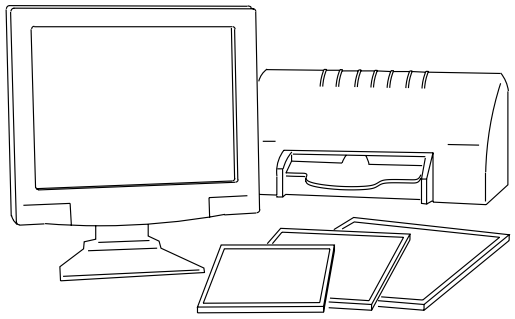
Kodak Point-of-Care CR 120/140 System

Hardware Guide

April 1, 2007



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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.

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Document Conventions

⚠ CAUTION:
Cautions point 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.

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*

General Safety Guidelines

- This product is designed and manufactured to ensure maximum safety of operation. Operate and maintain it in strict compliance with the safety precautions and operating instructions contained in this manual.
- This product meets all the safety requirements applicable to medical equipment. However, anyone attempting to operate the system must be fully aware of potential safety hazards.
- There are no user serviceable parts in this system. The product must be installed, maintained, and serviced by qualified service personnel according to procedures and preventive maintenance schedules in the product service manual. If your product does not operate as expected, contact your Service Representative.

- Do not modify this product in whole or in part without prior written approval from Carestream Health, Inc.
- Personnel operating and maintaining the CR System should receive training and be familiar with all aspects of operation and maintenance.
- To ensure safety, read all user manuals carefully before using the system and observe all Cautions, Importants, and Notes located throughout the manual.
- Keep this manual with the equipment.
- Reading this manual does *not* qualify you to operate, test, or calibrate this system.
- Unauthorized personnel are not allowed access to the system.
- If the product does not operate properly or fails to respond to the controls as described in this manual:
  - Follow the safety precautions as specified in this manual.
  - Stop using the scanner and prevent any changes to it.
  - Immediately contact the service office, report the problem, and await further instructions.
- The images provided by this system are intended as tools for the trained user. They are explicitly not to be regarded as a sole incontrovertible basis for clinical diagnosis.
- Be aware of the product specifications and of system accuracy and stability limitations. Consider these limitations before making any decision based on quantitative values. If you have any doubts, consult your Sales Representative.

⚠ CAUTION:
Do not use the product within six feet of a patient.

Electrical Hazards

⚠ CAUTION:
Do not remove or open system covers or plugs. Internal circuits use high voltage capable of causing serious injury. Fuses blown within 36 hours of being replaced by a qualified technician may indicate malfunctioning electrical circuits within the system. Have the system checked by qualified service personnel. Do not attempt to replace any fuse. Fluids that seep into the active circuit components of the system may cause short circuits that can result in electrical fires. Therefore, do not place any liquid or food on any part of the system.

Explosions and Implosion Hazards

CAUTION:

Do not operate the equipment in the presence of explosive liquids, vapors, or gases. Do not plug in or turn on the system if hazardous substances are detected in the environment. If these substances are detected after the system has been turned on, do not attempt to turn of the unit or unplug it. Evacuate and ventilate the area before turning off the system.

Overheating

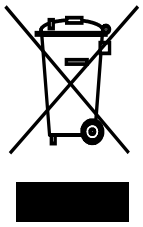
Do not block the air circulation around the Scanner. Always maintain at least 6 inches (15 cm) clearance around the Scanner to prevent overheating and damage to the system.

Laser Safety Instructions

During normal operation, always keep the scanner enclosed in its protective cover to prevent the outside area from being exposed to laser emission.

During normal operation, do not remove the cover. Only a qualified technician may remove the cover to service this product.

Recycling the Scanner

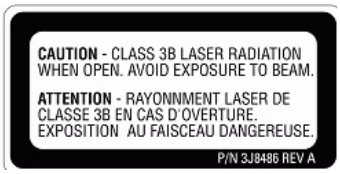


In the European Union, this symbol indicates that when the last user wishes to discard this product, it must be sent to appropriate facilities for recovery and recycling.

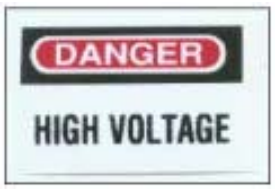
Contact your local authorized representative or refer to **www.kodak.com/go/recycle** for additional information on the collection and recovery programs available for this product.

Labeling Summary

Laser-emitting product



CLASS 3B LASER PRODUCT INSIDE



HIGH VOLTAGE

IEC Symbols Used

The system may have labels with one or more of the following symbols. These symbols indicate the IEC standards to which the system conforms.

Caution — consult accompanying documents

Protective earth points

Power ON

Power OFF

Device-Specific Safety Information

LIFTING HAZARD

The *Kodak* Point-of-Care CR 120/140 scanner weighs 45 kg (99 lb). Do not try to lift the scanner by yourself. Always seek assistance from another person. Lifting equipment that is too heavy may result in serious injury and/or damage to equipment.

⚠ CAUTION:
The *Kodak* Point-of-Care CR 120/140 scanner is a CLASS 1 Laser product.

- Do not remove the scanner cover.
- Only authorized service personnel may remove the cover.

COMPLIES WITH 21 CFR 1040.10 AND 1040.11 EXCEPT FOR DEVIATIONS PURSUANT TO LASER NOTICE NO. 50, DATED JULY 26, 2001.

CLASS 1 LASER PRODUCT, and IEC/EN 60825-1.

CLASS 1 EQUIPMENT.

INTENDED FOR CONTINUOUS OPERATION.

PRODUCT IS PROVIDED WITH ORDINARY PROTECTION AGAINST THE HARMFUL INGRESS OF WATER.

NOT SUITABLE FOR USE IN THE PRESENCE OF A FLAMMABLE ANESTHETICS MIXTURE WITH AIR OR WITH OXYGEN OR WITH NITROUS OXIDE.

The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- Use of the accessory in the patient vicinity.
- Evidence that the safety certification of the accessory has been performed in accordance with IEC 60601-1 or the system to IEC 60601-1-1 or local equivalent.

Health and Safety Compliance

The scanner was examined for compliance and has classifications and licenses as follows:

⚠ 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.

U.S.A

UL 60601-1 Medical Electrical Equipment 1st Edition, 2003

Canada

CAN/CSA 22.2 No. 601.1-M90 - Medical Electrical Equipment (R2001)

CAN/CSA 22.2 No. 601.1S1-94 - Supplement No. 1-94 to Medical Electrical Equipment (R1999)

CAN/CSA 22.2 No. 601.1B-90 - Amendment 2 to Medical Electrical Equipment (R2002)

International

IEC 60601-1: 1988, +A1 (1991), +A2 (1995) Medical Electrical Equipment

IEC 60825 - 1: 1993 +A1:1997 + A2:2001 Safety of Laser Products.

Regulatory Information

The Product conforms to the following safety standards: IEC 60601-1:2001, IEC 60601-2:2001 Medical Electrical Equipment General Requirements for Safety; EN 60601-1-2:2001 Safety of Laser Products - Part 1: Equipment Classification, Requirements and User's Guide; IEC 60825-1 Safety of Laser Products.

Electromagnetic Emissions/Immunity

1. 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.

2. Communications Equipment

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

3. 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.

4. Other Equipment

   The CR 120/140 scanner should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the scanner should be observed to verify normal operation in the configuration in which it will be used.

5. Cable, Accessory and Transducer Information for the CR 120/140

scanner.

Port Type	Port Description	From	To	Cable Type	Cable Length
Power	AC power	CR 120/140	AC Mains (via UPS)	Unshielded	1.5 m
Signal	USB	CR 120/140	PC	Shielded	2.5 m

6. Shielded Locations

   Not applicable.

Electromagnetic Emissions for Group 1, Class A Equipment		
The CR 120/140 scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the CR 120/140 scanner should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The CR 120/140 scanner 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 B	The CR 120/140 scanner is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings 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 Systems Fully Compliant with IEC 60601-1-2:2001			
The CR 120/140 scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the CR 120/140 scanner 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 differential mode +/- 2 kV common mode	+/- 1 kV differential mode +/- 2 kV common mode	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% 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.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CR 120/140 scanner requires continued operation during power mains interruptions, it is recommended that the CR 120/140 scanner be powered from an uninterruptible power supply.
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.			

Electromagnetic Immunity for NonLife Supporting Equipment and Systems

The CR 120/140 scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the scanner should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the CR 120/140 scanner, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.17 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 v/m 80 MHz to 2.5GHz	3 v/m	$d = 1.17 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.33 \sqrt{P}$ 800MHz to 2.5GHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, 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.

Electromagnetic Immunity for NonLife Supporting Equipment and Systems

[a] 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 CR 120/140 scanner is used exceeds the applicable RF compliance level above, the CR 120/140 scanner should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CR 120/140 scanner.

[b] 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 CR 120/140 Scanner

The CR 120/140 scanner is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the scanner can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the scanner 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.

CE Conformity

This product conforms to the requirements of council directive 93/42/EEC. The *Kodak* Point-of-Care CR 120/140 is a Class I medical device. The *Kodak* Point-of-Care CR 120/140 bears the following mark of conformity: CE .

European Authorized Representative

Carestream Health Deutschland GmbH
Product Safety
Hedelfinger Str. 60
70327 Stuttgart, Germany
Telephone: 49-711-406-2993

USA Regulations

The FDA cleared the system for sale in the USA.

CAUTION:
Federal US law restricts this device for sale by or on the order of a physician.

2 Using the Scanner

The *Kodak* Point-of-Care CR 120/140 System is designed for medical professionals to read phosphor x-ray screens (CR).

The system consists of the *Kodak* Point-of-Care CR 120/140 scanner and includes:

- *Kodak* Quality Control software for *Kodak* Point-of-Care CR Systems
- Plug and play USB2 interface
- Optional image viewing and archiving software that supports the Digital Imaging and Communications in Medicine (DICOM)3.0 standard, such as *Kodak* Acquisition Software for *Kodak* Point-of-Care CR Systems
- Optional screens and cassettes in the following standard sizes: 8" x 10"; 10" x 12"; 14" x 14"; 14" x 17"; 24 x 30 cm.

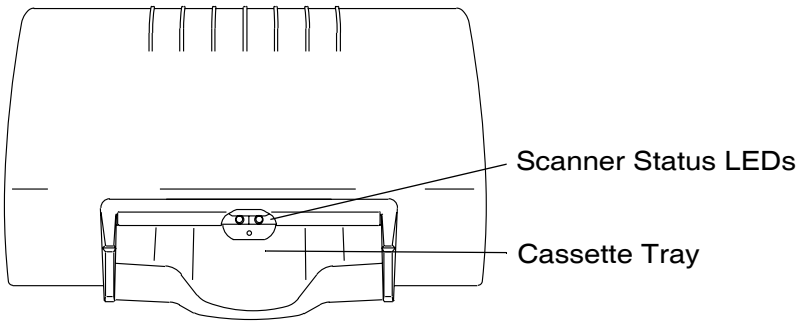
Operational Principles

The *Kodak* Point-of-Care CR 120/140 System is a digital imaging system for image acquisition and processing of static projection radiography that uses a phosphor screen with energy storage capability as an x-ray image receptor.

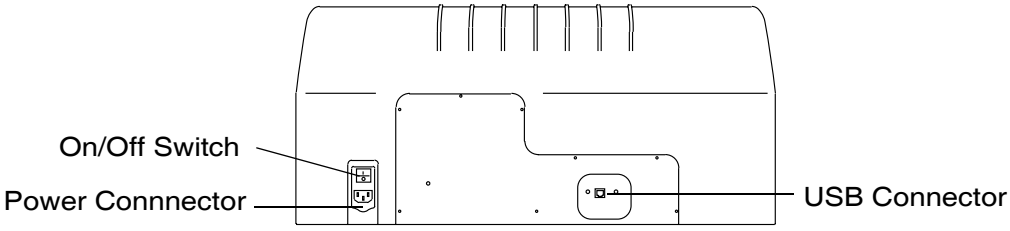
After exposure, a laser beam, which stimulates luminescence proportional to the local x-ray exposure, reads the screen. The luminescence signal is digitized and processed.

The *Kodak* Point-of-Care CR 120/140 scanner enables you to read a screen quickly and erase it for the next exposure.

Scanner Views



Front View of Scanner



Rear View of Scanner

Scanner Status Indicators

Two light-emitting diode (LED) status indicators are located on the front of the *Kodak* Point-of-Care CR 120/140 scanner above the cassette entry slot. Each indicator can appear green or orange; the color can be either steady or blinking.

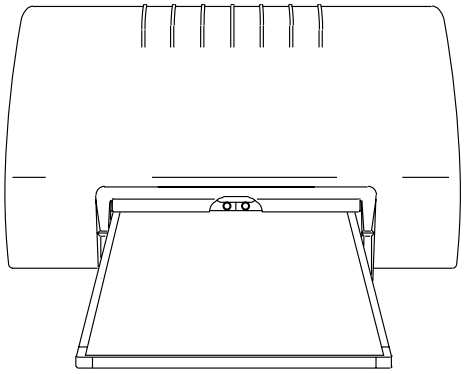
The colors indicate the following:

System Status	Left LED	Right LED
Ratation Motor Calibration	Green blinking	Green blinking
Scanner warming up, please wait.	Green blinking	Green blinking
Insert Cassette	Green	Green
Loading Cassette/Plate	Green blinking	Green blinking
Ready for Scan	Green	Green
Scanning	Green blinking	Green blinking
Saving image and erasing	Green blinking	Green blinking
Unloading Cassette/Plate	Green blinking	Green blinking
Error	Orange blinking	Orange blinking

Loading a Cassette

The image screen is contained in the cassette. The only time that the screen should be out of the cassette is when the scanner automatically loads it into the Scanner Drum for reading.

1. Verify that the Scanner status is "Insert Plate."
2. Insert the cassette into the scanner with:
   - The blank side up.
   - The open edge toward the Scanner.
   - The cassette centered exactly in the Scanner slot.



3. Slightly push the cassette into the scanner.

   The scanner status indicates "Loading Cassette." The screen is automatically "pulled" and loaded into the Scanner. When the screen is loaded, the status changes to "Ready for Scan."

   You can now scan, erase, or unload the screen. For further instructions, refer to the *Kodak* Point-of-Care CR 120/140 System Software Guide.

NOTE: If you do not take any action within two minutes, the cassette is automatically ejected, and a message is displayed.

Cleaning the Rollers

Periodically clean the rollers to remove dust and small particles. The roller-cleaning device enables you to clean the rollers that feed the screenscreenfrom the cassette into the Scanner.

The cleaning device includes the following items:

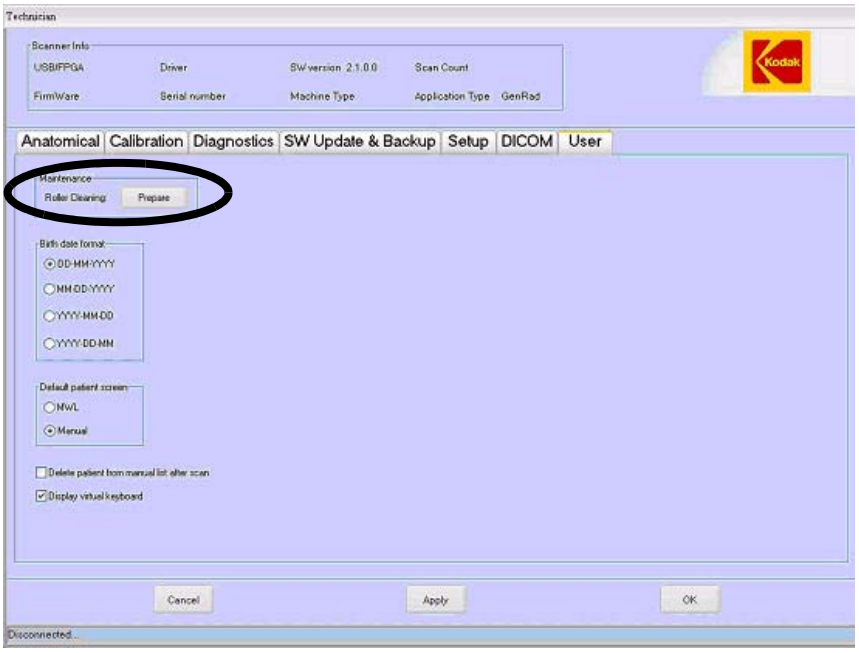
- Cleaning Tray
- Cleaning Plate with adhesive strips covered with protective paper / a protective envelope.

Using the Cleaning Plate to Clean the Rollers

1. Remove any cassettes and screens from the Scanner.
2. Open the *Kodak* QC software.
3. In the Scanner Interface, click the **Setup** button.

   The Password dialog box opens.
4. Click **Login**.

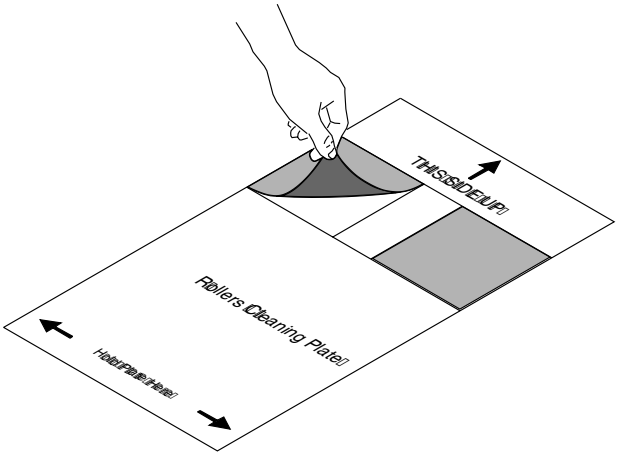
   The User screen opens.
5. In the **User** tab, click the **Prepare** button.



The following message appears:

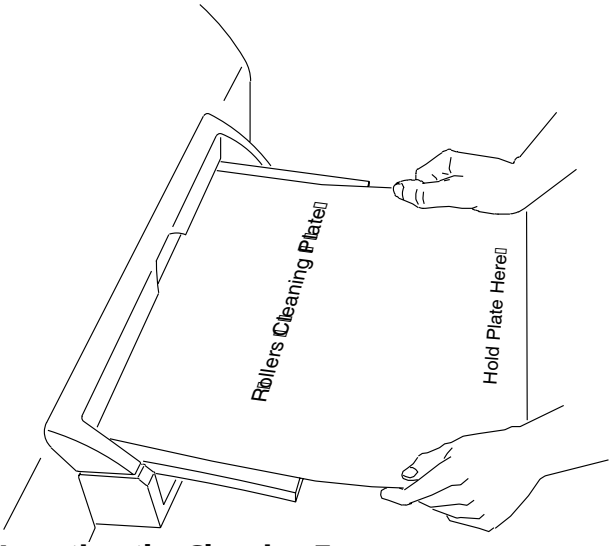
6. Insert the Cleaning Tray, making sure that it locks into place.
7. Click **OK**.

   The rollers begin to rotate.
8. Remove the protective paper from the cleaning plate to expose the adhesive.



Removing the Protective Strips

9. Place the cleaning plate on the tray. Make sure the cleaning plate is placed in the correct direction, as specified on the plate.

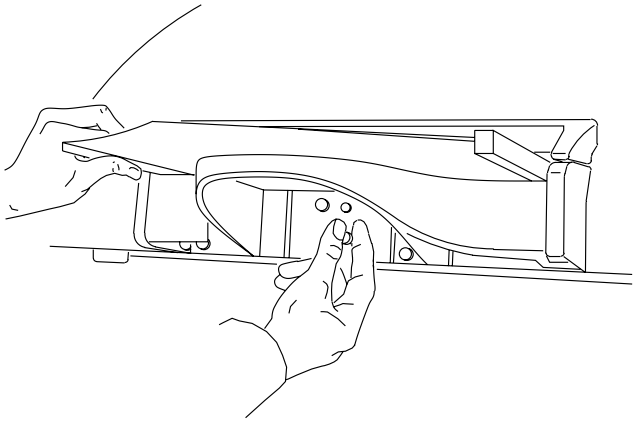


Inserting the Cleaning Tray

10. While holding onto the plate, push the plate slightly into the Scanner. It should go in almost entirely, with approximately 1/4 remaining outside.

    The following message appears:

11. Click **OK** and remove the Plate.
12. Disconnect the cleaning tray by completely pulling out the knob underneath the front tray until it comes to a stop.



Disconnecting the Cleaning Tray

The Scanner performs a reset (homing cycle).

NOTE: If the homing is not performed, turn the scanner off and then back on.

13. Repeat the cleaning process two more times.

Cleaning the Scanner

Clean the outer surfaces only with water using a soft, lint-free cloth. Dampen the cloth, then wipe the outer surfaces lightly.

⚠ CAUTION:

Do not use alcohol or alcohol-based products to clean any of the scanner components.

3 Specifications

Weight: 45 kg (99 lb)

Dimensions (W x D x H): 733 x 655 x 340 mm (39" x 26" x 14")

Screen type: *Kodak* Flexible GP Phosphor Screen

CR 140

Screen Size	Pixel pitch (μm)	Matrix Size	Spatial resolution (lp / mm)	Scan Time (sec.) (TTFI)	Cycle Time Screens / Hour
14" x 17"	173	2120 x 2548	2.5	60	40
14" x "17" HR	86	4216 x 5092	4.2	122	22
14" x 14"	125	2916 x 2916	3.5	80	34
14" x 14" HR	86	4216 x 4216	4.2	122	22
10" x 12"	125	2092 x 2508	3.5	63	40
10" x 8"	100	2628 x 2116	4.2	72	38
24 x 30 cm	125	1988 x 2468	3.5	62	40

CR 120

Screen Size	Pixel pitch (μm)	Matrix Size	Spatial resolution (lp / mm)	Scan Time (sec.) (TTFI)	Cycle Time (sec.) Screens / Hour
14" x 17"	173	2120 x 2548	2.5	110	21
14" x "17" HR	86	4216 x 5092	4.2	210	13
14" x 14"	125	2916 x 2916	3.5	147	17
14" x 14" HR	86	4216 x 4216	4.2	210	13
10" x 12"	125	2092 x 2508	3.5	113	22
10" x 8"	100	2628 x 2116	4.2	138	20
24 x 30 cm	125	1988 x 2468	3.5	108	23

Carestream Health, Inc.
Rochester, N.Y. 14608

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