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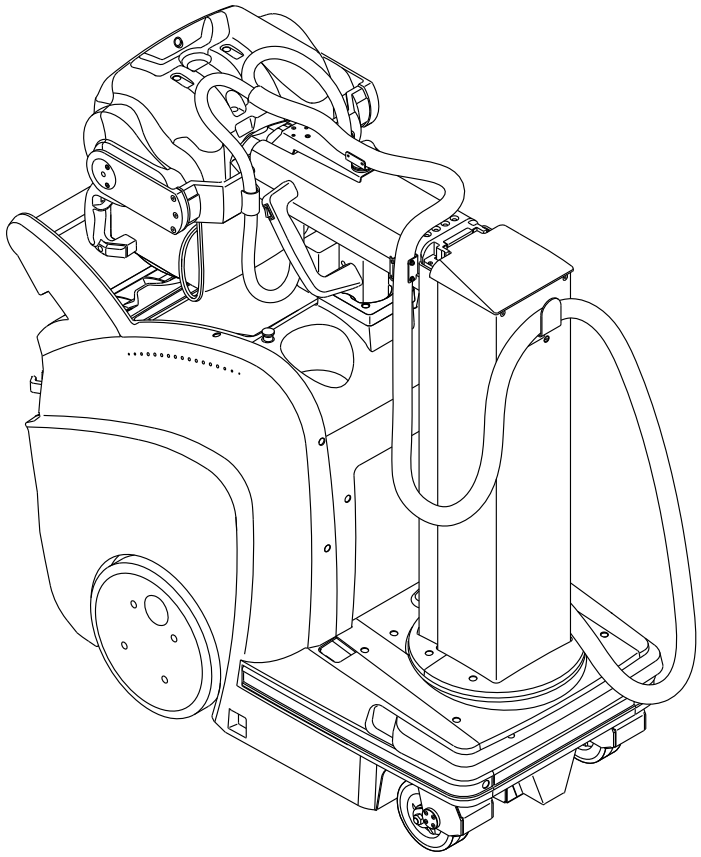
Site Specifications
for the
DRX-Revolution Mobile X-ray System



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Confidential

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This equipment includes parts and assemblies sensitive to damage from electrostatic discharge. Use caution to prevent damage during all service procedures.

Table of Contents

Section 1: Safety and Regulatory Information

Overview

Important

For complete safety and regulatory information, users should review the *DRX Revolution Mobile X-ray System Safety and Regulatory Information* Guide.

Personnel operating and performing maintenance on the equipment should receive training for the DRX-Revolution Mobile X-ray System and understand all of the phases of operation and maintenance. To provide safety, all users should read this section carefully before using the system.

Indication for Use

The DRX-Revolution Mobile X-ray System emits radiation when digital radiographic images are created and when the Detector Array is not in use. Read all safety labels on the equipment.

Safety Agency Marks

The DRX-Revolution Mobile X-ray System includes the Safety Agency marks for the U.S., Canada, and international sites. The DRX-Revolution Mobile X-ray System also includes a CB Certificate and CB Report from a CB Scheme safety agency. The CB Report includes all the national deviations.

Conforming Standards for the DRX-Revolution Mobile X-ray System—Safety

USA

- UL 60601-1:2003

Canada

- CAN/CSA-C22.2 No. 601.1-M90

Europe

- EN 60601-1:1990/AC:1994
- EN 60601-1-1:2001
- EN 60601-1-3:1994
- EN 60601-1-4:1996/A1:1999
- EN 60601-1-6:2004
- EN 60601-2-32:1994

International

- IEC 60601-1:1988 + A1 + A2
- IEC 60601-1-1:2000
- IEC 60601-1-3:1994
- IEC 60601-1-4:1996 + A1
- IEC 60601-1-6:2004
- IEC 60601-2-32:1994

Conforming Standards—EMC

Equipment and standards meet the following requirements:

- IEC 60601-1-2:2001 + A1:2004 Medical Electrical Equipment—Electromagnetic Compatibility Requirements and Tests, including CISPR 11:2003 + A2:2006 emissions to Class A limits.

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.

- 93/42/EEC MDD (Medical Device Directive)—Europe Only
- ICES-001 Issue 4: Class A Radiated and Conducted Emissions—Canada

For European Market Only

EC REP

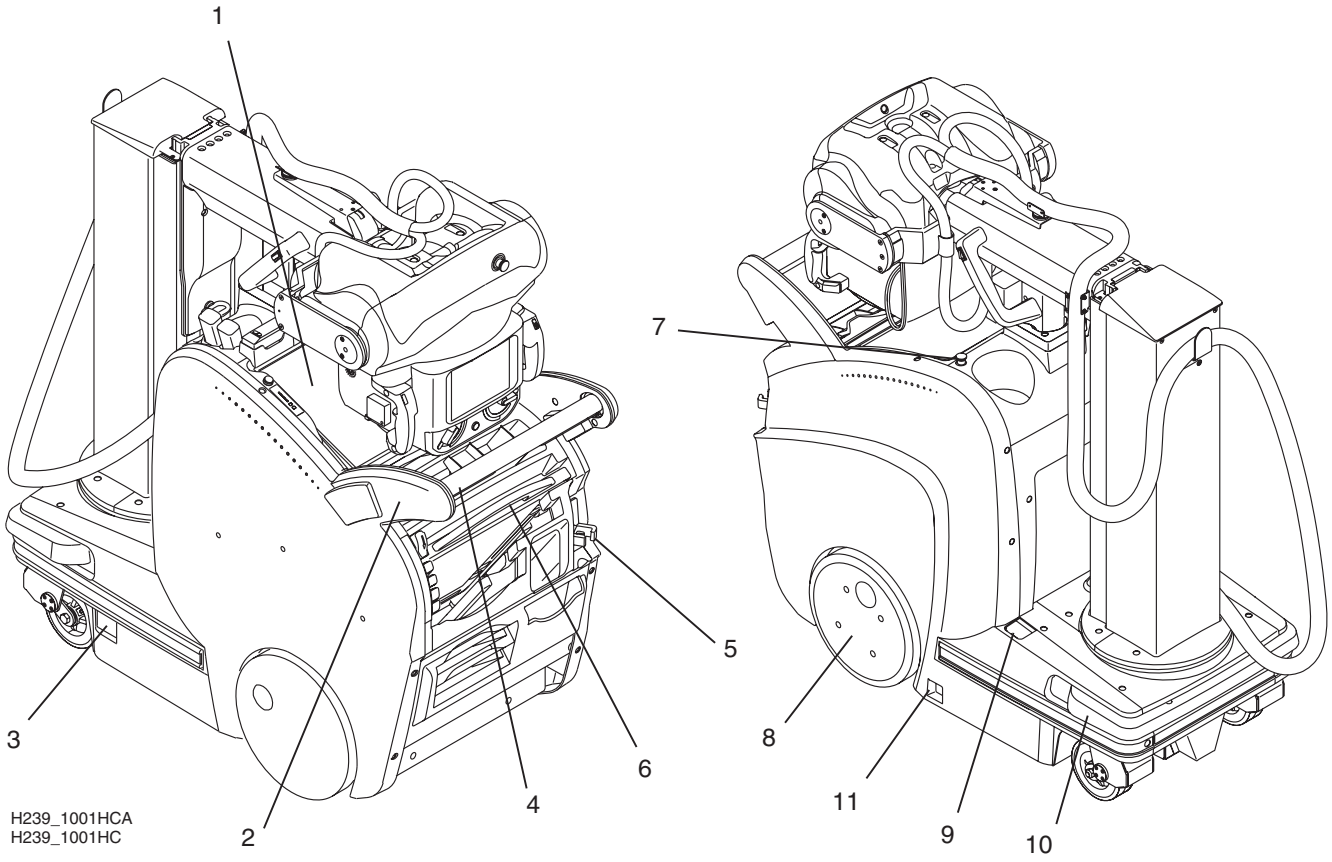
Carestream Health France
1, Rue GaililÈe
93192 NOISY-LE-GRAND CEDEX
FRANCE

Section 2: Product Description

Components

The DRX-Revolution Mobile X-ray System is a mobile digital radiographic system that incorporates a self-contained X-ray generator, image receptor, imaging display, and software for acquiring medical diagnostic images outside a standard X-ray room. It is a mobile diagnostic system intended to generate and control X-rays for the examination of various anatomical regions.

The system is designed for use in all locations of a hospital or a clinical site, including patient rooms, operating rooms, emergency departments, trauma bays, Intensive Care Units (ICU), and other patient treatment areas.



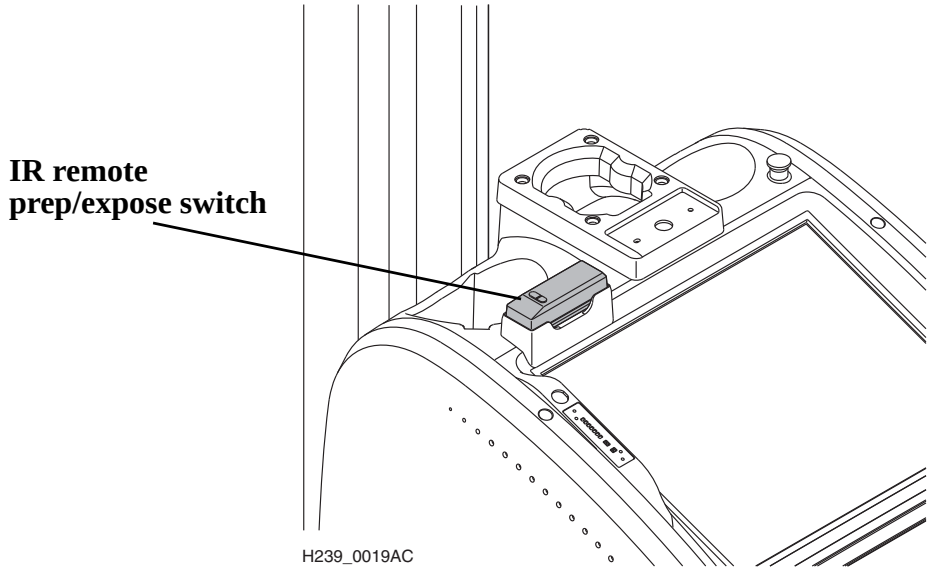
Item	Component
1	Primary monitor
2	Emergency brake
3	DC Circuit breaker (1 of 2 circuit breakers, found on each side of unit)
4	Drive handle
5	Prep/expose switch
6	DRX-1 detector
7	Emergency stop
8	Motorized drive wheel
9	Retractable AC power cord
10	Bumper sensor
11	AC Circuit breaker (1 of 2 circuit breakers, found on each side of unit)

Optional Wireless Prep/Expose Switch

The (IR) remote includes a prep/expose switch on top and a collimator light switch. A cord connects the receiver unit to the cart. The infrared (IR) wireless remote is available as an option.

Important

Multiple systems with the infrared (IR) remote prep/expose switch must not be used in the same area.
The IR remote prep/expose switch is not uniquely correlated to a specific system. Any IR remote prep/expose switch can fire any other mobile system that uses a remote switch, including Other Manufacture (OM) system, if ready.



Tethered Detector

If the power goes off, an emergency bin release and a detector tether are available. To operate the emergency bin release, insert the end of a paper clip into the pin hole to the left of the lock.

The DRX-1 Detector can be used wirelessly or tethered. The tether cannot be used with the grid operation.

RISK OF ELECTRIC SHOCK:

Exposures may be made with a tethered detector, but are not to be made with the machine plugged into the AC mains. The machine can be plugged in while making a wireless exposure only.

Section 3: Equipment and System Specifications

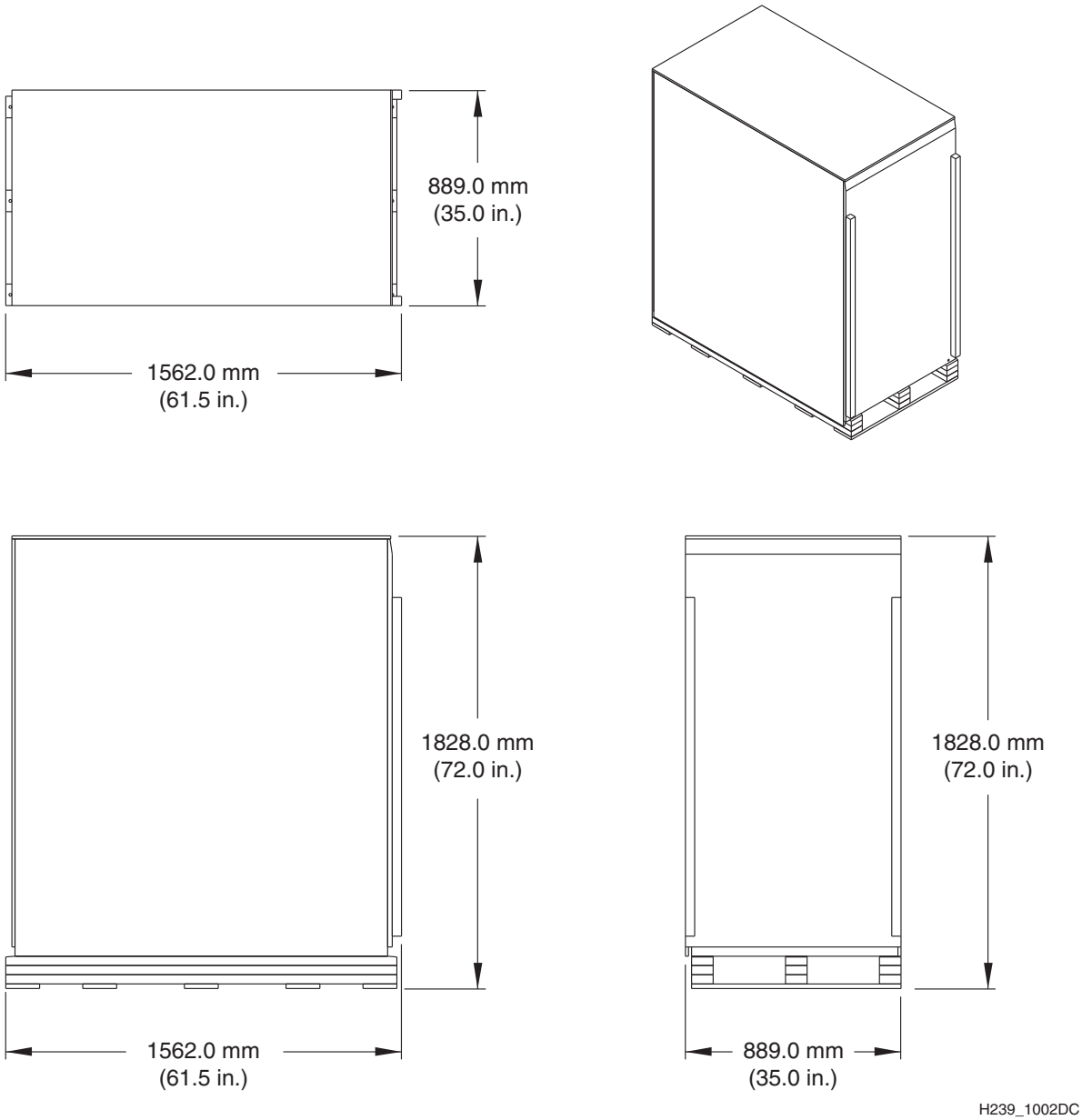
Packaging Specifications

DRX-Revolution Mobile X-ray System

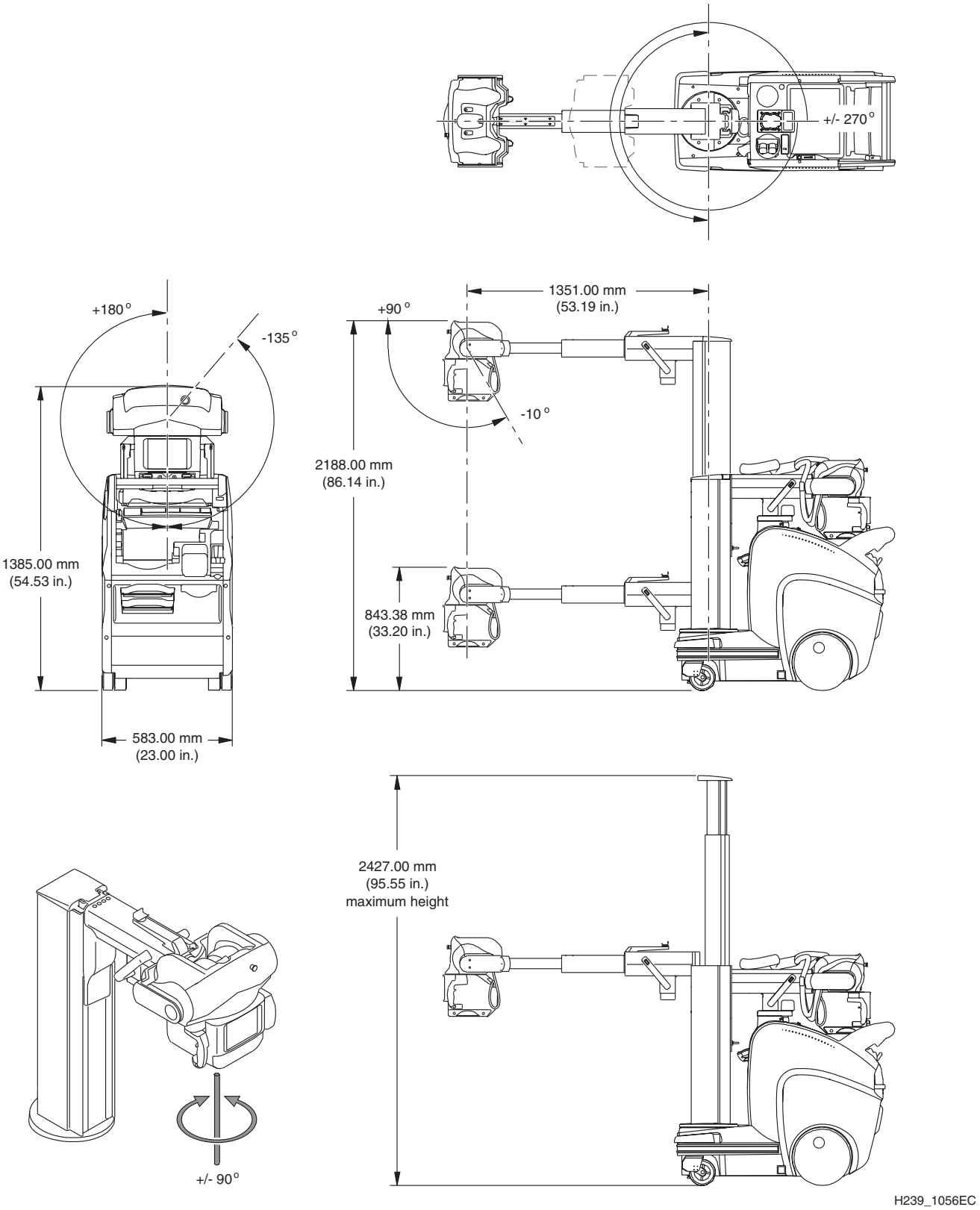
Measurement	Packed Crate Dimensions	Unpacked Cart Dimensions	Notes
Width	889.0 mm (35.0 in.)	583.0 mm (23.0 in.)	
Height	1828.0 mm (72.0 in.)	1385.0 mm (54.5 in.)	The tube head is docked.
Length	1562.0 mm (61.5 in.)	1290.0 mm (50.8 in.)	
Weight	697kg (1537 lbs)	575 kg (1268 lbs)	

(54.5 in.)

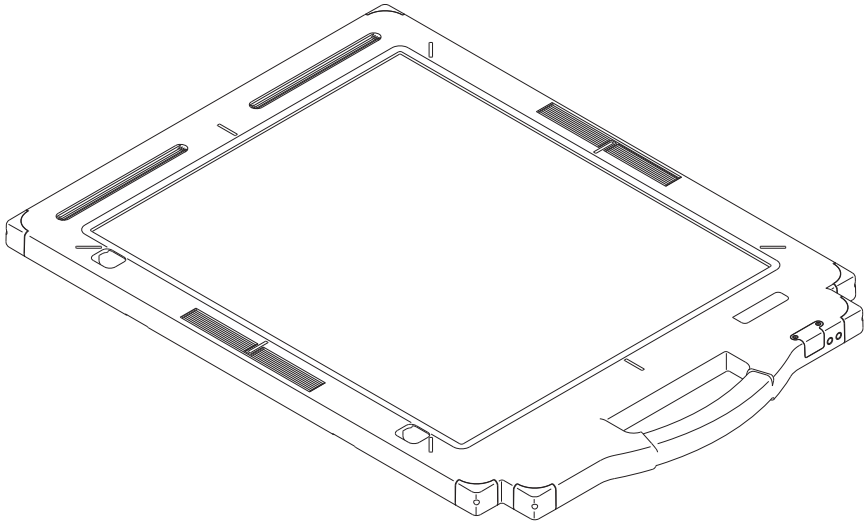
Dimensions of Cart Packed and Unpacked



Dimensions of Cart Operational



Accessory Dimensions—Grid Alignment Holder



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Measurement	Grid Alignment Holder Dimensions
Size	445.0 mm x 616.0 mm x 24.9 mm (17.5 in. x 24.2 in. x 0.98 in.)
Weight	1.86 Kg (1.20 lb)

DRX-1 System Product Information

DRX-1 System Detector

Detector Size	38.35 x 45.95 x 1.55 cm (15.00 x 18.10 x 0.6 in.)
Image Area	35.4 x 42.5 cm (14.0 x 16.7 in.)
Detector Weight	3.4 kg (7.5 lb)
Electrical Ratings	2–18 V (dc), 3 A

Technical Specifications

Detector Type	GOS / Amorphous Silicon
Pixel Pitch	139 µm
Active Image Area	35.4 x 42.5 cm (14.0 x 16.7 in.)
Usable Pixel Matrix	2544 x 3056 pixels
Limiting Resolution	3.6 up/mm (line pairs mm)
MTF (%), RQA-5 Beam	
0.5 cyc/mm, Typical	78
1.0 cyc/mm, Typical	54
2.0 cyc/mm, Typical	22
3.0 cyc/mm, Typical	9
DQE (%) +/-2ó <10%, RQA-5, 4 µGy	
0.0 cyc/mm, Typical	33
0.5 cyc/mm, Typical	29
1.0 cyc/mm, Typical	23
2.0 cyc/mm, Typical	13
3.0 cyc/mm, Typical	5
Energy Range	40–150 kVp
Pixel Fill Factor	100 %
Scan Method	Progressive
A/D Conversion (bits)	14 bits
Housing Material	Aluminum
Sensor Protection Material	Carbon fiber and aluminum plate (2.0 mm thick)

Environmental

Temperature Range	Operating + 15 to + 30° C (+ 59 to +86° F)
	Shipping – 23 to + 66° C (– 9.3 to + 150° F)

Environmental

Relative Humidity, Non-Condensing	Operating 10–86 %
	Storage 10–86 %

DRX-1C System Detector

Technical Specifications

Receptor Type	Amorphous Silicon on glass, no tiling
Conversion Screen	Deposited CsI (TI)
Pixel Size Resolution Limit	 139 x 139 µm 3.6 cyc/mm
Usable Pixel Area	35.0 x 42.3 cm 13.8 x 16.6 in. 2520 x 3032 pixels
MTF (%), RQA-5 Beam 0.5 cyc/mm, typical 1.0 cyc/mm, typical 2.0 cyc/mm, typical 3.0 cyc/mm, typical	 82 59 29 15
DQE (%)±2σ<10%, RQA-5, 2.5 µGy 0.0 cyc/mm, typical 0.5 cyc/mm, typical 1.0 cyc/mm, typical 2.0 cyc/mm, typical 3.0 cyc/mm, typical	 65 59 51 35 18
Energy Range	40–150 kVp
Pixel Fill Factor	100 %, pixel readout is behind pixel receptor layer
Scan Method	Progressive
A/D Conversion	14 bits

Supported Data Interfaces

Wireless	802.11 A or N
Tethered	10/100 Ethernet

Environmental

Shock	High shock tolerance
Temperature Range	Operating + 15 to + 30° C (+ 59 to + 86° F) Ambient-Storage + 15 to + 30° C (+ 59 to + 86° F) Shipping (with special packaging) – 23 to + 66° C (– 9.3 to 150.8° F)
Relative Humidity, Non-Condensing	Operating 10–86 % Storage 10–86 %

Mechanical

Size	35.00 x 43.00 cm (13.80 x 16.90 in.) cassette (ISO 4090) 38.35 x 45.95 x 1.55 cm (15.10 x 18.10 x 0.60 in.)
Weight	3.49 kg (7.70 lb)
Housing Material	Aluminum
Sensor Protection Material	Carbon fiber and aluminum plate (2.0 mm thick)

DRX-1 System Battery

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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*.

Technology	• Lithium-polymer technology • Smart battery technology prevents overcharge
Size	21.00 x 15.00 x 0.67 cm (8.20 x 5.90 x 0.26 in.)
Weight	0.40 kg (0.88 lb)
Electrical Ratings	14.8 V (dc), 2.1 A (nominal) capacity
Image per Charge	190 maximum images per charge
Expected Life	500 charge/discharge cycles results in ~80 % full charge energy
Safety Certification	IEC60601-1:1988 + A1:1991 + A2:1995

Mode of Operation

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

DRX-1 System Wireless Network Specifications

Technical Specifications

Network Protocol	TCP/IP
Network Type	Isolated private wireless LAN (WLAN)
Wireless Protocol	802.11
Band 1/2 Antenna Frequency Band Available Channels (fixed at installation)	 5.15–5.35 GHz 36, 40, 44, and 48
Band 4 Antenna Frequency Band Available Channels (fixed at installation)	 5.745–5.825 GHz 149, 153, 157, 161, and 165
Maximum Power of Detector Radio	50 mW
Number of Antennas on Detector	One each on 2 sides
IP addressing	Static private IP addresses for detectors, AP
Agency approvals	FCC Part 15
Typical Data Size	One 15 MB file per image
Dual Homed PC (2 NIC cards)	Hospital network connection, private network connection

Security

WPA2-PSK AES	Factory and user-loaded keys, WPA2 - Personal, FIPS 140-2 compliant AES encryption
SSID	Broadcast
Private Patient Identification Data	No patient ID data exchanged with detector
Pass Phrase	Non-default Pass Phrase

Important

- The system can have no more than three clients associated with the AP, where only one of the clients will be actively communicating with the AP.
- The DRX-Revolution Mobile X-ray System AP channel and transmit power are set at installation.
- Because of the intermittent bursts of data lasting only a few seconds, and the low transmission power, the impact of the DRX-Revolution Mobile X-ray System WLAN on the Hospital mobile devices is minimal.

Hospital Wireless Network Specifications

The DRX-Revolution Mobile X-ray System supports connectivity to the hospital's PACS, HIS/RIS, and printer destinations in three configurations:

- Wired,
- Wireless, or
- Wired and wireless

Configuration Deployed	IP Address Required	Network Connection Information Required	Registration of the DRX-Revolution Mobile X-ray System with Hospital Destination (if required)	Registration of Destination in the DRX-Mobile
Wired only	1 static or DHCP IP address (If DHCP, IP address must be on permanent lease).	• Static or DHCP address (If DHCP, make sure it has a permanent lease) • Subnet Mask • Default Gateway	You can register: • 1 static or DHCP IP address (run ipconfig /all to find out the DHCP IP address) • 1 AE Title	• AE Title • IP address • Port of the destinations
Wireless only		• SSID • Authentication Mode (For example: WAP2-PSK) • Encryption (TKIP, AES) • Network Key (Pre-shared Key) • Static or DHCP IP address • Subnet Mask • Default Gateway		
Wired and wireless	2 static or DHCP IP addresses	Both wired and wireless data are listed above.	You can register: • 2 static or DHCP IP addresses • 1 AE Title	

The DRX-Revolution Mobile X-ray System has the following configuration requirements:

- The DRX-Revolution Mobile X-ray System supports only 1 AE Title/Host name value, regardless of the connectivity option deployed.
- If the hospital supports both wired and wireless configurations, then the PACS, HIS/RIS, or printer destinations require the DRX-Revolution Mobile X-ray System to register the AE Title and IP address with them. The destinations must be able to register 2 static or DHCP IP addresses (wired and wireless) to one AE Title (DRX-Mobile).
- Storage commitment is not supported for wireless connectivity.

The wireless network of the hospital must have a sufficient quality of service and range for image delivery and worklist operations in the locations the DRX-Revolution Mobile X-ray System will service. The minimum wireless infrastructure requirements are:

- Minimum is 802.11 g. Supported 802.11 a/b/g/n access point or router hardware.
- Minimum data rate of 24 Mbps at the wireless client (DRX-Revolutio Mobile). CISCO AP requirements to achieve this rate are
  - Minimum signal strength of -77 dBM at the wireless client (DRX-Revolutio Mobile)
  - Minimum signal-to-noise ratio of 12 dBm at the wireless client (DRX-Revolutio Mobile)
- There is no greater than 60 % of the maximum client association capacity of the access point.
- The access points where the DRX-Revolution Mobile X-ray System will travel must be broadcasting the same SSID.

Operator Console to Hospital Network Wireless Communications

Technical Specifications

Network Protocol	TCP/IP
Network Type	Wireless LAN (WLAN)
Wireless Protocol	802.11 a/b/g/n
Frequency Band	2.4 GHz and 5 GHz
IP Address	DHCP or Static IP for wireless or wired connection
Client Adapter Model	Intel WiFi 6300 AGN

Security

Authentication	EAP–PEAP–MS–CHAPv2 EAP-LEAP EAP-PSK • The configuration with PEAP authentication is acceptable for use in the field • The use of the certificate file, to store authentication data, requires a CSH service engineer to connect to the system, either on site or remotely, to update the file • if the hospital changes the authentication specifics or the issued certificate expires, on the network side, without making the necessary changes to the certificate file, the wireless communication to the hospital might stop functioning and requiring a service call to connect. • Authentication methods that require user-entered credentials at every login are not supported
Encrypition	WPA2-Enterprise or Personal with AES or TKIP
Intrusion Detection/Prevention System	Agent runs on the console to prevent unauthorized processes or services from running.

Enterprise Security

Radius Server Supported	Cisco Secure ACS v4.2
Authentication Protocol Supported	• EAP-PEAP/MSCHAPV2 • EAP-TLS
Supported Certificate Extensions	.pem, p7b, p12, pfx, cer, crt, der

Section 4: Site Specifications

Receiving, Operation, and Storage Requirements

Preparing a Staging Area

If the equipment must be stored before installation, the customer should:

- Provide a staging area for a Carestream Health authorized service provider to unpack and energize the unit.
- Verify that the path between the storage and the staging areas can hold the width of the crates. See Packaging Specifications on Page 7.
- Provide a place to discard the shipping crates and the packing materials.

Important

- The customer must prepare the site before the installation of the DRX-Revolution Mobile X-ray System.
- The equipment is not delivered until the site is ready. Carestream Health orders the shipment of the DRX-Revolution Mobile X-ray System to the installation site by the carrier. The shipment includes one shipping crate, with a built-in ramp for removing the unit from the crate.
- The storage and staging areas can be in the same or separate sites, which is determined by space requirements, operation requirements, and traffic flow.
- If the path from the receiving area to the storage and staging area is too narrow to hold the shipping crates, call your Carestream Health authorized Service Provider in advance. A specialist unpacks the crates at the site.

Main Electrical Site Requirements

Important

The following amperage and kilowatt values assume an equipment load under normal conditions. The values do not reflect requirements for total electrical service needed.

All electrical connections should conform to the National Electrical Code and to state and local regulations for the country or locality in which the equipment is installed.

Electrical Site Requirements

Electrical requirements include:

- 100 / 120 / 200 / 240 V (ac)
- 14.4 / 12.0 / 7.2 / 6.0 A
- Single Phase 50/60Hz
- 1440 VA

2D Barcode Reader Charger Requirements

Electrical Site Requirements

Important

The following amperage and kilowatt values assume an equipment load under normal conditions. The values do not reflect requirements for total electrical service needed. All electrical connections should conform to the National Electrical Code and to state and local regulations for the country or locality in which the equipment is installed.

Electrical requirements include: 100-240 V (ac) .5 A Single Phase 50/60Hz

Transit and Storage Requirements

Important

The receiving and storage area(s) must be dry and able to provide the correct humidity and temperature control required for the equipment.

Temperature	–20 to 55° C (–4 to 131° F), provided the Detector Array is shipped in a Carestream Health-approved insulated shipping container.
Relative Humidity	10 - 86 % (allow condensation dry time before installing)
Atmospheric Pressure	644 - 1016 hPa (483–763 mm Hg)
Altitude	–31 to 3658 m (–102 to 12,000 ft)

Operating Requirements

Temperature	18–30° C (64–86° F)
Relative Humidity	30–65 % (allow condensation dry time before installing)
Maximum Gradient	5° C (9° F) - temperature must remain constant and stable
System BTU Output	Single Detector System - 23,770 BTU over an 8-hour interval for DRX-Revolution Mobile X-ray System with 1 Detector or 2971.25 (~2972) Dual Detector System - 24,725 BTU over an 8-hour interval for DRX-Revolution Mobile X-ray System with 2 Detectors or 3090.625 (~3091)

Publication History

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