

CARESTREAM CR Mammography Cassette with EHR-M3 Screen



The CARESTREAM CR Mammography Cassette with EHR-M3 Screen is designed for computed radiography (CR) in mammography screening and diagnostic applications. The EHR-M3 screen yields optimal image quality with reduced noise and improved detective quantum efficiency (DQE). The cassette:

- Positions the screen in closer proximity to the chest.
- Supports the use of automatic exposure control (AEC) devices.

The screen is an upgrade of the EHR-M2 mammography screen. The EHR-M3 screen:

- has a new CR storage phosphor preparation (smaller particle size) and screen formulation.
- is designed to improve the image quality of specific systems.

Recommended Uses

The CARESTREAM CR Mammography Cassette with EHR-M3 Screen is for use in mammography imaging with the following systems:

- KODAK DIRECTVIEW CR850/950/975 Systems with the KODAK CR Mammography Feature
- KODAK DIRECTVIEW Classic/Elite CR Systems with the KODAK CR Mammography Feature

System Requirements

- EHR-M3 and EHR-M2 screens are not intended for use in the same CR reader.
- CR systems must be calibrated for either EHR-M3 or EHR-M2 screens.
- The KODAK CR Mammography Feature must be fully installed and enabled.
- Version 5.x software must be running on the CR system. All of the non-clinical testing used to validate this product has been completed on Version 5.25 software.

CR System Overview

The KODAK DIRECTVIEW CR 850/950/975 and Classic/Elite CR Systems process and produce digital images directly from latent images captured on storage phosphor screens. You can reproduce, reprocess, and distribute images to other output and storage devices.

The Classic/Elite CR Systems are designed for flexibility in distributed radiography applications where the user console and reader can be located apart to optimize workflow. In addition, the console and reader can be co-located for central processing environments.

The CR Systems manage patient and examination information associated with captured and stored images. They can interface with a PACS Broker, such as a MITRA broker to obtain patient demographic data from the site HIS/RIS. The data is sent to the CR System where it is associated with the proper image. Use the CR System to:

- Read images on a phosphor screen exposed using conventional X-ray generators.
- Modify images and change image orientation.
- Enter examination and patient information using the KODAK DIRECTVIEW Remote Operations Panel (ROP), the bar code scanner, or the touch screen monitor.
- Correct erroneous patient or examination information.
- Store images that have incomplete patient or study data until the required data is added and the image is accepted.
- Create collections of related images and data (a procedure).
- Send exams to DICOM storage devices, physicians' diagnostic viewing stations, and DICOM laser imagers.

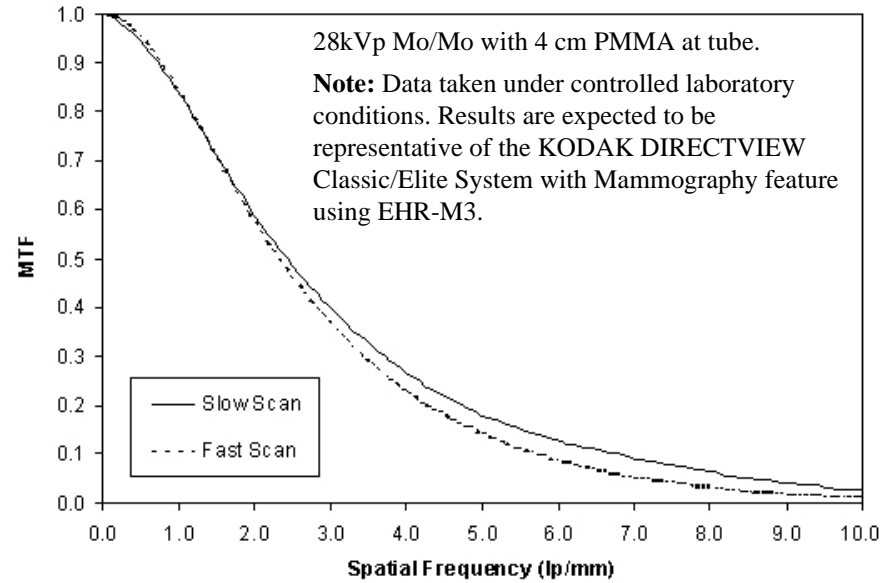
Conformity and Standards

- EN 62366:2008 Medical devices – Application of usability engineering to medical devices.
- EN ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes.
- EN ISO 14971:2007 Medical devices – Application of risk management to medical devices.
- EN 980:2008 Symbols for use in the labeling of medical devices.
- EN 1041:1998 Information supplied by the manufacturer with medical devices.
- ISO 7000:2004 Graphical symbols for use on equipment – Index and synopsis.
- EN ISO 4090:2004 Photography – Medical radiographic cassettes / screens / films and hard-copy imaging films – Dimensions and specifications.

Laboratory Test Results

Note: Diagnostic image quality is the result of full system performance including mammography screen, proper exposure technique, proper scanner calibration, and image processing software. Actual results are system specific.

KODAK DIRECTVIEW Classic/Elite V5.2 – EHR-M3 Screen, 18 cm x 24 cm



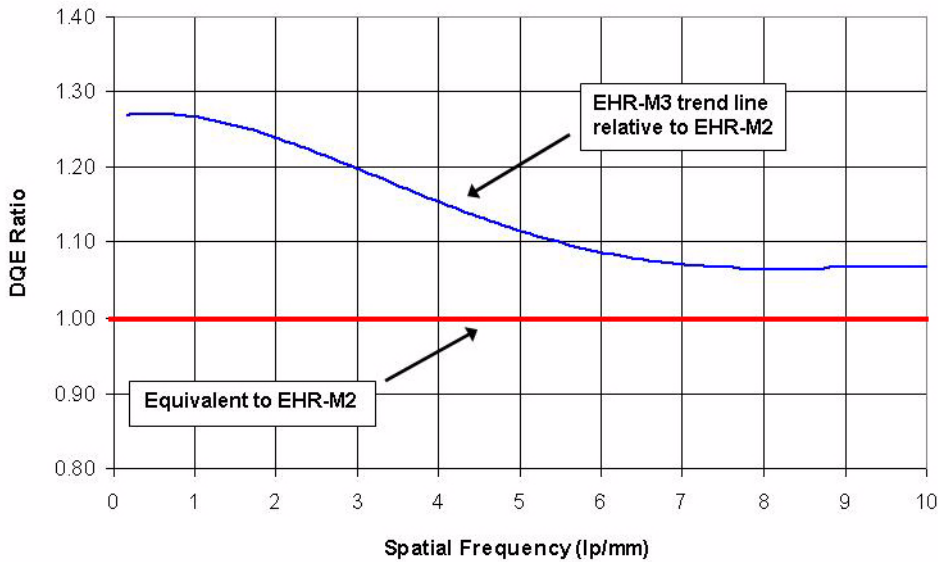
Spatial Frequency for Specified MTF

Spatial Frequency (lp/mm)	Slow Scan	Fast Scan
0.5	0.9455	0.9579
1.0	0.8463	0.8536
2.0	0.5868	0.5748
3.0	0.4010	0.3708
4.0	0.2631	0.2262
5.0	0.1798	0.1420
6.0	0.1291	0.0884
7.0	0.0916	0.0521
8.0	0.0628	0.0310
9.0	0.0398	0.0167
10.0	0.0267	0.0088

Non-Clinical Test Results

Detective Quantum Efficiency (DQE)

Normalized M3 Screen to M2 Screen Ratio Plot



The DQE of the EHR-M3 screens shows superior results across the entire frequency range in the slow scan direction.

Contrast to Noise Ratio (CNR)

The assessment of image quality is primarily achieved with the measurement of the CNR. This measurement requires a uniform phantom with a test object of slightly varying attenuation. Testing was performed at 50, 60, and 70 mm thickness with the EHR-M3 screen providing adequate CNR performance similar to the EHR-M2 screen and demonstrating its capability of passing the CNR test.

Note: The European Protocol for the CNR test is a relative test; although M3 and M2 perform similarly in the relative test, the M3 has a higher absolute CNR value.

CNR For 2.4 mGy

PMMA Thickness	T/F	kVp	mAs	MGD (mGy)	Acceptable Dose Limit (mGy)	M3 CX8395-4		M2 Production		CNR Passing Requirement
5 cm	MR	26	212	2.43	3.00	9.55	115%	7.81	115%	100%
6 cm	MR	30	178	3.14	4.50	8.16	98%	6.63	98%	95%
7 cm	RR	30	191	2.87	6.50	8.07	97%	6.28	92%	90%

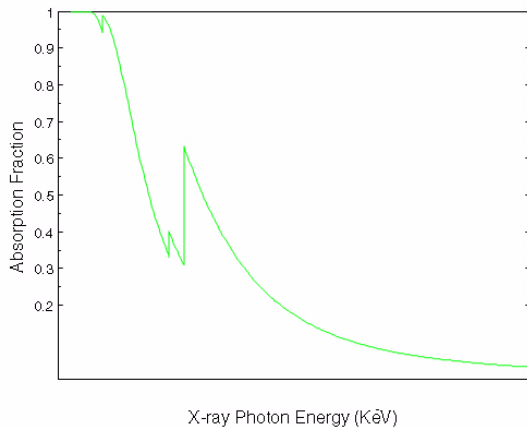
CNR For 2.0 mGy

PMMA Thickness	T/F	kVp	mAs	MGD (mGy)	Achievable Dose Limit (mGy)	M3 CX8395-4		M2 Production		CNR Passing Requirement
5 cm	MR	26	174	2.00	2.40	8.93	115%	7.25	115%	100%
6 cm	MR	30	146	2.56	3.60	7.54	97%	6.07	96%	95%
7 cm	RR	30	157	2.36	5.10	7.43	96%	5.74	91%	90%

Absorption

X-Ray Absorption Efficiency

X-ray Absorption Efficiency – EHR-M3



Sizes

CARESTREAM CR Mammography Cassettes with EHR-M3 Screens are available in two sizes:

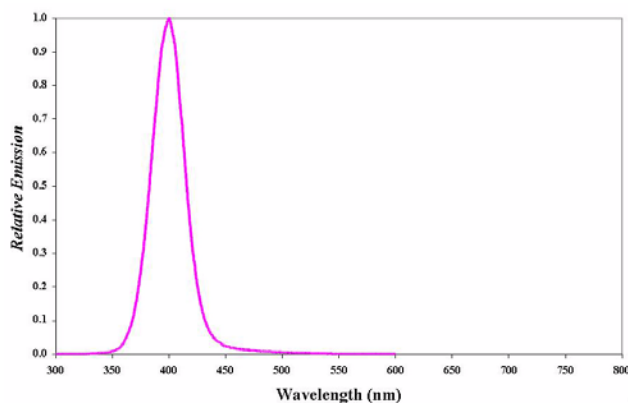
- 18 cm x 24 cm (7 in. x 9.5 in.)
- 24 cm x 30 cm (9.5 in. x 12 in.) – a larger version of the cassette with a larger AEC area and specifications for cassette length, width, and thickness that are compliant with ISO 4090 requirements.

Storage and Lifetime

The expected life of the CR mammography cassette is five years. The expected life of the EHR-M, EHR-M2 and EHR-M3 screens are 10,000 actuations, but this number will vary according to handling practices and environmental conditions. Careless handling and dirty environments can shorten the useful lifetime of an imaging plate. The cassette warranty is one year for return and repair.

Emission

EHR-M3 Phosphor Emission



Important

When cleaning a cassette and screen, take care to maintain the integrity of the phosphor screen and avoid introducing artifacts. Inspect all phosphor screens monthly and clean as necessary with KODAK Screen Cleaner used according to the manufacturer's instructions. When wear is evident, replace the screen.

Temperature Range

The normal temperature operating range for EHR-M3 screens is 59°F to 86°F (15°C to 30°C), 15% to 76% relative humidity, non-condensing.

CR Mammography Total Quality Tool



Important

It is recommended that you test all the cassettes used in your system twice annually with the CR Mammography Total Quality Tool's cassette testing feature. Follow your local regulations as required.

The CR Mammography Total Quality Tool evaluates various aspects of image quality on KODAK DIRECTVIEW CR Systems and CR Mammography Cassettes. You can use the tool to verify that the system is functioning within normal operating specifications.

It is recommended that you perform CR System Image Quality Tests monthly on a dedicated mammography cassette to ensure that the test results accurately reflect the CR System's operating condition. Follow your local regulations as required.

If dedicated cassettes are unavailable:

- Choose a cassette of each size.
- Verify the quality of each cassette using the CR Mammography Total Quality Tool's cassette testing feature.
- Use the same cassettes each time you test.

Requirements for CR Mammography Total Quality Tool

- The exposure level for test images must be limited to 50 ± 5 mR ($0.438 \text{ mGy} \pm 0.044 \text{ mGy}$) @ 28 kVp.
- A solid-state or ion-chamber X-ray exposure meter (dosimeter) calibrated for mammography use with a minimum of 5% accuracy and 2% repeatability specifications.

Handling and Storing the Screens

Handle the phosphor screens with care. For best results:

- Make sure your hands are clean and dry.
- Wear clean, powder-free, nitrile or latex gloves.
- Hold the screens by the edge.
- Avoid contact with the screen's white (phosphor) side.

Under normal conditions, phosphor screens will eventually show wear. This wear may occur from abrasion of the protective overcoat or inadvertent physical damage to the surface. Screen wear can result in artifacts on radiographs.



Caution

Screen damage can result from contact with certain materials used in facilities performing radiography. Contact with the following materials may cause visible or hidden damage to the screen and could result in immediate or future image artifacts: isopropyl alcohol, hydrogen peroxide and other peroxides, citrus-based cleaners, hand lotions, waterless hand sanitizers, surfactants, and lubricants. **Avoid contact between these materials and phosphor screens.**



Caution

Scatter radiation may cause image artifacts. **Do not store CR cassettes and screens in the exam room during patient studies.**

Cleaning the Screens and Cassettes



Caution

Read and follow the instructions in Material Safety Data Sheets (MSDS) for KODAK Screen Cleaner. Cleaning agents other than those recommended can contain chemicals that cause visible or hidden damage to the screen and could result in immediate or future image artifacts. Do not use soaps or detergents containing brightening agents. **Never use isopropyl alcohol (isopropanol, rubbing alcohol) to clean screens or cassettes.**

Cleaning the Screens

Cleaning Materials for Screens

- Clean, dry, non-abrasive, lint-free wipe/cloths
- KODAK Screen Cleaner, CAT No. 845-4977

Cleaning Method for Screens



Caution

Excessive amounts of the screen cleaner may damage the screen. **Do not pour the solution directly on the screen.**

1. Fold a non-abrasive, lint-free wipe or cloth and dampen with a small amount of the solution.
2. Wipe the screen thoroughly, one section at a time. Fold the cloth to expose a fresh area for each section of the screen.
3. If necessary, apply pressure to remove persistent dirt.
4. Dry the screen thoroughly. See "Drying the Screens and Cassettes" on page 5.

Cleaning the Cassettes

Cleaning Materials for Cassettes

- A soft cloth
- A mild soap-and-water solution or KODAK Screen Cleaner

Cleaning Method for Cassettes



Caution

Prevent all liquids from entering the cassette.

1. Clean the outer cassette surfaces using a soft cloth moistened with a mild soap-and-water solution or KODAK Screen Cleaner.
2. Dry the cassette thoroughly. See "Drying the Screens and Cassettes" on page 5.

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Disinfecting the Screens or Cassettes

If the cassette is visibly contaminated with blood or body fluids, removal of the blood and/or body fluids followed by intermediate-level disinfection is indicated prior to use.



Caution

A dilute bleach solution may cause eye irritation and dry skin. Wash hands with soap and water following use. Consult the manufacturer's MSDS for additional information prior to use.

Disinfection Materials

- Dilute bleach solution – one part of 5.25% sodium hypochlorite with 10 parts of water
- A commercially prepared equivalent solution of dilute bleach that does not contain any materials that can cause screen damage. See “Cleaning the Screens and Cassettes” on page 4.

Disinfection Method for Dilute Bleach Solution

1. Thoroughly wipe with a soft lint-free cloth dampened (but not dripping) with dilute bleach.
2. Contact the contaminated surface for up to 15 minutes for adequate disinfection.
3. Wipe off the bleach residue with a soft, lint-free cloth dampened with water.
4. Wipe the surface dry with a soft, lint-free cloth. See “Drying the Screens and Cassettes” on page 5.

Disinfection Method for Commercially Prepared Equivalent Solution

Use the commercially prepared equivalent solution of dilute bleach according to the manufacturer's instructions.

Drying the Screens and Cassettes



Caution

Do not leave the screen to air-dry. Do not insert a damp storage phosphor screen into a cassette. The screen and cassette must be thoroughly dry.

1. Wipe the screen thoroughly dry with a clean, dry, non-abrasive, lint-free cloth to remove residual cleaner.
2. Wipe the outer cassette surfaces with a clean, dry, soft cloth to remove residual cleaner.
3. Repeat the drying procedure with dry cloths until all surfaces are completely dry.

4. Verify that all external and internal surfaces are thoroughly dry before reassembling and returning the screens and cassettes to use.

Disposing or Recycling of the Screen and Cassette



Caution

Given the presence of barium, this screen may be considered a hazardous or special waste at the end of its useful service life. For disposal or recycling information, contact your local authorities.



Caution

The CR Mammography Cassette contains lead. Disposal of lead is regulated for environmental considerations. For disposal or recycling information, contact your local authorities.