dropping or handling the detector roughly could result in damage. If the detector is dropped or handled roughly, or if there is any indication that the image quality is affected, perform a calibration.
- Do not submerge any components of the System in liquid.
- Perform periodic maintenance to ensure continued safe use of the equipment.
- The System must be repaired only by authorized service personnel.

Patient Vicinity



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Caution
The System Console, Battery Charger, Network Switch, and Wireless Access Point are not medical electrical equipment and should not be placed in the patient vicinity.

Caution
Keep all electronic devices (wireless or hard wired) 91cm (3 ft) from the detector when in use.

Installing the Hardware

All equipment installations and adjustments must be performed by personnel authorized by Carestream Health only.

Accessory Information

The use of equipment and/or hardware that does not comply with the equivalent product safety and EMC requirements of this product may lead to a reduced level of safety and/or EMC performance of the resulting system.

Consideration relating to the choice of accessory equipment used with this product shall include:

- Use of the accessory in the patient's vicinity.
- Evidence that the safety certification of the accessory has been performed in accordance with applicable coordinated harmonized product safety standards per IEC 60601–1–1.
- Evidence that applicable emission certification of the accessory has been performed.

Battery Information

A battery is required for wireless or tethered use. For complete information about the batteries used with the DRX detectors, see the *CARESTREAM DRX-1 System Battery and DRX Detector Battery User Guide* or the *Quick Reference Card for the CARESTREAM DRX-1 System and the DRX-Mobile Retrofit Kit.*

Installing the Battery

Use only Carestream batteries in DRX detectors.

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. Push the battery down firmly until the latch catches.

Removing a Single-Point Latch Battery

A battery may have a single-point latch or a two-point latch.

Prerequisites:

A DRX battery that has a single-point latch.

1. Place the detector on a flat surface outside of the patient vicinity.
2. Place a tool such as the tip of a ballpoint pen in the release slot, and push down on the latch.

The battery releases for easy removal.

Removing a Two-Point Latch Battery

Prerequisites:

A DRX battery that has a two-point latch, such as the DRX Detector Battery.

1. Place the detector on a flat surface outside of the patient vicinity.
2. With one hand, press and hold the round button to release the latch.
3. With the other hand, pull the tab away from the battery.
   Do these steps simultaneously so that the battery releases for easy removal.

Turning the System On

1. Press the **On** switch on the Console. For systems that have a UPS, press the **On** switch on the UPS.
2. Press the **On** switch on the computer and monitor.
3. When the software initializes, the system is ready for use.
4. Insert a fully charged battery into the detector.

Turning the System Off

1. Select the **Quick Menu** in the lower left corner of the screen.
2. Select **Shut Down**.
3. Turn **Off** the monitor.
4. For systems with a UPS, turn **Off** the UPS.
5. Turn **Off** the Console.

The DRX-1 System Console may be completely powered up or powered down via the switch located adjacent to the Mains cord connector. Alternatively, to power down, the Mains cord may be disconnected at the cord connector.

Caution

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Caution

This device must be positioned where the operator has easy access to the appliance coupler (cord disconnect device).

Caution

The customer is responsible for ensuring that Ethernet interface to their network conforms to isolation requirements of IEC60601:1: 2005.

Turning the DRX-1 System Console and the DRX-1 System Console Model C On and Off

The Console may be completely powered up or powered down via the switch located adjacent to the Mains cord connector. Alternatively, to power down, the Mains cord may be disconnected at the cord connector.

Tether Operation

Tether Interfaces

There are two system tether interfaces: the CARESTREAM DRX-1 System Tether Interface and the CARESTREAM DRX-1 Tether Interface Model DRX-TPC1.

DRX-1 System Tether Interface

Caution

Do not allow the detector to come in direct contact with a patient while the detector is connected to a tether with the DRX-1 System Tether Interface. This interface must be located outside of the patient vicinity.

CARESTREAM System Tether Interface Specifications	
Size	16 x 30 x 7 cm (6 x 12 x 3 in.)
Weight	2.3 kg (5.0 lb)
Electrical Ratings	100–240 V (ac), 0.75 A 50/60 Hz

Turning the DRX-1 System Tether Interface On and Off

The DRX-1 System Tether Interface may be powered up or powered down via the switch located adjacent to the Mains cord connector. Alternatively, to power down, the Mains cord may be disconnected at the cord connector.

DRX-1 System Tether Interface Model DRX-TPC1

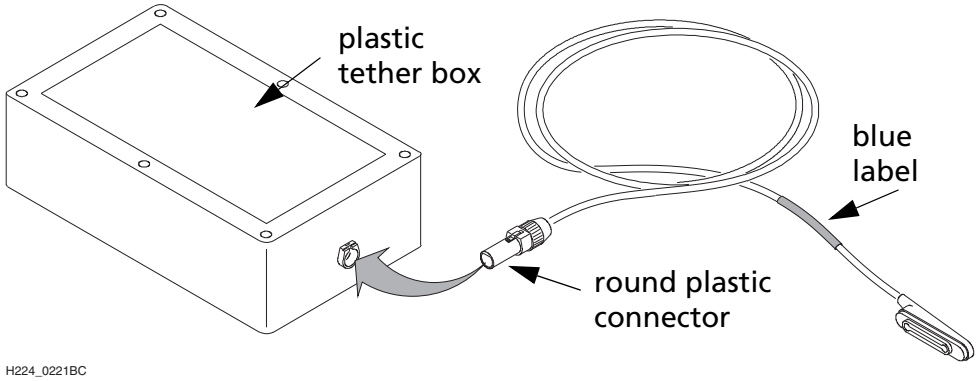
The DRX-TPC1 Tether Interface may be used with a tether in the patient vicinity. The tether is identified by a blue wrapping on the tether cable.

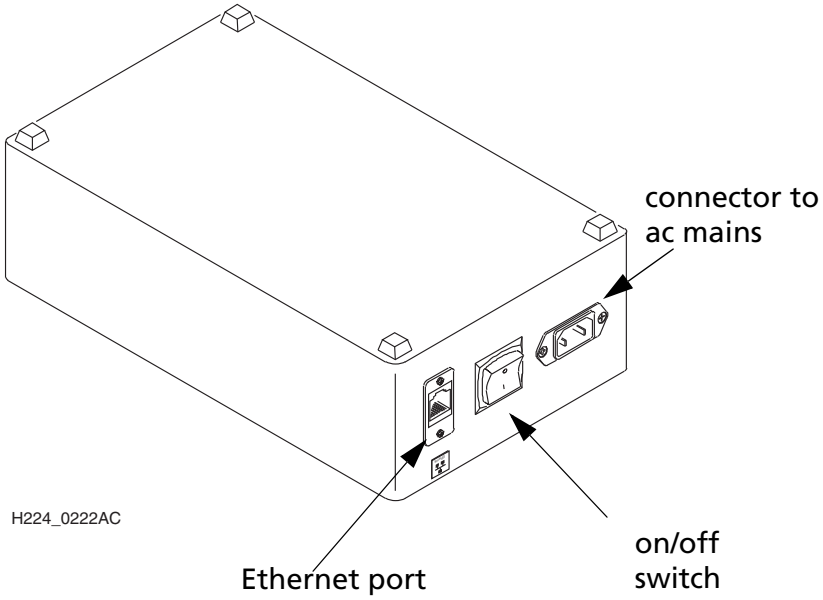
The plastic DRX-TPC1 Tether Interface box is identified with a square Class II mark on the CARESTREAM DRX-1 System Tether Interface Data Plate:

CARESTREAM DRX-1 System Tether Interface Model DRX-TPC1 Medical Electrical Equipment Specification	
Specifications	
Size	25.0 x 15.0 x 8.0 cm (9.8 x 5.9 x 3.1 in.)
Weight	0.9 kg (2.0 lb)
Electrical Ratings	100–240 V (ac) 50/60 Hz 1A input
Operating Environment	
Temperature	15–30 °C (59–86 °F)
Maximum Altitude	3000 meters (9842 ft)
Relative Humidity	10–86 %
Altitude	If your location is more than 3000 meters (9843 ft) above sea level, a Mains isolation transformer may be required. Contact Carestream Health for guidance.

Transport and Storage	
Temperature	–23 to 66 °C (–10 to 150 °F)
Altitude	–31 to 3658 meters (–102 to 12,000 ft)
Relative Humidity	10–86 %
Atmospheric Pressure	644 to 1016 hPa

Setting Up the Model DRX-TPC1 Tether Interface





Caution

This device must be positioned where the operator has easy access to the appliance coupler (cord disconnect device).

Cleaning

Cleaning the Hardware

Our instructions serve as a guideline for best practices. The cleaners listed in our instructions ensure that the paint finish does not fade or cause harm to the rubber screw covers, etc. We are also aware that each facility will have its own requirements, guidelines and approved cleaners. If your facility has such requirements, use what is mandated as long as it does not cause harm to the surfaces being cleaned. Carestream will not be responsible for replacement of parts that are shown to be damaged by improper cleaning agents

Caution
Do not operate the equipment when cleaning the equipment.

Caution
Do not spray cleaning solution directly onto the equipment. Moisten a cloth with a 70 % isopropyl alcohol solution and apply to patient contact areas after each contact.

Caution
Isopropyl alcohol is a flammable solvent. Read and follow instructions in the Material Safety Data Sheet (MSDS).

Caution
Do not immerse the equipment in liquid.

System Maintenance

Caution
Do not attempt mechanical or electrical repair of the System. Contact authorized service personnel if any unit does not perform to your satisfaction.

The System must be maintained in good operating order at all times to provide safe conditions for operating personnel and patients. The System must also be maintained to prevent possible loss of patient or image data.

Maintenance Schedule

Caution
The System must be repaired only by authorized service personnel.

Daily:

- Clean the equipment.
- Check the equipment integrity (see below).
- Perform Daily Refresh Calibration if required. See **"Running Detector Calibrations"** in the *.DRX-1 System Online Help*

Biannually

- Perform an X-ray Calibration. See **"Running Detector Calibrations"** in the *CARESTREAM DRX-1 System Online Help*.

Periodically, or as needed:

- Recalibrate the touchscreen on the Console as needed. Recalibration instructions are included in the *CARESTREAM DRX-1 System Online Help*.
- Report any unusual conditions to your authorized service representative.

Check the Equipment Integrity

To make sure that the equipment is functioning and operating safely, check that:

- The fastening hardware connects tightly.
- All name plates, legal labels, and warning labels are legible and secure.
- No cables have abrasions or damage, particularly in locations where cables are draped and subject to stress.

Grid Recommendation

Artifacts are not visible when the 103 line pair/inch low frequency stationary grid is used.

Protective Enclosures

Caution

When there is a risk of fluids contacting the detector, place the detector in a protective bag. If you are using a protective enclosure around the detector, remove the enclosure immediately after use to prevent the detector from overheating.

Power Failures

There are various types of power disruptions that can affect a system: voltage sags, voltage surges, brownouts, line noise, high voltage spikes, frequency variations, switching transients, and harmonic distortions. These disruptions can be minimized by an Uninterruptible Power Supply (UPS). The DRX-1 System Console Model C does not include a UPS.

Note

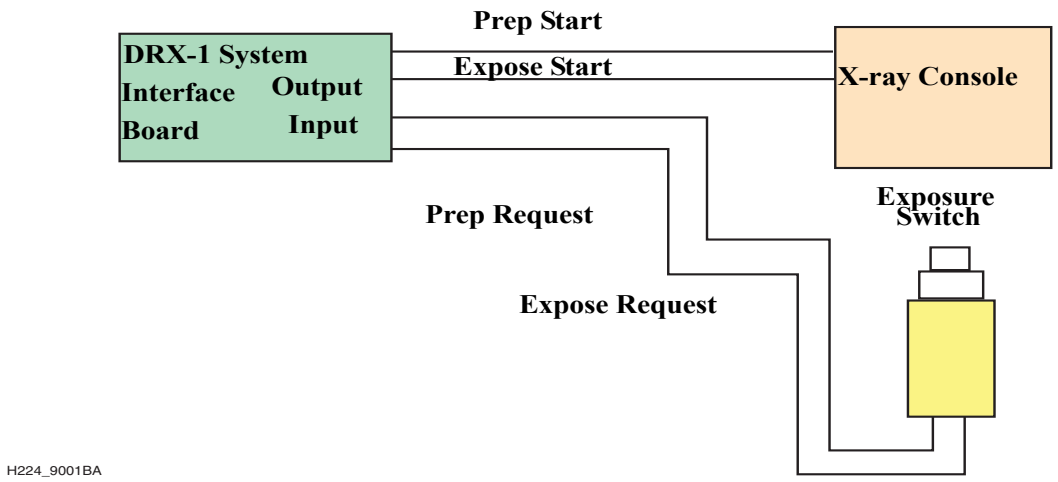
A UPS provides back-up power in the event of a power failure. A UPS also conditions the power provided to the System. Back-up power will last for a specific length of time, dependent on the UPS energy storage capacity and the power requirements of the equipment. If you choose to provide a UPS for your System, follow the manufacturer's recommendation for use and battery replacement.

Table 1: UPS Specification: 700 VA UPS for Console/Monitor Only Usage

Power Level	700 VA, 490 W
Regulation (Normal Mode)	Nominal output voltage ± 2 %
Regulation (Battery Mode)	Nominal output voltage ± 3 %
Voltage Waveform	Normal Mode: Sine Wave; < 5 % THD with full PFC and nonlinear load
Battery Mode notification	An audible alarm is recommended.

Compatibility with Other Manufacturers' Equipment

The System is a digital X-ray image capture system. The System connects with existing analog X-ray equipment using a safety certified electrical isolation device (DRX-1 System Interface). The isolation device is designed to prevent any failures, loss of power, or a power surge in the System from affecting the X-ray equipment.

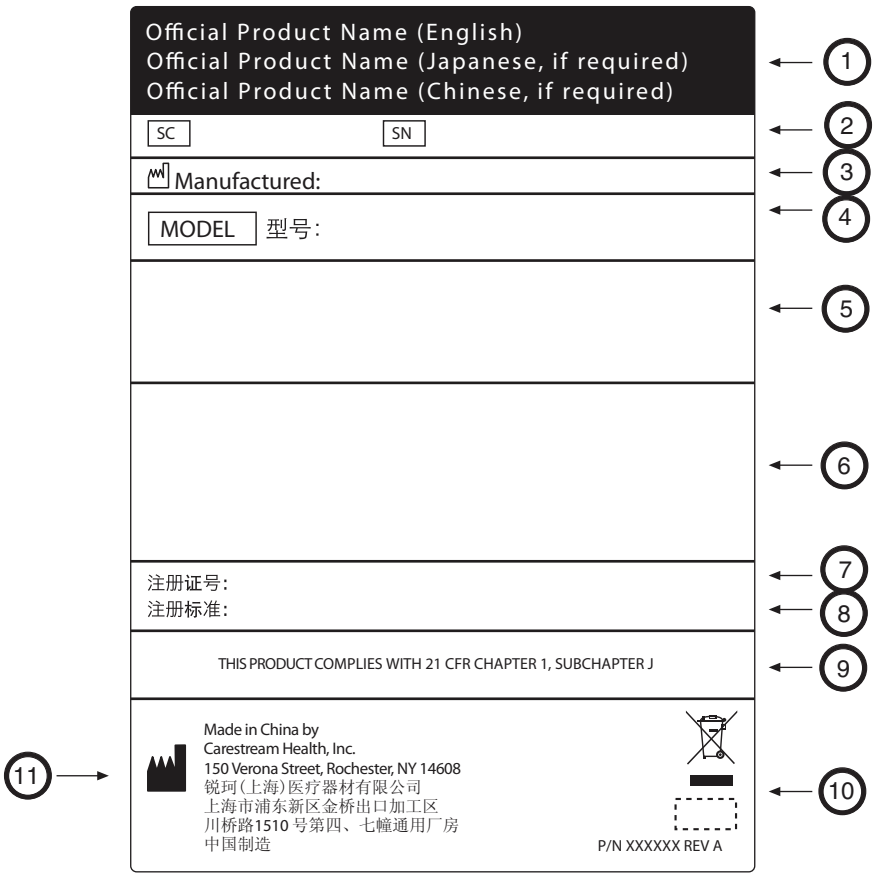


The System uses an existing exposure switch connector on the X-ray equipment. No modification to the X-ray equipment is required. The intended use of the X-ray equipment is not affected, and the X-ray equipment remains certified by the X-ray equipment manufacturer.

Model-specific documentation and cables are provided to allow service personnel to connect and run functional testing on the System. The System is compatible with the X-ray equipment listed on the *CARESTREAM DRX-1 System Compatibility List*. Contact your local authorized service provider for further information.

Labels

Sample Data Plate Label



1	Official Product Name
2	Service Code and Serial Number
3	Manufactured Date
4	Model Type as required/consistent with product safety test reports
5	Voltage range, rated frequency in hertz and amps/consistent with product safety test reports: V = volts, Hz = hertz, A = amperes
6	Symbols for product safety, EMC, and CE marking
7	SFDA registration number
8	SFDA Product Standard number

9	Compliance statement according to FDA requirements for laser products
10	Label manufacturer registration number and material specification
11	Made in statement

Publication History

Revision	Date	Change
A	2013-01-10	Initial release

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