
SUMMARY OF SAFETY AND EFFECTIVENESS DATA

1.1 GENERAL INFORMATION

Device Generic Name:	CR Digital Mammography System
Device Trade Name:	KODAK DirectView CR Mammography Feature KODAK DirectView CR Mammography Cassette
Applicant's Name and Address:	Carestream Health, Inc. 150 Verona Street Rochester, New York 14608
Date of Panel Recommendation:	Not applicable, refer to section 1.11
PMA (Pre-market Approval Application):	P080018
Date of GMP Inspection:	October 2-3, 2008
Date of Notice of Approval to Applicant:	November 3, 2010

1.2 INDICATIONS FOR USE

The KODAK DirectView CR Mammography Feature together with KODAK DirectView CR Mammography Cassette comprise a device which, when used in conjunction with a KODAK DirectView CR System and a mammographic x-ray machine, generates digital mammographic images that can be used for screening and diagnosis of breast cancer. It is intended for use in the same clinical applications as traditional screen-film based mammographic systems. The mammographic images can be interpreted by a qualified physician using either hardcopy film or softcopy display at a workstation.

1.3 DEVICE DESCRIPTION

KODAK DirectView CR Mammography

Computed Radiography (CR) mammography is a transition from screen-film mammography to digital mammography using the same cassette-based workflow. In CR mammography, a storage phosphor screen replaces the screen-film. The storage phosphor screen captures a latent image. Laser scanning extracts the latent image; electronics convert it to digital data. Image processing software produces a final digital image for diagnostic interpretation and archiving.

KODAK DirectView CR Mammography is designed to be used with the KODAK DirectView CR System, which has been used in general radiology for the past two decades. There are currently five models of the CR system on which KODAK DirectView CR Mammography may operate: CR 850, CR 950, CR 975, Classic CR, and Elite CR ("CR 850/950/975/Classic/Elite"). These models are similar, differing primarily in mechanical frame and the handling and throughput of cassettes. The studies were performed using the CR System software version 5.1 (V5.1).

The KODAK DirectView CR Mammography Feature allows the general radiology CR 850/950/975/Classic/Elite to recognize the CR Mammography Cassettes with EHR-M Screen and scan the EHR-M screen at 48.5 μm pixel spacing. It also applies mammography-specific image processing to the digitized image. To acquire a mammographic image, the KODAK DirectView CR

Mammography Cassette with EHR-M screen is exposed using mammography x-ray equipment in the same manner as a traditional screen-film cassette. The KODAK DirectView CR Mammography Cassettes are available in two sizes: 18 x 24 cm and 24 x 30 cm. They have an Enhanced High Resolution storage phosphor screen that is specific for Mammography (EHR-M). The cassettes comply with relevant aspects of ISO 4090, allowing them to be compatible with standard mammography x-ray equipment and their Automatic Exposure Control (AEC). The processed image can be displayed using mammography cleared output devices (printers and/or workstations) for interpretation.

Carestream Health also makes available an optional automated test tool, the KODAK DirectView CR Mammography Total Quality Tool (M-TQT). The M-TQT consists of software, hardware, and labeling that facilitates the routine analysis, recording, and tracking of test results from test phantoms, flat-field images, and erased cassettes.

Softcopy or Hardcopy Display

The images output by the KODAK DirectView CR Mammography can be displayed using mammography cleared output devices such as printers (hardcopy) and workstations (softcopy):

- Primary interpretation of hardcopy images shall be performed on a printer cleared for mammography and supporting the DICOM 3.0 standard. The printer shall have a 50 micrometer (μm) pixel pitch or less and a maximum film optical density of at least 3.6.
- Primary interpretation of softcopy images shall be performed on a workstation cleared for mammography and supporting the DICOM 3.0 standard. The workstation display(s) for primary interpretation shall have a minimum image array size of five megapixels.

1.4 CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

There are no known contraindications. Warnings and precautions can be found in the device labeling.

1.5 ALTERNATIVE PRACTICES AND PROCEDURES

There are various methods for screening and diagnosis of breast cancer. The methods include clinical breast examination, screen-film mammography, ultrasound, digital mammography, and magnetic resonance imaging. After a breast abnormality is diagnosed, a biopsy may be performed to determine the presence or absence of cancer.

1.6 MARKETING HISTORY

KODAK DirectView CR Mammography has been distributed to customers outside of the US since May of 2005. There have not been any problems or product issues, including adverse events, that have been determined to be reportable or that have resulted in the need to file a report in any country. In addition, there have not been any recalls conducted for this product, and the product has not been withdrawn from marketing in any country for any reason related to the safety or effectiveness of the device.

The KODAK DirectView CR Systems have been marketed since 1993 and have never been withdrawn for any reason related to safety or effectiveness.

1.7 POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Potential adverse effects of mammography include:

- Excessive breast compression
- Excessive x-ray exposure
- Electric shock
- Infection and skin irritation
- Abrasion or puncture wound

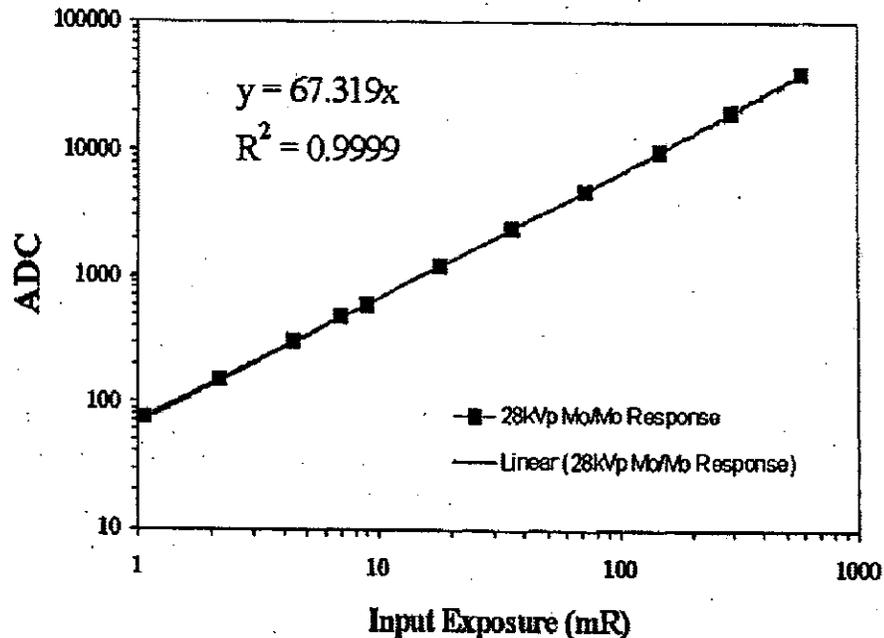
No adverse events were observed in patients enrolled in the clinical study.

1.8 SUMMARY OF NON-CLINICAL STUDIES

Technical testing to characterize KODAK DirectView CR Mammography was performed.

1. **Sensitometric Response:** This is a measure of the sensitivity of the image acquisition system to different levels of x-ray exposures. **Figure 1** below shows the sensitivity of the KODAK DirectView CR Reader with EHR-M phosphor screen to a 28kVp Mo/Mo beam with 4cm added PMMA placed at the x-ray tube collimator.

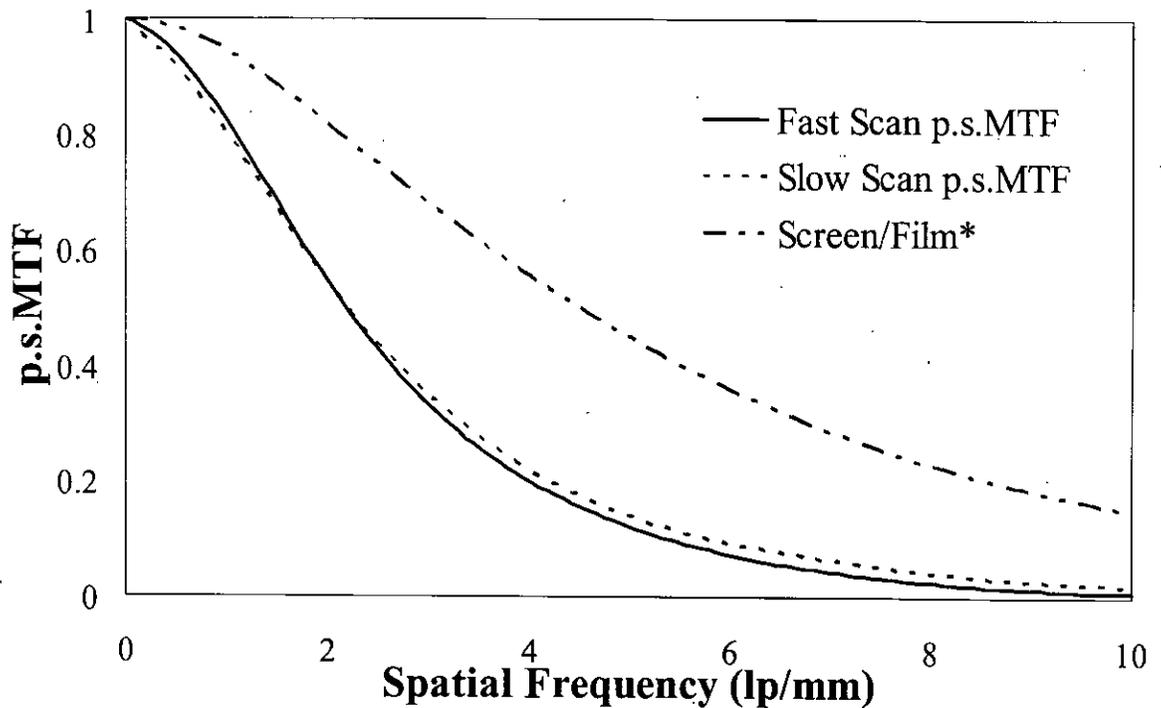
Figure 1: Sensitivity of the KODAK DirectView CR Reader with EHR-M phosphor screen to a 28kVp Mo/Mo beam with 4cm added PMMA placed at the x-ray tube collimator



2. **Spatial Resolution:** Image sharpness is characterized by measuring the image receptor modulation transfer function (MTF) and the spatial resolution. The spatial resolution of the

KODAK DirectView CR Reader with EHR-M phosphor screen measured using a 28kVp Mo/Mo beam with 4cm added PMMA at the x-ray tube collimator is shown in **Figure 2** below. The CR Reader scans the phosphor screen at a pixel raster of 48.5 μm producing a Nyquist frequency of 10.3 line pairs (lp)/mm. The data shows that the fast (laser scan) and slow (screen transport) direction for spatial resolution are similar and noise aliasing is negligible due to the low value of the pre-sampled MTF above the Nyquist frequency.

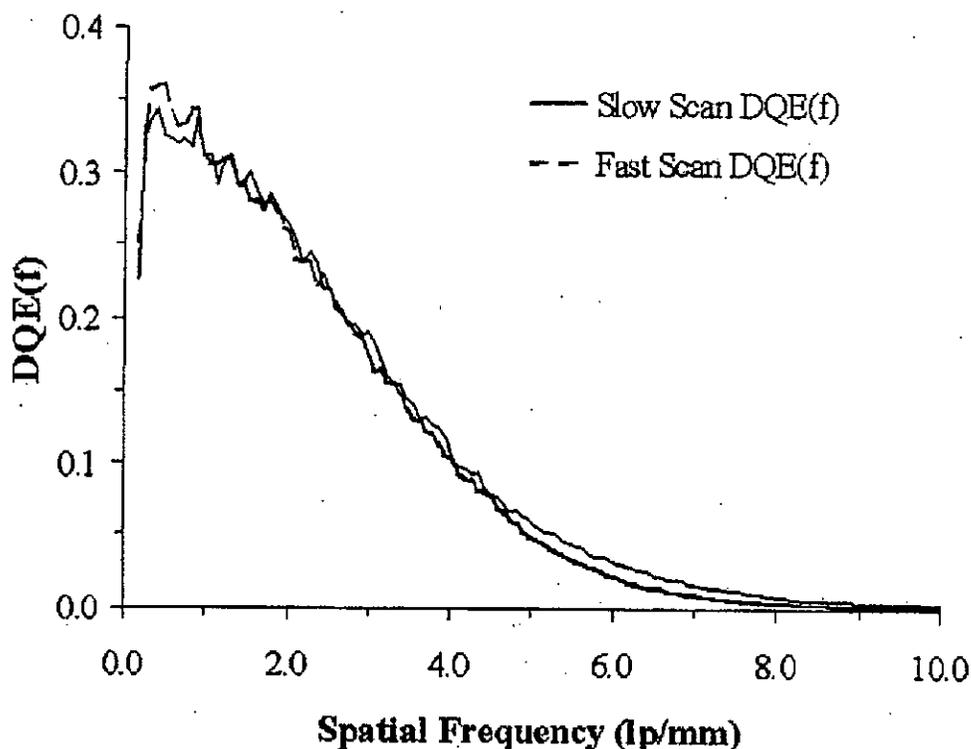
Figure 2: Pre-sampled MTF in fast and slow scan directions (28kVp Mo/Mo & 4cm PMMA)



* Kodak Min-R EV film with Kodak Min-R EV 150 screen

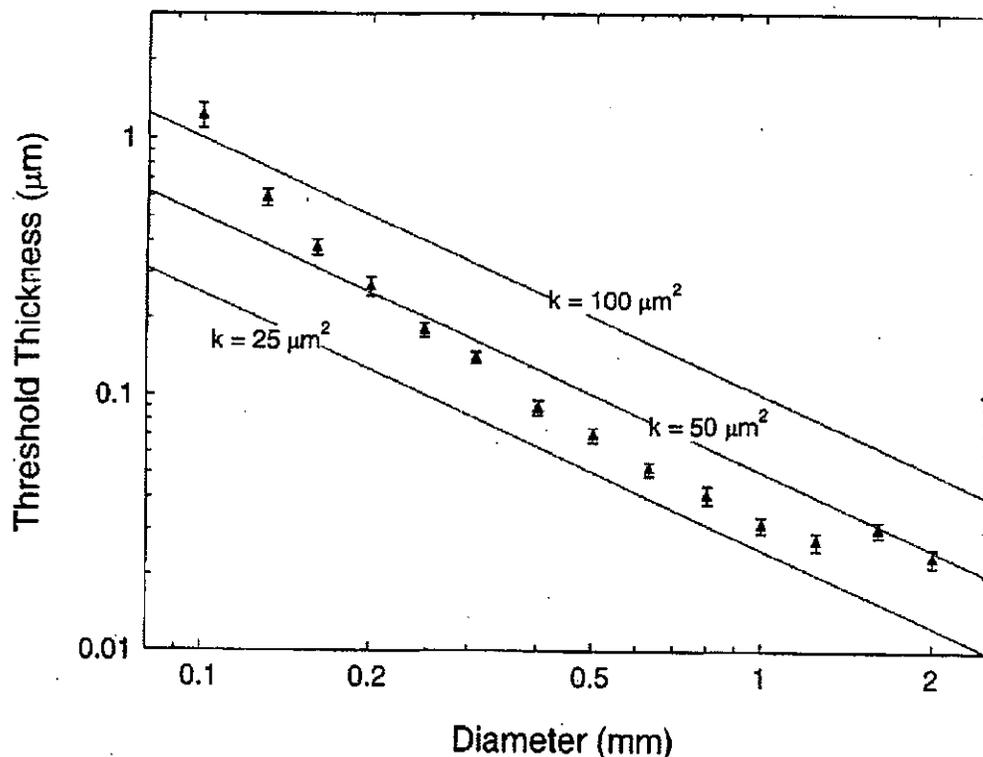
- Signal-to-Noise Ratio (SNR):** This is quantitative measure of the efficiency of SNR transfer of the image acquisition system as measured by the DQE as a function of spatial frequency (see **Figure 3** below). The output SNR of the system is compared with the SNR of the incoming x-ray photon stream. Calculation of the DQE of the KODAK DirectView CR Reader with EHR-M phosphor screen measures the SNR capabilities of the system.

Figure 3: DQE(f) for a 28kVp Mo/Mo beam with 4cm added PMMA filtration and an exposure of 6.9 mR in both the fast scan and slow scan directions



- 4. Exposure Dynamic Range:** The dynamic range of the KODAK DirectView CR Reader with EHR-M phosphor screen is ~96dB, using the full 16-bit range of the analog to digital converter (ADC). Dynamic range was calculated from a measurement of the maximum signal level of the scanner, 970mR for a 28kVp Mo/Mo beam with 4cm added PMMA, and the level of dark noise that is present in the scanner electronics, from an unexposed EHR-M phosphor screen.
- 5. Phantom Image Tests and Dose:** Image quality is also determined by analysis of phantom images. Carestream Health evaluated the visibility of different features of the American College of Radiology (ACR) accreditation phantom and the CDMAM contrast-detail mammography phantom. Subjective scoring of the CDMAM phantom and the ACR phantom are used to qualify the detection capabilities of the KODAK DirectView CR Reader with EHR-M phosphor screen. Image quality is sufficient to pass the Mammography Quality Standards Act (MQSA) phantom test. **Figure 4** below presents the mean threshold thickness as a function of target diameter obtained on the KODAK DirectView CR Reader with EHR-M phosphor screen using the CDMAM phantom.

Figure 4: Mean threshold thickness as a function of target diameter



* Error bars represent 90% confidence limits. Lines of constant threshold-thickness-diameter product are shown for 25, 50, and 100 μm^2

In another phantom image test, an ACR Mammography Accreditation Phantom (RMI-156) was imaged on a mammographic x-ray machine using typical clinical techniques. This phantom approximates a 4.5cm thick 50/50 breast. The experimental configuration for the image acquisition was as described in the MQSA instructions with x-ray technique factors of 28kVp, Mo/Mo, 56mAs, resulting in a calculated mean glandular dose of 1.19mGy^a. Images were scored on softcopy, read by board certified medical physicists qualified for scoring ACR phantoms. The results are listed in Table 1:

Table 1: FDA-Approved Phantom Score

Image number	Fiber Score	Speck Group Score	Mass Score
1	5.0	4.0	3.5
2	4.5	4.0	3.5
3	5.0	4.0	3.0
4	5.0	4.0	3.0

^a This is a typical clinical configuration. Due to the wide variety of different x-ray machine capabilities and user preferences for noise and image sharpness, there is no single specific recommendation for acquisition techniques. The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) / 300 millirad (mR) per exposure.

These tests show that image quality obtained with the KODAK DirectView CR Reader with EHR-M phosphor screen is sufficient to pass the MQSA phantom test.

1.9 SUMMARY OF CLINICAL STUDIES

Carestream Health conducted a clinical study designed to demonstrate the safety and effectiveness of KODAK DirectView CR Mammography.

Objectives

The purpose of the study was to confirm the non-inferiority of KODAK DirectView CR Mammography in comparison to screen-film mammography for the screening and diagnosis of breast cancer using the following clinical performance measures:

1. Receiver Operator Characteristics (ROC)
2. Sensitivity and Specificity
3. Recall rate

Study Design

This study consisted of two multi-center, prospective enrollment cohorts (at 10 sites in the US and one site in Canada). It was conducted to assess the clinical performance of KODAK DirectView CR Mammography in the screening and diagnosis of breast cancer. The four standard mammogram views were obtained (RMLO, RCC, LMLO, LCC) using both screen-film mammography and CR mammography. Performance was assessed by comparison of KODAK DirectView CR Mammography with current standard screen-film mammography in a Multiple-Reader, Multiple-Case (MRMC) Reader Study.

The imaging evaluation consisted of an Enriched Reader Study. The reading rooms were set up to simulate a clinical screening environment. No prior films, patient histories, or other information accompanied the interpretation of images. To provide randomization of cases, each radiologist started the read at a different case for each session. All radiologists received training at the start of the study on the mammographic workstation used for softcopy image review, and the multi-viewer used for displaying hardcopy films. Magnifiers were allowed for use.

Eleven (11) radiologists who had experience with digital mammography and were not associated with sites where the pivotal study images were acquired were selected to participate. Image review was conducted with a minimum of 4 weeks between interpretations of the same case on the corresponding sets of digital and screen-film mammograms. For each subject, radiologists recorded the following that were used to evaluate performance:

- Breast Imaging Reporting and Data System (BI-RADS®) rating for each breast - category 1 (negative mammogram), category 2 (benign finding), category 3 (probable benign finding), category 4 (suspicious abnormality), and category 5 (highly suggestive of malignancy)¹
- Probability of malignancy (0-100%) for each breast

All cases were presented in the following order: RCC, LCC, RMLO, LMLO.

Study Enrollment

Eligibility for enrollment was extended to women entering the facility for a routine screening mammogram in addition to those recommended for biopsy.

Enrollment continued until a complete dataset of 50 biopsy-proven cancers and 150 screening-negative cases were available, comprising the Enriched Reader Study population. Cancer cases were simultaneously stratified to meet criteria of cancers found in a U.S. screening population for cancer type, lesion size and breast density. Study enrollment totaled 431 subjects.

Enrollment Inclusion Criteria

Women with the following conditions were included:

- Age 40 or older
- Good general health (able to be still to reduce the potential of motion in the images)
- Able and willing to provide a written Informed Consent form

Enrollment Exclusion Criteria

Women with any of the following conditions were excluded:

- Under age 40
- Pregnant or suspicious of being pregnant
- Breast implants
- Breasts too large to be adequately positioned on a 24 x 30 cm cassette
- Personal history of breast cancer treated with a lumpectomy
- Unable or unwilling to provide a written Informed Consent form

Criteria for Evaluation

1. Co-primary Effectiveness Endpoints: difference of means of area under the ROC curve, sensitivity, and specificity between the CR and screen-film mammography
2. Secondary Effectiveness Endpoints: recall rate

Statistical Methods

Inferential tests were performed at the 5% level of significance based on one-sided two-sample t-test for non-inferiority with a non-inferiority limit of 0.10.

The null hypotheses were that the ROC curve area, sensitivity, and specificity of screen-film mammography were greater than 0.10 more than the ROC curve area, sensitivity, and specificity for CR digital mammography.

- **For ROC curve area**, analyses were conducted based on the probability of malignancy, using the Multiple-Reader Multiple-Case Software DBM MRMC, for each reader in the study

and for the combined results of all 11 readers. The area under the ROC curves of the two modalities for each of the 11 readers and the overall results, the corresponding 95% confidence intervals (CI) based upon normal approximation, and the differences between the two ROC curve areas with the corresponding 95% confidence bound were computed at both the subject level and at the breast level. The null hypotheses would be rejected if the overall combined results of the 11 readers indicated that the upper 95% confidence bound of the difference was less than or equal to 0.10.

- **For sensitivity, specificity and recall**, analyses were calculated based on BI-RADS ratings. The estimated mean sensitivities / specificities / recall rates of the two imaging modalities, the corresponding 95% confidence intervals (CI) and the differences between the two sensitivities / specificities / recall rates with the corresponding 95% confidence bound were computed at both the subject level and at the breast level. Each null hypothesis was rejected if the overall combined results of the 11 readers indicated that the 95% confidence bound of the difference was within or equal to 0.10.

Safety Results, Device Failures, and Replacements

There were no foreseen or perceived clinical issues associated with the safety of subjects during the course of this study. No major device malfunctions occurred during the study and no malfunctions were observed or recorded that affected the outcome of the study.

Results

Demographics

- The mean age was 58.2 for the Enriched Reader Study population and 62.1 for the cancer cases.
- The Enriched Reader Study population and cancer cases used were similar in race distribution, with >80% of subjects being Caucasian and most of the remainder being African-American.

Characteristics of Cancer Subjects

All 50 cancer subjects had at least one object observed.

- 26 (52%) of the cancers were masses, the majority classified as spiculated (53.8%). 11 (42.3%) of the 26 masses were ≤ 10 mm in size, 11 (42.3%) were between 11-19 mm and 4 (15.4%) were ≥ 20 mm.
- 18 (36%) of the cancers were microcalcifications only, 10 (55.6%) were categorized as pleomorphic, 5 (27.8%) were categorized as amorphous and 3 (16.7%) were categorized as fine linear.
- 6 (12%) of the cancers were architectural distortions, 2 (33.3%) of the 6 architectural distortions were ≤ 10 mm in size, 2 (33.3%) were between 11-19 mm and 2 (33.3%) were ≥ 20 mm.
- Breast composition of the cancer subjects was 8 (16%) almost entirely fat, 22 (44%) scattered fibroglandular, 15 (30%) heterogeneously dense and 5 (10%) homogeneously dense.

Enriched Reader Study

The table below presents the effectiveness results of ROC, Sensitivity, Specificity, and Recall Rate of the Enriched Reader Study at the breast level.

Table 2: Principal Effectiveness Results – Enriched Reader Study

	Screen-Film	KODAK CR	Mean Difference	Upper 95% Confidence Bound of Difference	p-value
Breast Level					
ROC (n=397)					
AUC	0.91 (0.87,0.95)	0.90 (0.86,0.94)	0.01	0.04	<0.001
Sensitivity (n=51)					
BI-RADS ≥ 3	0.81 (0.74,0.88)	0.78 (0.71,0.86)	0.03	0.09	0.024
BI-RADS ≥ 4	0.71 (0.65,0.77)	0.65 (0.57,0.72)	0.07	0.13	0.183
Specificity (n=346)					
BI-RADS ≥ 3	0.85 (0.81,0.89)	0.87 (0.82,0.91)	-0.01	0.00	<0.001
BI-RADS ≥ 4	0.95 (0.94,0.97)	0.96 (0.94,0.97)	0.00	0.01	<0.001
Recall Rate					
Disease-negative views, n=346	0.15 (0.11,0.19)	0.13 (0.09,0.18)	0.01	-0.00	<0.001
All views, n=397	0.13 (0.09,0.17)	0.12 (0.08,0.16)	0.01	-0.00	<0.001

ROC

The average areas under the ROC curves were 0.91 for screen-film and 0.90 for the CR system (see Figure 5). The difference in the overall ROC areas was 0.01. Since the upper 95% confidence limit of the difference (0.036), was less than or equal to 0.10 ($p < 0.001$) we reject the null hypothesis in favor of the alternative hypothesis that the ROC area for screen-film is not more than 0.10 greater than the CR system. For the primary endpoint of the AUC it was concluded that the CR system is not inferior to screen-film.

Two ROC curves crossing implies that for some region of the x-axis (false positive fraction (FPF)) one diagnostic has a higher sensitivity than the other and in the complement FPF region the opposite is true. This fact can make it difficult to interpret a difference in AUCs. To further investigate the crossing, an additional analysis of partial area under the ROC curve was conducted. Analyses at four intervals of specificity were performed (80 to 100%, 85% to 100%, 90% to 100%, and 95% to 100%).

The partial area analyses were consistent with the results of the area under the curve analysis of the ROC, and, hence, support the conclusion that the CR system is not inferior to screen-film mammography.

Similar conclusions were made for the breast level and subject level results.

Figure 5: Overall receiver operating characteristic (ROC) curves for screen-film mammography and KODAK DirectView CR mammography (breast level analysis)

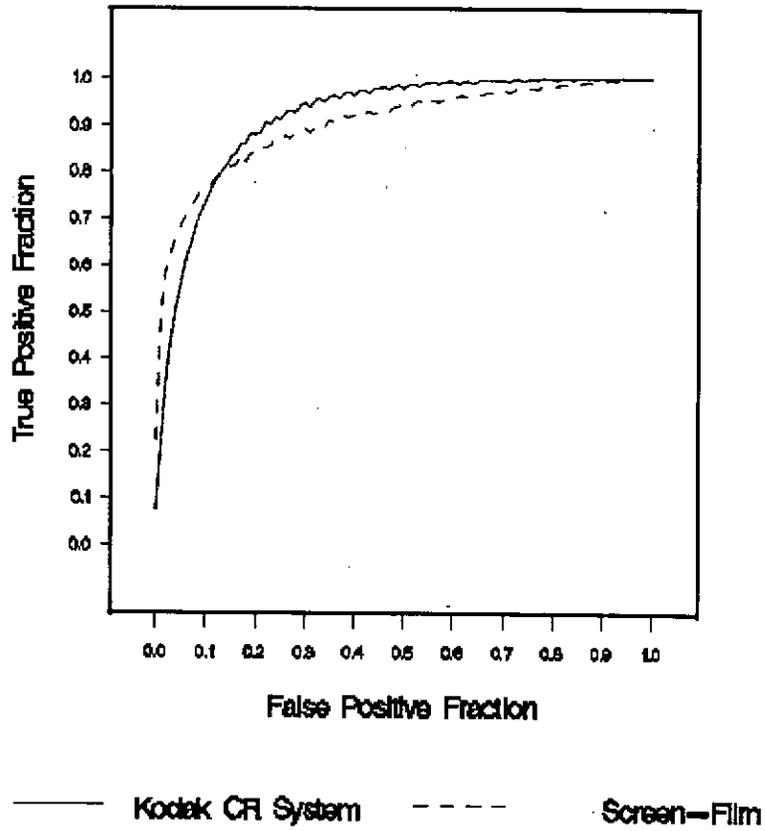


Table 7 ROC Curve Areas for Individual Readers (Enriched-Reader Study Population, Breast Level Analysis)

Reader Number (c)	Film Mammography (n=397)	KODAK CR System (n=397)	Mean Difference
	ROC Area (a,b)	ROC Area (a,b)	
1	0.929	0.842	0.09
2	0.943	0.915	0.03
3	0.893	0.863	0.03
4	0.931	0.876	0.05
5	0.918	0.924	-0.01
6	0.926	0.913	0.01
7	0.835	0.920	-0.08
8	0.879	0.888	-0.01
9	0.869	0.924	-0.06
10	0.923	0.883	0.04
12	0.956	0.943	0.01

Note: (a) For breast level analysis, the probability of malignancy score for every breast was analyzed.
 (b) The analysis was performed using Multiple-Reader Multiple-Case Software DBM MRMC.
 (c) Reader #11 withdrew before beginning the study.

Sensitivity

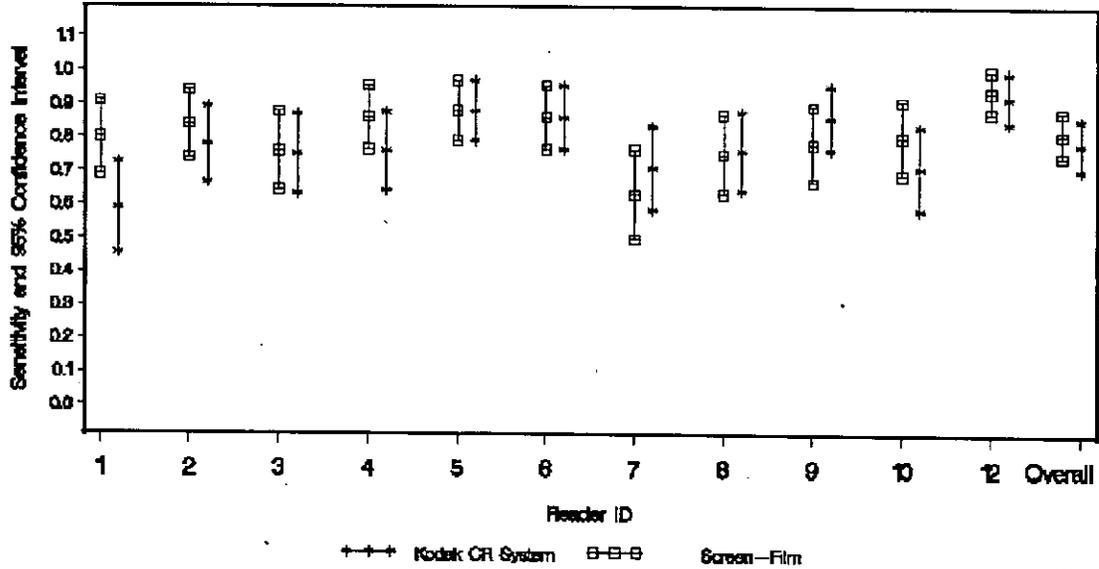
When BI-RADS ≥ 3 was considered positive, the overall sensitivities of screen-film and CR at the breast level were 0.81 and 0.78, respectively, with a mean difference of 0.03. The null hypothesis was rejected ($p=0.024$) because the upper 95% confidence bound of the difference of 0.09 was less than 0.10. It was concluded that the CR system is not inferior to screen-film for this sensitivity (BI-RADS ≥ 3) outcome.

When BI-RADS ≥ 4 was considered positive the overall sensitivities of screen-film and CR at the breast level, are 0.71 and 0.65, respectively, with a mean difference of 0.07 which was within the hypothesis difference of 0.10; however, the null hypothesis was not rejected ($p=0.18$) because the upper 95% confidence bound of the difference (0.13) was greater than the maximum difference stated in the hypothesis (0.10). Though the difference is small, it could not be concluded from the Enriched Reader Study that that the CR system was non-inferior to screen-film for this sensitivity (BI-RADS ≥ 4) outcome.

Non-inferiority was established using the primary endpoint of BI-RADS analysis with BI-RADS ≥ 3 considered positive, in keeping with the way the readers used the BI-RADS scale in the study. Interpretation of the scale for use with screening may have been inconsistent when the BI-RADS 0 option is eliminated, since BI-RADS 0 is the primary assessment score for positive screening mammograms in clinical practice.

Estimated Sensitivity by Reader

Figure 7
 Sensitivity of Screen-film Mammography and KODAK CR System: Breast Level Analysis
 Positive Imaging Diagnosis Defined as BI-RADS ≥ 3
 Cancer Cases



Specificity

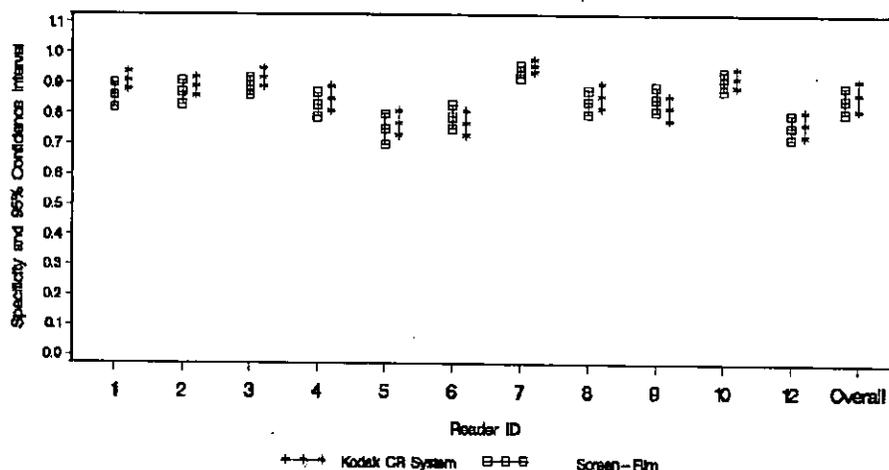
When BI-RADS ≥ 3 was considered positive, the overall specificities of screen-film and CR System were 0.85 and 0.87, respectively, with a mean difference of 0.01 and an upper 95% confidence bound of the difference of 0.00. The null hypothesis was rejected ($p < 0.001$) because the upper 95% confidence bound of the difference of 0.00 was less than 0.10. It was concluded that KODAK DirectView CR Mammography was not inferior to screen film for this specificity (BI-RADS ≥ 3) outcome. Similar conclusions were made for the breast level and subject level results.

When BI-RADS ≥ 4 was considered positive, the overall specificities of the screen-film and CR were 0.95 and 0.96 for screen-film and CR respectively, with a mean difference of 0.01 and an upper 95% confidence bound of the difference of 0.00. The null hypothesis was rejected ($p < 0.001$) because the upper 95% confidence bound of the difference of 0.00 was less than 0.10. It was concluded that KODAK DirectView CR Mammography was not inferior to screen-film for this specificity (BI-RADS ≥ 4) outcome. Similar conclusions were made for the breast level and subject level results.

Estimated Specificity by Reader

Carostream Health Inc
 Protocol Number: 7H2108X
 Comparison of CR Digital Breast Images with Screen-Film Images Phase II

Figure 11
 Specificity of Screen-film Mammography and KODAK CR System: Breast Level Analysis
 Positive Imaging Diagnosis Defined as BIRADS ≥ 3
 Enriched-Reader Study Population



Recall Rate

The estimated recall rates of screen-film and CR System for all views were 0.13 and 0.12, respectively, with a mean difference of 0.01 and an upper 95% confidence bound of the difference of 0.00. Similar results were obtained for disease-negative views. This demonstrated that the recall rate of the CR System was not inferior to that of screen-film. Similar conclusions were made for the breast level and subject level results.

Clinical Image Evaluation

A dataset composed of images from six subjects (see Table 3) with BI-RADS Assessment Categories of 1 or 2 was evaluated by an independent and expert mammographer from FDA. These images consisted of craniocaudal (CC), mediolateral oblique (MLO) and diagnostic views. The evaluation concluded that the images were of final interpretive quality.

Case #	Breast Density Type	BIRADS
1	Dense	2
2	Scattered Fibroglandular	2
3	Scattered Fibroglandular ⁺	2
4	Dense	1
5	Fatty ⁺	1
6	Fatty ⁺	1

⁺ Case includes benign microcalcifications.

Conclusions

The results of this study and the clinical image evaluation demonstrated that the performance characteristics of CR mammography were non-inferior to the performance characteristics of screen-film mammography in diagnosing and screening women for breast cancer. The results further

provided a reasonable assurance of the clinical utility and effectiveness of the device according to its intended use for both hard copy and soft copy display.

1.10 CONCLUSIONS DRAWN FROM THE NON-CLINICAL AND CLINICAL STUDIES

The results of the non-clinical and clinical studies described above provide a reasonable assurance of the safety and effectiveness of the KODAK DirectView CR Mammography for screening and diagnostic breast imaging. These findings therefore support FDA approval of the KODAK DirectView CR Mammography for clinical use in screening and diagnostic mammography.

1.11 PANEL RECOMMENDATIONS

In accordance with the provisions of section 515(c)(2) of the Federal Food, Drug and Cosmetic Act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Radiological Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

1.12 CDRH DECISION

CDRH issued an approval order on November 3, 2010.

The applicant's manufacturing facilities were inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

1.13 APPROVAL SPECIFICATIONS

Direction for use: See the labeling.

Hazards to Health from Use of the Device See Indications, Contraindications, Warnings, Precautions and Adverse Reactions in the labeling.

Post-Approval Requirements and Restrictions: See approval order.

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