

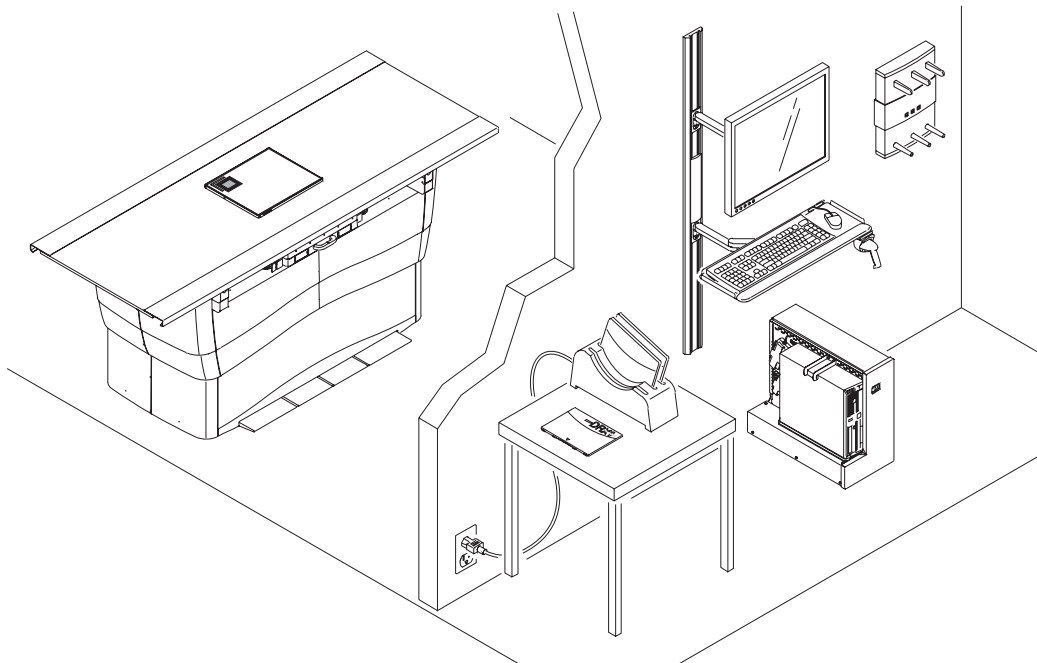
# **CARESTREAM DRX-1 System**

## **Safety and Regulatory Information**

### **with**

## **Hardware**

## **User's Guide**



**Carestream**   
HEALTH

**Version 2.0**

**PN 7H8166**

**22 January 2009**



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# 1 Safety and Regulatory Information

The information contained 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.

Carestream Health reserves the right to change this information without notice, and makes no warranty, express or implied, with respect to this information. Carestream Health shall not be liable for any loss or damage, including consequential or special damages, resulting from any use of this information, even if loss or damage is caused by Carestream Health's negligence or other fault.

## 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.**

## Intended Use and Indications for Use

The CARESTREAM DRX-1 System is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications wherever conventional screen-film or Computed Radiography (CR) systems may be used. Excluded from the indications for use are mammography, fluoroscopy, tomography, and angiography applications.

## Safety and Related Information

### Medical Equipment Classification

#### CARESTREAM DRX-1 System Detector 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.

#### 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.

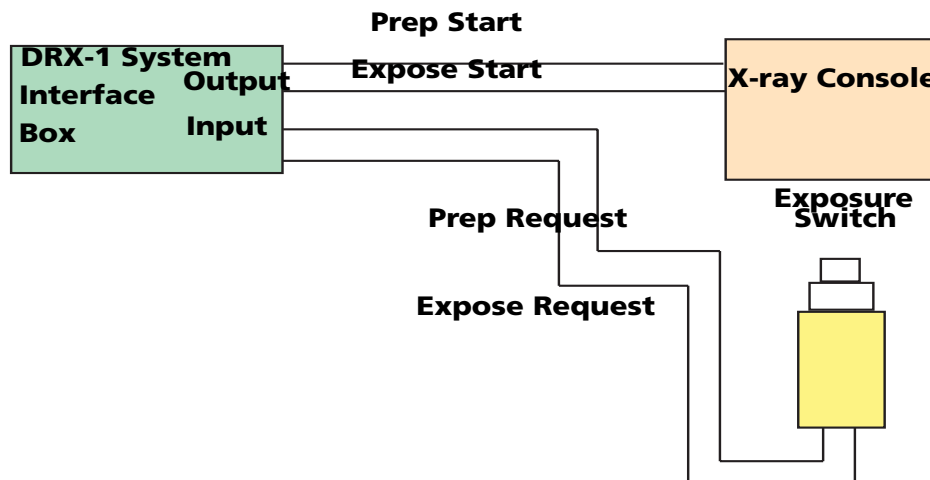
- The CARESTREAM DRX-1 System includes the following components:  
 CARESTREAM DRX-1 System Detector (one or more)  
 CARESTREAM DRX-1 System Battery (any quantity)  
 CARESTREAM DRX-1 System Battery Charger  
 CARESTREAM DRX-1 System Tether Interface  
 CARESTREAM DRX-1 System Console  
 CARESTREAM DRX-1 System Access Point

**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.

**Compatibility with Other Manufacturer's Equipment**

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



H224\_9001BA

The DRX-1 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 DRX-1 System. The DRX-1 System is compatible with the X-ray equipment listed on the Certificate of Compatibility available from your local authorized service provider. Contact your local authorized service provider for further information.

### Product Safety Standards

#### The following Product Safety Standards are applicable to:

- CARESTREAM DRX-1 System Detector
- CARESTREAM DRX-1 System Tether Interface

#### USA

UL 60601-1:2003 - Medical Electrical Equipment

#### Canada

CAN/CSA-C22.2 No. 601.1-M90 (R2001) 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 (R2002) - Amendment 2 to CAN/CSA-C22.2  
No. 601.1-M90

#### Europe

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 60601-1:1988 + 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

#### The following Product Safety Standards are applicable to:

- CARESTREAM DRX-1 System. The DRX-1 System includes the following components:
  - CARESTREAM DRX-1 System Detector (one or more)
  - CARESTREAM DRX-1 System Battery (any quantity)



CARESTREAM DRX-1 System Battery Charger  
CARESTREAM DRX-1 System Tether Interface  
CARESTREAM DRX-1 System Console  
CARESTREAM DRX-1 System Wireless Access Point

<b>USA</b>	UL 60601-1:2003 - Medical Electrical Equipment, 1st Edition
<b>Canada</b>	CAN/CSA-C22.2 No. 601.1-M90 (R2001) 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 (R2002) - Amendment 2 to CAN/CSA-C22.2 No. 601.1-M90
<b>Europe</b>	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
<b>International</b>	IEC 60601-1:1998 + 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

**The following Product Safety Standards are applicable to:**

- CARESTREAM DRX-1 System Battery

<b>USA</b>	UL 60601-1:2003 - Medical Electrical Equipment, 1st Edition
<b>Canada</b>	CAN/CSA-C22.2 No. 601.1-M90 (R2001) 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 (R2002) - Amendment 2 to CAN/CSA-C22.2 No. 601.1-M90
<b>Europe</b>	EN 60601-1:1990 + Amendment 1:1993 + Amendment 2:1995 - Medical Electrical Equipment
<b>International</b>	IEC 60601-1:1988 + Amendment 1:1991 + Amendment 2:1995 - Medical Electrical Equipment

**The following Product Safety Standards are applicable to:**

- CARESTREAM DRX-1 System Battery Charger
- CARESTREAM DRX-1 System Console
- CARESTREAM DRX-1 System Wireless Access Point

<b>USA</b>	UL 60950-1, Information Technology Equipment - Safety - Part 1: General Requirements
<b>Canada</b>	CAN/CSA C22.2 No. 60950-1-03, Information Technology Equipment - Safety - Part 1: General Requirements
<b>Europe</b>	EN 60950-1:2001 + A11, Information Technology Equipment - Safety - Part 1: General Requirements
<b>International</b>	IEC 60950-1:2001, Information Technology Equipment - Safety - Part 1: General Requirements

## EMC Standards for Detector and System

IEC 60601-1-2:2004 EMC requirements and tests, Medical Electrical Equipment including CISPR 11:1999+A2:02, Group 1, Class A.

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

1. This device may not cause harmful interference.
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 and, if not installed and used in accordance with the instruction manual, 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.**

NOTE: For CARESTREAM DRX-1 System Battery Charger or Battery EMC information and instruction for use, see the CARESTREAM DRX-1 System Battery Charger User's Guide.

## Safety

This product complies with 21 CFR 1020.30/31 Performance Standards for Radiation Safety - Radiographic Equipment.

## Additional Guidance and Manufacturer's Declaration - Electromagnetic Emissions/Immunity

### 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 the following documentation.

### **Communications Equipment**

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

The wireless version of the Carestream DRX-1 System Detector operates with the 802.11n protocol in the 5 GHz frequency band. The radio output power is 50 mW (nominal).

 **CAUTION:**

### **Replacement of Cables, Accessories, or Transducers**

The use of cables, accessories or transducers other than those specified below 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 CARESTREAM DRX-1 System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Carestream DRX-1 System should be observed to verify normal operation in the configuration in which it will be used.

Cable, Accessory and Transducer Information for the Carestream DRX-1 System will be available prior to production release of the product.

### **Shielded Locations**

The typical location of the CARESTREAM DRX-1 System will be in a shielded room only because the system functions with sources of X-Ray energy. The CARESTREAM DRX-1 System is fully compliant with the requirements of IEC 60601-1-2:2004 without being located in a shielded room.


<b>Guidance and Manufacturer's Declaration - Electromagnetic Emissions</b>		
<p>The CARESTREAM DRX-1 System is intended for use in the electromagnetic environment specified below. The customer or the user of the CARESTREAM DRX-1 System should assure that it is used in such an environment.</p>		
<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic Environment - Guidance</b>
RF Emissions  CISPR 11	Group 1	The CARESTREAM DRX-1 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.  The CARESTREAM DRX-1 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.
RF Emissions  CISPR 11	Class A	
Harmonics Emissions  IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions  IEC 61000-3-3	Complies	

**Electromagnetic Immunity for Equipment and Systems Fully Compliant with IEC 60601-1-2:2004**

The CARESTREAM DRX-1 System is intended for use in the electromagnetic environment specified below. The customer or the user of the CARESTREAM DRX-1 System should assure that it is used in such an environment.

<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment-Guidance</b>
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	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec.	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment.  Note: Most components in the CARESTREAM DRX-1 System are powered from an uninterruptible power supply.  IEC 61000-4-11 is applicable only to the CARESTREAM DRX-1 System tether Interface.
Power frequency (50/60Hz) 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 a.c. mains voltage prior to application of the test level.

<b>Guidance and Manufacturer's Declaration - Electromagnetic Immunity</b>			
The CARESTREAM DRX-1 System is intended for use in the electromagnetic environment specified below. The customer or the user of the CARESTREAM DRX-1 System should assure that it is used in such an environment.			
<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment - Guidance</b>
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 v/m 80 MHz to 2.5GHz</p>	<p>3 Vrms</p> <p>3 v/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the CARESTREAM DRX-1 System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> <p><math>d = 1.17 \sqrt{P}</math></p> <p><math>d = 1.17 \sqrt{P}</math> 80 MHz to 800 MHz</p> <p><math>d = 2.33 \sqrt{P}</math> 800MHz to 2.5GHz</p> <p>where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacture and d is recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup>, should be less than the compliance level in each frequency range<sup>b</sup>.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

**Guidance and Manufacturer’s Declaration - Electromagnetic Immunity**

<sup>a</sup> Field strengths from fixed transmitters, such as base station for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CARESTREAM DRX-1 System is used exceeds the applicable RF compliance level above, the CARESTREAM DRX-1 System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CARESTREAM DRX-1 System.

<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 v/m.

**Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the CARESTREAM DRX-1 System**

The CARESTREAM DRX-1 System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CARESTREAM DRX-1 System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the CARESTREAM DRX-1 System as recommended below, according to the maximum output of the communications equipment.

Rated Maximum Output Power of Transmitter  Watts	Separation Distance According to Frequency of Transmitter  Meters		
	150 kHz to 80 MHz  $d = 1.17 \sqrt{P}$	80 MHz to 800 MHz  $d = 1.17 \sqrt{P}$	800 MHz to 2.5 GHz  $d = 2.33 \sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.37	0.37	0.737
1	1.17	1.17	2.33
10	3.7	3.7	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.



## DRX-1 System Product Information

### DRX-1 System Detector

### CARESTREAM DRX-1 System Detector



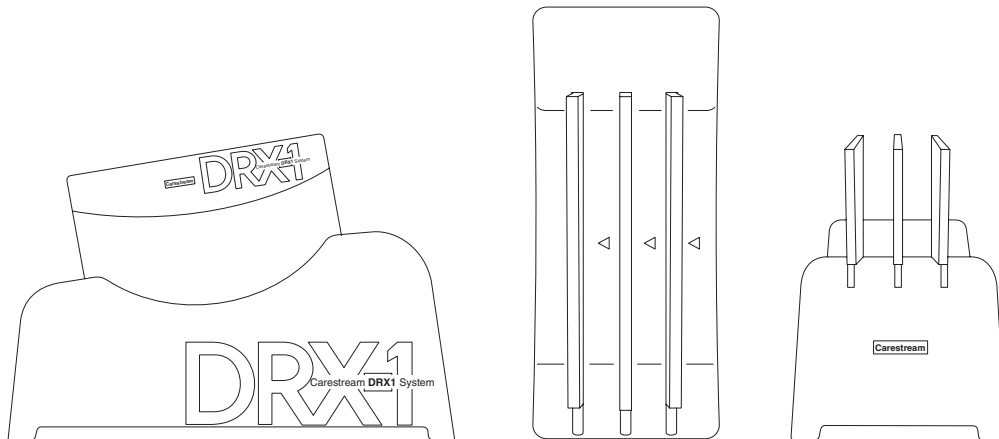
<b>Detector Size</b>	38 x 46 x 1.6 cm
<b>Detector Image Area</b>	35 x 43 cm
<b>Detector Weight</b>	4 kg (8.5 lb.)
<b>Detector Weight-Applied Limit</b>	Applied to a single 5 cm (2 in.) point: 23 kg (50 lb.) Distributed evenly over the detector area: 125 kg (275 lb.)
<b>Electrical Ratings</b>	12-18V DC, 3A

NOTE: For Computer, CARESTREAM DRX-1 System Battery Charger, and CARESTREAM DRX-1 System Battery regulatory information and instruction for use, see the manufacturer's User Guide.

## DRX-1 System Battery Charger

NOTE: For complete information on the CARESTREAM DRX-1 System Battery Charger, see the *CARESTREAM DRX-1 Battery Charger User's Guide*.

### CARESTREAM DRX-1 System Battery Charger



<b>Size</b>	38 x 14 x 18 cm
<b>Weight</b>	2.26 kg (5 lb.)
<b>Electrical Ratings</b>	100-240VAC, 50/60 Hz, 1.0A
<b>Power Output:</b>	12 V to 16.8 V, Constant Current/Constant Voltage, Lithium Ion charge method, 1A max charge current.

**DRX-1 System Battery** NOTE: For complete information on the care and handling of the DRX-1 System Battery, see the *CARESTREAM DRX-1 System Battery User's Guide*.

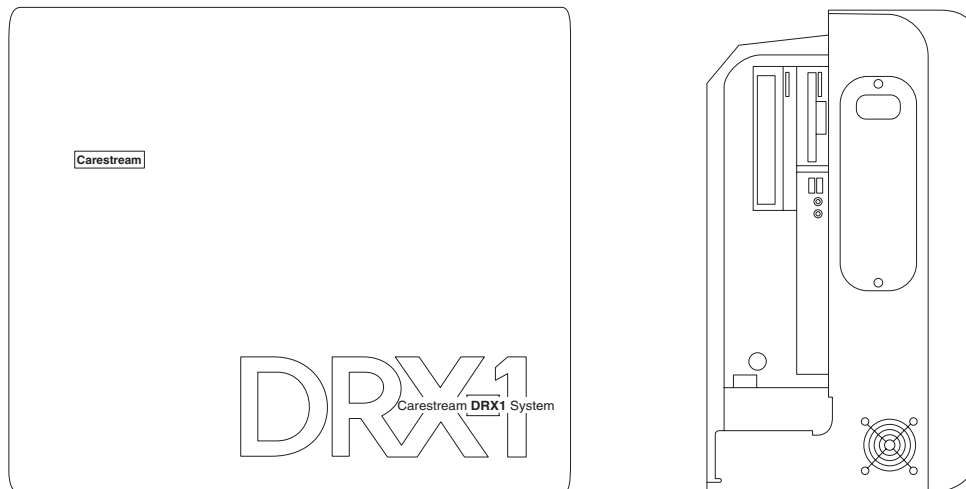
<b>Size</b>	21 x 15 x 0.5 cm
<b>Weight</b>	0.4 kg (12.4 oz.)
<b>Electrical Ratings</b>	14.8V DC, 2.1Ah (nominal) capacity

**⚠ CAUTION:**  
**The System console is not medical electrical equipment and should not be placed in the patient vicinity.**

See “Patient Vicinity” on page 1-17.

## DRX-1 System Console

### CARESTREAM DRX-1 System Console



<b>Size</b>	57 x 50 x 28 cm
<b>Weight</b>	41 kg (90 lb.)
<b>Electrical Ratings</b>	100V ac, 50/60 Hz, 4A; 100-127 V ac, 60 Hz, 4.0A; 220-240V ac, 50/60 Hz, 4A

### **DRX-1 System Interface Box (Internal)**

<b>Size</b>	13 x 18 x 8 cm
<b>Weight</b>	0.45 kg (1 lb.)
<b>Electrical Ratings</b>	12V DC, 0.5A

### **DRX-1 System Wireless Access Point**

See *CISCO Wireless Access Point User Guide* for Specifications.

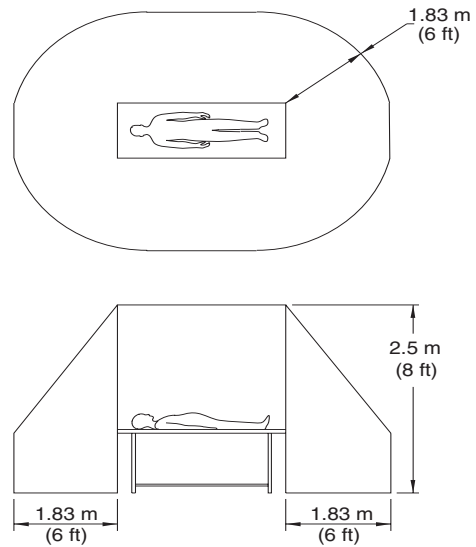
<b>Electrical Ratings</b>	100-240V AC
---------------------------	-------------

### **DRX-1 System Tether Interface**

<b>Size</b>	16 x 24 x 7 cm
<b>Weight</b>	02.3 kg (5 lb.)
<b>Electrical Ratings</b>	100-240V AC, 0.75A

NOTE: For Computer, CARESTREAM DRX-1 System Battery Charger, and CARESTREAM DRX-1 System Battery regulatory information and instruction for use, see the *CARESTREAM DRX-1 System Battery Charger User's Guide* and the *CARESTREAM DRX-1 System Battery User's Guide*.

## Patient Vicinity



**⚠ CAUTION:**  
 The System Console, Battery Charger, 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 hardwired) three feet from the detector when in use.

## Mode of Operation

DRX-1 Detector	Continuous
DRX-1 System Tether Interface	Continuous

## Labels

### Detector Weight Limit Label



#### CAUTION:

Since the detector is not a patient support device, it must be placed on a suitable surface such as a table or floor before applying patient weight to it. The weight label indicates acceptable limits of use that will not damage the detector. To prolong the life of the detector, and minimize potential internal detector damage, observe the following weight restrictions:

- The maximum concentrated weight over a small area of the detector surface (50 mm diameter) must not exceed 23 kg (50 lb.).
- The maximum distributed weight applied uniformly over the entire detector surface is 125 Kg (275 lb.).

### Maximum Exposure Time Label



This label indicates a requirement of one-second maximum exposure time for the DRX-1 System Detector. This label should be adhered close to the Console or on the DRX-1 System Monitor so that it is readily seen. The label means:CAUTION: MAXIMUM EXPOSURE TIME IS ONE SECOND.

**Battery Charger Dataplate Label**



**DRX-1 Battery Dataplate Label**



**DRX-1 System Detector Dataplate Label**



**System Console Label**





**System Tether Interface**

CARESTREAM DRX-1 System Tether Interface CARESTREAM DRX-1 系统在线工作接口	
SC	SN
 MANUFACTURED: 100-240V~ 50/60 Hz 0.75A 交流100-240伏~ 50/60赫兹 0.75安培	
 EMB001-1	 
This class A digital apparatus complies with Canadian ICES-001. Cet appareil numérique de la classe A est conforme à la norme NMB-001 du Canada.	
 Made in U.S.A. by CARESTREAM HEALTH, INC. ケアストリーム ヘルス社 生产企业: CARESTREAM HEALTH, INC. 注册地址: 160 Verona Street Rochester, NY 14606 美国制造	   

**System Label**

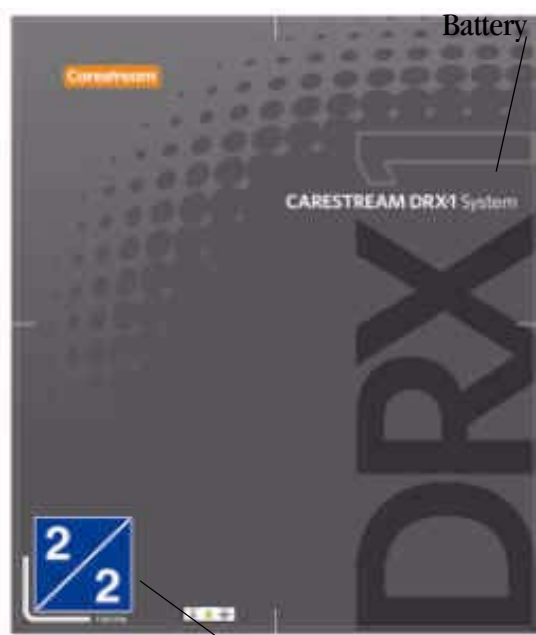
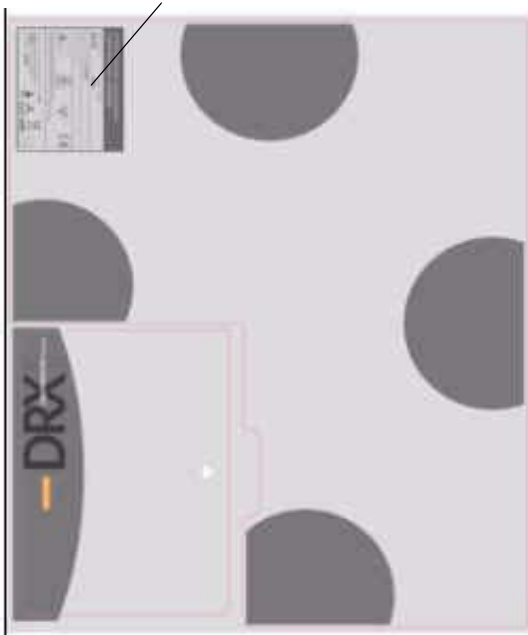
CARESTREAM DRX-1 System CARESTREAM DRX-1 系统	
SERVICE CODE: 服务代码:	 SERIAL NUMBER: 序列号:
 MANUFACTURED; 生产日期:	
 Made in U.S.A. by 美国制造 生产企业: CARESTREAM HEALTH, INC. 注册地址: Rochester, NY 14606	
R/N BG2526-REV	

**System Interface Box**



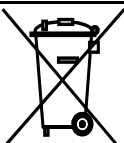
**Detector Labeling**

**Dataplate Label**



**Identification Label**

## 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 CARESTREAMDRX-1 System Battery see the *CARESTREAM DRX-1 System Battery Charger User's Guide* or the *CARESTREAM DRX-1 System Battery User's Guide*.

## 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:**

<b>System Environmental</b>	10-30°C, 10-86% RH, maximum altitude 3048 meters, 70-106kPa
<b>Battery Charger Environmental</b>	Operating: 0° C to 30° C (32° F to 86° F) Storage: -20° C to 70° C (-4° F to 158° F)

### For European Market Only

Authorized European Agent:



Carestream Health France  
 LES MERCURIALES  
 40, rue Jean Jaures  
 93176 BAGNOLET CEDEX  
 France

### General Contact Information

Carestream Health, Inc.  
 150 Verona Street  
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# 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 DRX -1 System and view 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 CARESTREAM DRX-1 System lets you change a traditional film or 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.

The Console can download patient data from the RIS (or input from the Console) and initiates prep and expose functions.

The battery-powered DRX-1 System 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.

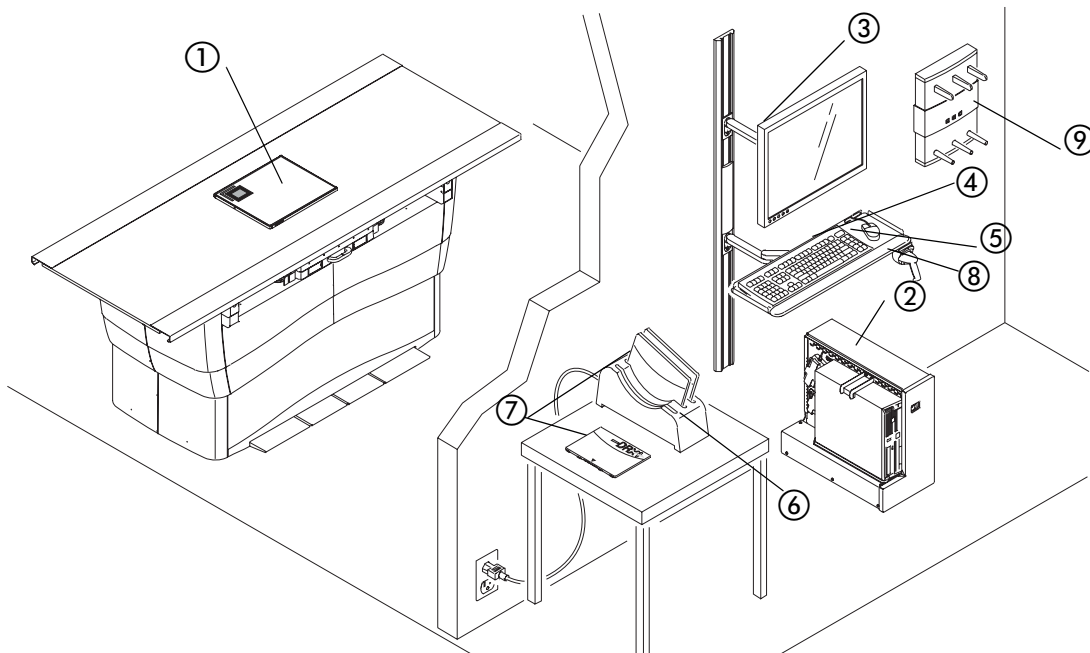
The DRX-1 System Detector operates in a wireless state, using a battery for power and allowing wireless communication for control and data transmission. The detector may optionally be used with a tether in a Wall Stand Bucky. The tether provides power and communications to the detector while it is in the Bucky.

Console application:

- A radiographer views or prepares the patient data and acquisition procedures for the examination.
- A radiographer captures radiographic images using the CARESTREAM DRX-1 System Detector.
- A radiographer sends radiographic images and associated patient data from the CARESTREAM DRX-1 System Detector to an output device such as hard copy, soft copy, or archive devices.

Follow all safety labels on the equipment.

## CARESTREAM DRX-1 System



1. DRX-1 System Detector—Captures radiographic images of human anatomy for display.
2. Console—Controls and records all responses in the imaging process.
3. Monitor—Lets you view the Image Viewer Screen and DIRECTVIEW Software.
4. Keyboard—Lets you access the **Image Viewer Screen** and DIRECTVIEW Software.
5. Mouse—Lets you access the **Image Viewer Screen** and DIRECTVIEW Software.
6. DRX-1 System Battery Charger—Charges 3 DRX-1 batteries at one time.
7. DRX-1 System Battery —Provides power to the detector.
8. Bar-code Scanner—Reads the detector bar-code, enters patient data.
9. DRX-1 System Wireless Access Point—Provides communication for the Wireless System.

---

## Cautions

- ⚠ CAUTION:**  
For continued safe use of this equipment, follow the instructions contained in this operating manual.
- ⚠ CAUTION:**  
Study this manual carefully before using the equipment and keep it at hand for quick reference.
- ⚠ CAUTION:**  
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 observation, proper patient positioning, and use of the protective devices provided.
- ⚠ CAUTION:**  
The detector is fragile and contains glass. Handle with care! Dropping or rough handling the detector could result in damage. If the detector is dropped or handled roughly, or if there is any indication of reduced image quality, perform a calibration."
- ⚠ CAUTION:**  
Do not submerge any components of the CARESTREAM DRX-1 System in liquid.
- ⚠ CAUTION:**  
Perform periodic maintenance to ensure continued safe use of the equipment.
- ⚠ CAUTION:**  
The system must be repaired only by authorized service personnel.

## Installing the Hardware

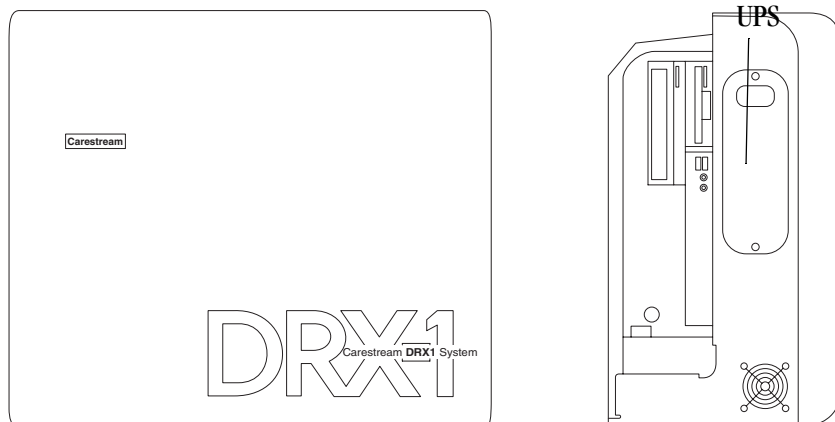
All equipment installations and adjustments must be performed by personnel authorized by Carestream Health only.

**Attaching Accessories** 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.

## Turning the System On and Off



### To turn the DRX-1 System On:

1. Press the **ON** switch on the UPS.
2. Press the **ON** switch on the computer and monitor.
3. When the software initializes, select the **DRX-1 icon** on the monitor.

### To turn the DRX-1 System Off:

1. Select the **Quick Menu** in the lower left corner of the monitor.
2. Select **Shut Down**.
3. Turn **Off** the monitor.
4. Turn **Off** the UPS.

You can remain in hold-on-prep for up to 15 seconds with the CARESTREAM DX-1 System Detector and the detector will function properly. In the event of an aborted exposure, the detector can acquire a subsequent image in four seconds.



**NOTE:** In the event of an aborted exposure, the detector acquires the image and processes it normally. This may result in less than optimal image quality.

**Exposure Time:**

The CARESTREAM DRX-1 System Detector can acquire images from exposures of up to 1 second.

## CARESTREAM DRX-1 System Battery



**CAUTION:**

To assure proper operation, use only the CARESTREAM DRX-1 System Battery.

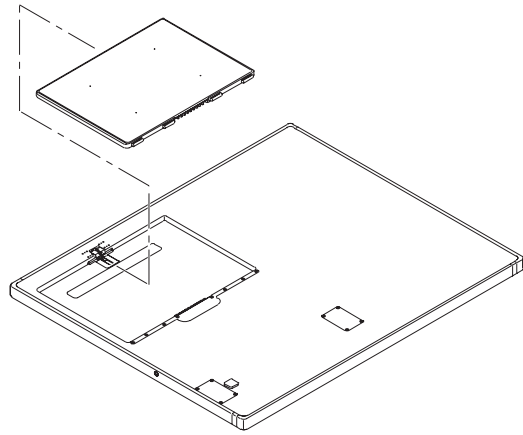
The DRX 1 System provides a battery charger with three charging slots for batteries for the DRX-1 System detector. You can purchase additional batteries separately. The battery is keyed for proper orientation in the detector.

- A battery is required for wireless or tethered use.
- Minimum battery life 500 charge and discharge cycles where the cell capacity remains above 80% of initial capacity.
- Expected life 1.5 years, assuming 1 charge per day.
- New battery provides approximately 90 image acquisitions (3.0 hrs heavy usage).
- A battery charge state is indicated on the Console. The detector determines if the installed battery is not properly charging, and provides this battery status to the Console.

### Installing the Battery

1. A fully-charged battery in the DRX-1 System Battery Charger will be indicated by a green light. The battery fits into the detector only one way. Place a fully-charged battery in the battery footprint in the DRX-1 detector so that the contacts on the back edge of the battery are inserted first.

### Installing the Battery

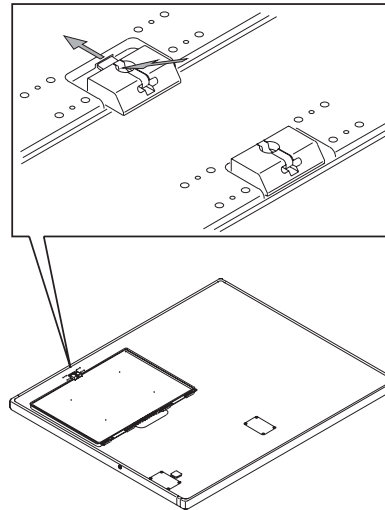


2. Push the battery firmly down until the latch catches.

NOTE: See the *CARESTREAM DRX-1 System Battery Charger User Guide* for information on the battery and charger use, specifications, and disposal.

**Removing the Battery** Place a tool such as a ball-point pen in the release slot and push down on the latch. The battery releases and pops up for easy removal.

### Battery Compartment Latch



## Labeling the Detector

The labels that come with the detector help you:

1. Uniquely identify the detector.

2. Orient the detector correctly in use.

Go to **Key Operator Functions > Equipment Management** to view the selections of DRX-1 labels to choose from. Labels are grouped by colors and number series so that you can keep the same scheme in each room. Make sure the label you choose is not already in the system.



#### Applying the label:

1. Place the detector on a flat surface with the Tube Side facing you.
2. Place the label inside the Tube Side label as indicated near the tube side corner label on the detector.

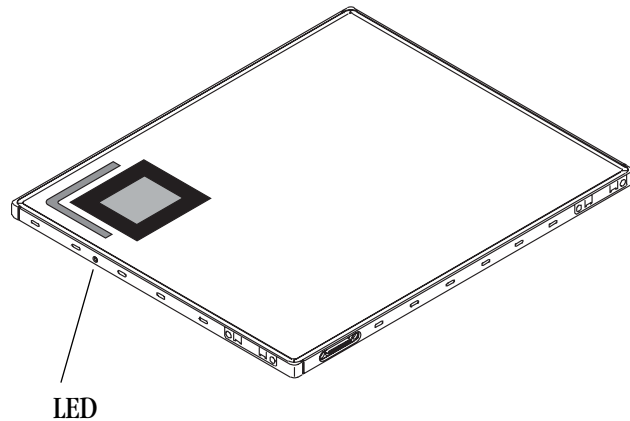


#### CAUTION:

**The detector is fragile and contains glass. Handle with care! Dropping the detector could result in damage or need for recalibration.**

## DRX-1 Detector LED

The detector has one LED that provides a status during operations. The single LED will alternate with blue and green flashes in various patterns. Green flashes relate to power. Blue flashes relate to connectivity. No flash pattern is displayed when the detector is acquiring an image.



LED Pattern	Meaning	Action
1 Green Flash	Standby, no study active; Console may not be connected. Low Power.	No action required. Detector is not being used.
2 Green Flashes	System is on, but not ready.	No action required. LED indicates the detector has been selected.
3 Green Flashes	System is on and enabled, but not ready.	Should not display in normal operation. If this pattern is visible, call Service.
4 Green Flashes	System is on and enabled, appears while pressing the prep switch.	Do not report an error if this pattern is not visible.
5 Green Flashes	Power fault has occurred. Detector is unusable.	Remove and re-insert the battery to clear the problem. If the problem persists, call Service.
1 Blue Flash	Detector is currently connected to the System Console.	No action required.
2 Blue Flashes	Detector not currently connected.	If this pattern occurs while detector is in use, call Service.
3 Blue Flashes	Detector has rebooted and has not yet connected to System Console.	If pattern occurs when the Detector should be in use, call Service.

## Positioning the Detector in the Bucky

For optimum performance, it is important to position the detector properly in the Wall Stand Bucky or the Table Bucky when performing an exam. To provide a visual guide for positioning, Service places a set of two positioning labels on each Bucky at installation to indicate how to orient the detector for portrait and landscape exams. To orient the detector properly, hold the detector so that the position of the ID label on the detector matches the

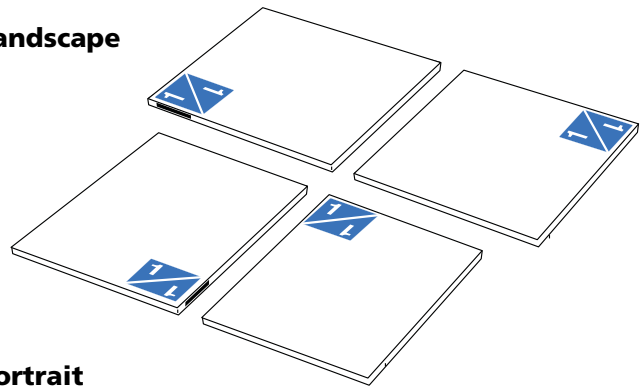
position of the orientation label on the portrait or landscape label on the Wall Stand or Table Bucky.

**Positioning Labels**



**Detector Positioning Labels**

**Landscape**



**Portrait**

### Example of Labels Applied to Table Bucky



## Range of Operation

### Using a Single Detector

A single detector may be placed in a Wall Stand Bucky, in a Table Bucky, on a table top, in a wheel chair, etc. The detector is registered with the Console for the room, but it may be registered with other Consoles in other rooms as well. Name the detector the same name as its icon and add a description to identify its location. See [“Acquiring the Image” on page 3-3](#) for a description of the Workflow.

### Using Two or More Detectors

Using two or more detectors in a room makes detector identification even more important. Make sure that the label on the detector matches the icon on the Console before exposing the patient. You must use the bar-code scanner while on the screen to read the bar-code on the detector when moving the detector to a new room.

**IMPORTANT:** *The system does not automatically select a detector. Supervise carefully to make sure that the correct detector is selected.*

**NOTE:** Leave the Wall Stand detector in the Bucky to reduce handling and assure correct detector selection.

See [“Acquiring the Image” on page 3-3](#) for a description of the Workflow.

## Using Detectors in Two or More Rooms

The identification labels make it easy to prevent mixing of detectors from one room to another. Keep a different color scheme for each room and then subsequent detectors can be assigned labels within that color.

You can register the same detector on two consoles. For example, you may use one detector as a “float” detector. The system is designed so that if the Console cannot communicate with the selected detector, the X-Ray generator will not fire. The workflow is the same. See the Online Help for information about workflow.

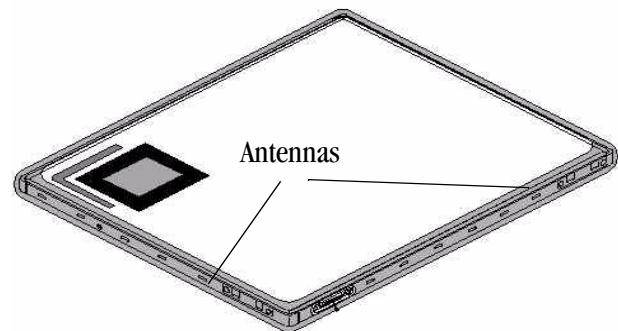
## Wireless Operation

Wireless operation lets you use the detector in an X-ray room without cabling. Wireless operation produces a direct digital image with the freedom to position the detector anywhere in the room. Wireless operation is intended for use in the table Bucky, in the Wall Stand Bucky, on the table top, or in the auxiliary positions, such as a wheel chair.

**NOTE:** A charged CARESTREAM DRX-1 System Battery must be installed for wireless use. See [“Installing the Battery” on page 2-5](#).

**NOTE:** The wireless IP address is registered with the system.

To assure good wireless communication, try to avoid obstructing the antennas on the two edges of the of the detector as shown.



If the wireless connection fails before an image is sent to the console, the detector can be connected to a tether to retrieve the image.

## Tether Operation

The primary function of the tether is to provide power and communications to the detector while it is positioned in a Bucky.



**CAUTION:**

**Do not allow the detector in tether mode to come in direct contact with a patient.**

The DRX-1 System Detector should be connected to the DRS-1 System Tether Interface when:

- The detector is located outside the patient vicinity.
- The detector is not being used for an exam.
- The detector is located inside a Bucky or other device that prevents direct patient contact.

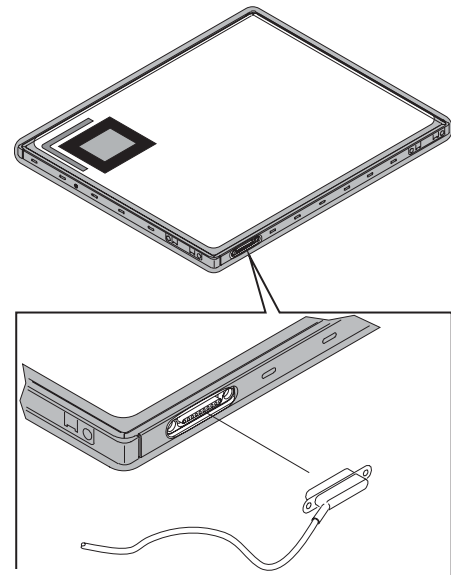
To use the detector in Tether Operation, connect the tether to the detector at the magnetic connector. If the tether is connected correctly, it will not interfere with the position of the detector. In addition, the tether:

- Provides power and communications to the detector when connected.
- Protects the detector from damage in handling.
- Eliminates the need to remove the detector to change a battery.
- Improves workflow.
- Does not interfere with grid or ion chamber operation.

To remove the DRX-1 System Detector from the tether and use it wirelessly, disconnect the tether. Make sure the DRX-1 System Detector comes into patient contact in wireless mode only.



## Tether Connection On Detector



**NOTE:** The detector will function properly with a non-charged battery installed when the tether is properly connected and operating. It is not necessary to remove the battery to recharge it if the battery has not reached end of life and can be re-charged.

**NOTE:** With a charged battery in place, image acquisition continues if there is a loss of tether connection.

**NOTE:** Additional tethers are available to replace damaged cables.

## Tether Interface Box

The Tether Interface Box and cables has its own AC Mains power cord and is located in the X-ray room. The Tether Interface Box is safety certified for casual patient contact.

## Cleaning the Hardware

**⚠ 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).

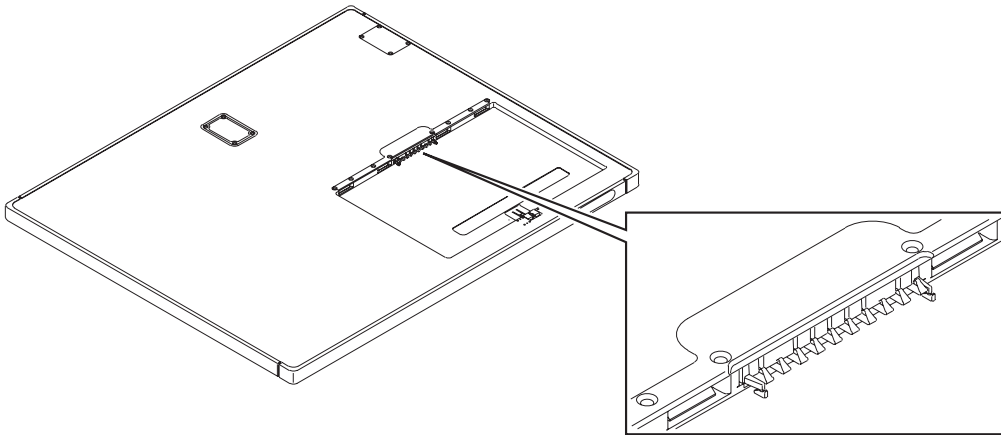
**⚠ CAUTION:**  
Do not immerse the equipment in liquid.

**To clean the detector:**

1. Disconnect the detector from its power source.
  - a. Remove the tether.
  - b. Remove the battery.
2. Moisten a cloth with a 70% Isopropyl alcohol solution.
3. Apply the moistened cloth to the equipment.

**To clean the battery footprint:**

1. Wipe the well clean of dust or debris with a soft cloth.
2. Use a brush or vacuum to clean out the prongs in the battery compartment well, or contact Service for assistance.



## With Each Occurrence of Patient Contact

**⚠ 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.

For each occurrence of patient contact:

- Moisten a cloth with the solution.

- Apply to the patient contact areas.



**CAUTION:**

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

## **System Maintenance**



**CAUTION:**

**Do not attempt mechanical or electrical repair of the CARESTREAM DRX-1 System. Contact your Service representative if any unit does not perform to your satisfaction.**

The CARESTREAM DRX-1 System must be maintained in good operating order at all times to provide safe conditions for operating personnel and patients. The DRX-1 System must also be maintained to prevent possible loss of patient or image data.

**With each occurrence of patient contact:**

- See “[With Each Occurrence of Patient Contact](#)” on page 2-14.

**Daily:**

- Clean the equipment.
- Check the integrity of the equipment.
- Daily Refresh Calibration. See **Running Detector Calibrations** in the *CARESTREAM DRX-1 System Online Help*.

**Monthly:**

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



**CAUTION:**

**The system must be repaired only by authorized service personnel.**

**Periodically or as needed:**

- Recalibrate the touch-screen 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.

## Checking the Equipment Integrity

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

- 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 following grids are used.

- 103 line pair/inch low frequency stationary grid

**Protective Enclosures** 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.

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