

**SUMMARY OF SAFETY AND
EFFECTIVENESS DATA (SSED)**

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I. GENERAL INFORMATION

Device Generic Name: Full Field Digital Mammography System

Device Trade Name: Siemens Mammomat *Novation*^{DR}

Applicant: Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

PMA Number: P030010

Date of Panel Recommendation: None

Date of Good Manufacturing Inspection: June 1-4, 2004

Date of Notice of Approval to Applicant: TBD

II. INDICATIONS FOR USE

The Siemens Mammomat *Novation*^{DR} Full Field digital Mammography System (*Novation*^{DR}) generates digital mammographic images that can be used for screening and diagnosis of breast cancer and is intended for use in the same clinical applications as traditional film-based mammographic systems. Mammographic images can be interpreted by either hardcopy film or by softcopy at a workstation.

III. DEVICE DESCRIPTION

The *Novation*^{DR} consists of an image acquisition system, hardcopy display, and softcopy workstation. It utilizes the Siemens Mammomat 3000 Nova mammography x-ray system (K932672) for the production of x-rays, for supporting compression of the breast, and for the physical support of the digital image receptor licensed from the Hologic Lorad SeleniaTM (SeleniaTM) system (P010025). It also uses the same image capture algorithms, image processing algorithms, and image display algorithms for softcopy display and hardcopy printouts. The *Novation*^{DR} maintains the same features as the Siemens Mammomat 3000 Nova including the Automatic Exposure Control (AEC) system and anode/filter combinations of Molybdenum/Molybdenum (Mo/Mo), Molybdenum/Rhodium (Mo/Rh), and Tungsten/Rhodium (W/Rh).

The Siemens Mammomat 3000 Nova x-ray stand holds the Hologic amorphous selenium (a-Se) digital image receptor with an active area of 24 x 29 cm which directly converts incoming x-ray photons to digital image data. At the acquisition workstation, the user enters the patient identification data (or receives it from a work list), acquires, processes, and displays the images for image preview. These images are then forwarded either for hardcopy printing or softcopy display to the MammoReport^{Plus} for review and diagnosis.

Users must ensure that they have completed the Siemens *Novation*^{DR} training program prior to conducting patient exams. The Siemens training program will address the personnel training requirements under MQSA regulations in product labeling to assure that the prospective users are aware of the required eight hours of training for any medical physicist, technologist, or interpreting physician.

IV. CONTRAINDICATIONS

None known.

V. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Mammomat *Novation*^{DR} labeling.

VI. 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

VII. ALTERNATIVE PRACTICES AND PROCEDURES

Various methods are available for screening or diagnosing of breast cancer. These include a clinical breast examination, screen-film mammography, ultrasound, and magnetic resonance imaging. Biopsy of a detected abnormality is often obtained to diagnose or rule out cancer.

VIII. MARKETING HISTORY

The system components (X-ray tube, support assembly, and compression paddle) of the Mammomat 3000 Nova mammography x-ray system (K932672) have been marketed since 1993 and have never been withdrawn for any reason related to safety or effectiveness. Since

March 2004, the *Novation*^{DR} has been marketed in the European Union and to date the *Novation*^{DR} system has never been withdrawn either from marketing for any reason related to safety or effectiveness.

IX. SUMMARY OF NON-CLINICAL STUDIES

Siemens performed a series of quantitative measurements meant to characterize the physics aspects of the licensed digital receptor and image display as implemented in the *Novation*^{DR} system. It was pivotal to establish the technical equivalence of the *Novation*^{DR} and the *Selenia*TM systems in order to legitimize the use of Hologic's clinical data. Technical testing encompassed characteristic curves, automatic exposure control (AEC), modulation transfer function (MTF), detector quantum efficiency (DQE), signal-to-noise ratio (SNR), noise power spectrum (NPS), sensitometric response, and phantom scoring.

1. Characteristic Curves

A characteristic curve is a plot of the image pixel intensity measured in analog-to-digital units (ADUs) versus the x-ray exposure level at the image receptor cover. Pixel intensity is the digital value measured in ADUs ranging from 0 to 2^{14} .

The *Novation*^{DR} detector has a linear response with a linearity of > 0.999 in a specified range. Figure 1.1 illustrates the characteristic curves of the *Novation*^{DR} image receptor.

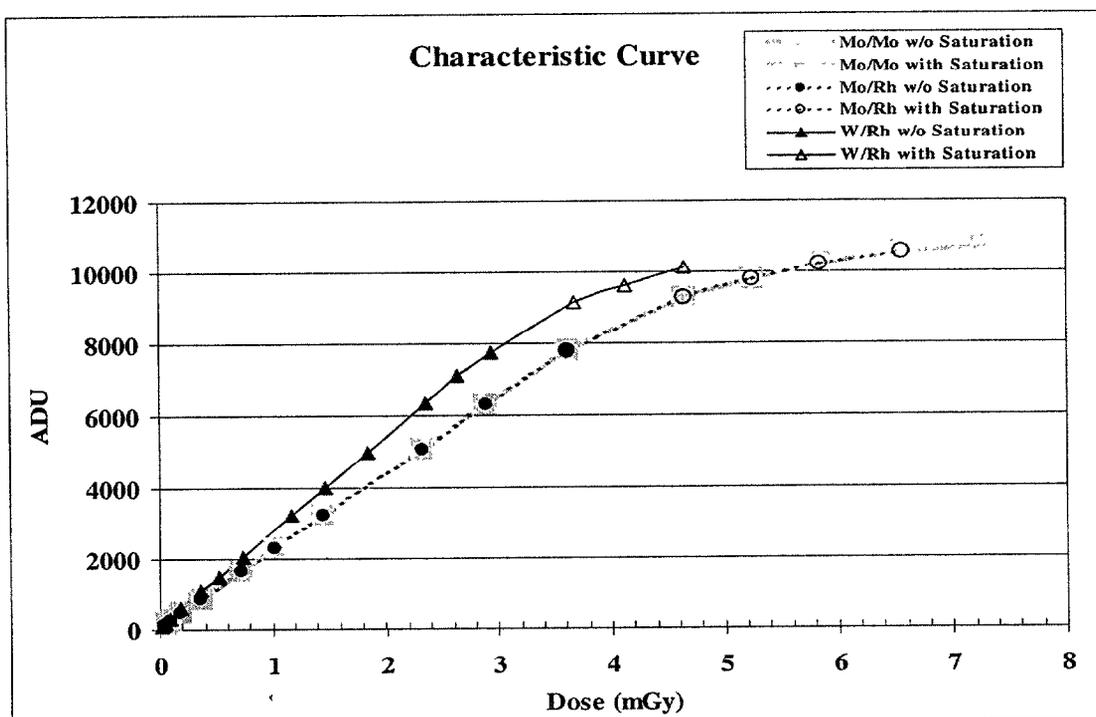


Figure 1.1 Characteristic curves for the *Novation*^{DR} image receptor.

2. Automatic Exposure Control (AEC)

Automatic exposure control (AEC) is a technology that is widely used in standard x-ray imaging and digital imaging systems. The objective of an AEC system is to optimize image quality while minimizing patient dose in an effort to produce consistent radiology images from patient to patient regardless of size or presence of pathology.

Approximately 1000 images were generated for the standard and magnification modes using the *Novation*^{DR} AEC system. In order to document the limits of the AEC performance, data was gathered for a range of phantom thicknesses simulating the population at large and consequently exercising all the anode/filter combinations (Mo/Mo, Mo/Rh and W/Rh).

Additional testing was performed to compare image quality between images obtained in the manual mode and those generated in the AEC mode, and to compare doses delivered by the film-screen system (Nova 3000) with doses delivered by the digital system (*Novation*^{DR}).

2.1 Automatic Exposure Control (AEC)-Enabled *Novation*^{DR}

The performance of the AEC using the *Novation*^{DR} was evaluated by acquiring data sets of varying kVs and varying breast equivalent thicknesses. AEC performance was measured in both standard and magnification imaging modes.

Figure 2.1 represents the digital signal fluctuation for each technique. The plot displays the $\pm 15\%$ from the average of each technique (solid line) and the measured standard deviation from the mean (dotted line). All data are within the MQSA requirement of $\pm 15\%$.

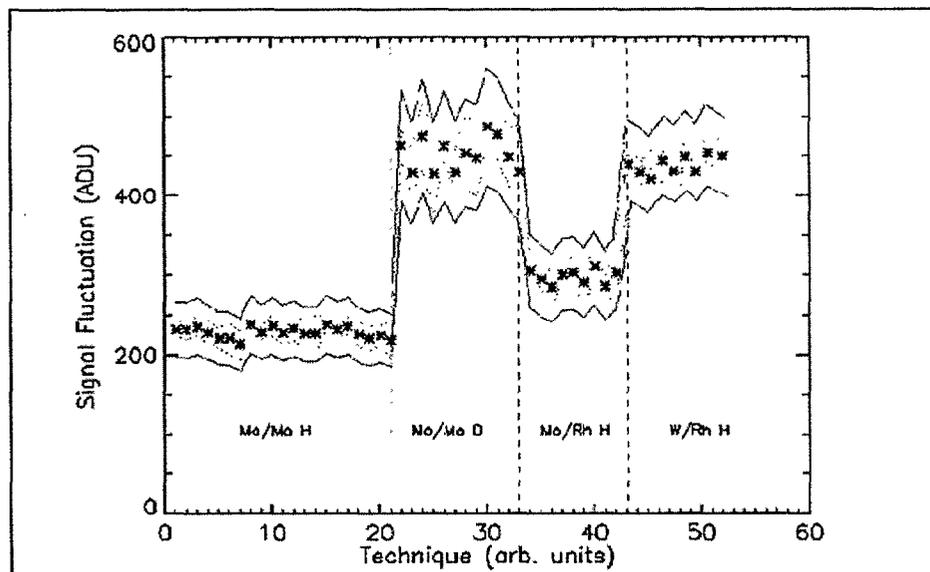


Figure 2.1 Digital signal fluctuation for each technique (target/filter combination) in standard mode.

2.2 Comparison of AEC and Manual Mode Between Siemens Film-Screen (Nova 3000) and Digital (*Novation*^{DR}) Systems

Testing was performed to compare the digital image quality generated by the manual mode to the AEC mode and the dose delivered by the film-screen system to the dose delivered by the digital system.

2.2.1 Manual Mode vs. AEC

A total of 90 images were acquired on the *Novation*^{DR} system using the target-filter combinations of Mo/Mo, Mo/Rh, and W/Rh.

Exposures were initially made in the AEC mode which were then followed by the manual mode. For the manual mode techniques, dose was chosen from the selected values of the AEC mode minus the 5 mAs scout pulse. The 5 mAs scout pulse was subtracted since this pre-exposure dose does not contribute to image quality. Percent deviation between the manual mode and the AEC modes for CNR and SNR was calculated for each combination of phantom thickness, kVp, and filtration in H mode (low dose) and D mode (high dose).

The results indicate that the percent deviations between SNR and CNR when comparing the AEC and Manual Modes of the *Novation*^{DR} for H and D mode were within an acceptance criteria of +/- 10%.

2.2.2 Dose Comparison for AEC Mode Between the Nova 3000 and the *Novation*^{DR}

Measurements were done to compare the dose delivered from the analog system (Nova 3000) to the dose delivered from the digital system (*Novation*^{DR}). Figure 2.2 shows the dose levels for the Nova 3000 and the *Novation*^{DR} using the AEC mode. The dose delivered by the *Novation*^{DR} (H mode – low dose) is approximately the same or slightly lower than the dose delivered by the Nova 3000.

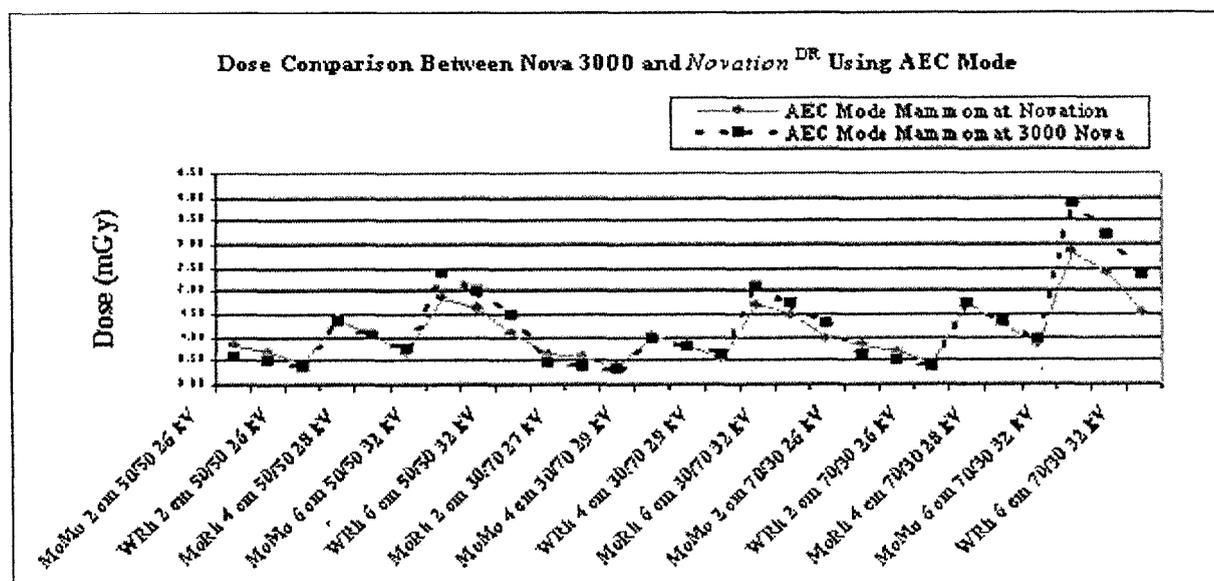


Figure 2.2 Dose comparison between Nova 3000 and *Novation*^{DR} Using AEC Mode

3. Modulation Transfer Function

Image sharpness of an imaging receptor is usually quantified by its modulation transfer function (MTF). The pre-sampling MTF was acquired using a 10 μ m slit oriented at about a 1° angle to the sampling grid of the detector with the anti-scatter grid removed. Figure 3.1 shows the MTF curves for the SeleniaTM and Novation^{DR}. Both systems have very similar MTF characteristics and demonstrate equivalence over the range 0 to 7 lp/mm.

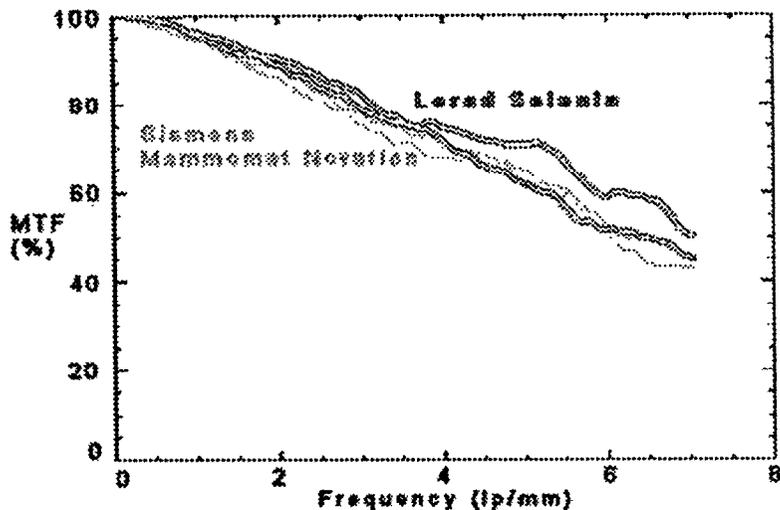


Figure 3.1 Novation^{DR} and Selenia (MTF) Modular Transfer Function

4. Detective Quantum Efficiency (DQE)

DQE characterizes the efficiency with which a receptor uses radiation. Image sharpness was characterized by measuring the image receptor modulation transfer function (MTF) and its limiting spatial resolution. The detective quantum efficiency (DQE) is computed using the following equation where G is the image receptor gain, X is the X-ray exposure (mR), MTF is the modulation transfer function, Φ is the incident X-ray fluence (photons/mm²/mR), and NPS is the noise power spectrum:

$$DQE = \frac{G^2 \cdot X \cdot MTF^2}{\Phi \cdot NPS}$$

DQE images were acquired at 28 kV for four different exposure levels (3.5, 7.1, 14.9, & 29.2 mR) on both the SeleniaTM and the Novation^{DR} systems. The DQE for an exposure level of 7.1 mR which would be clinically relevant is shown in Figure 4.1. Both systems have very similar DQE characteristics and demonstrate equivalence.

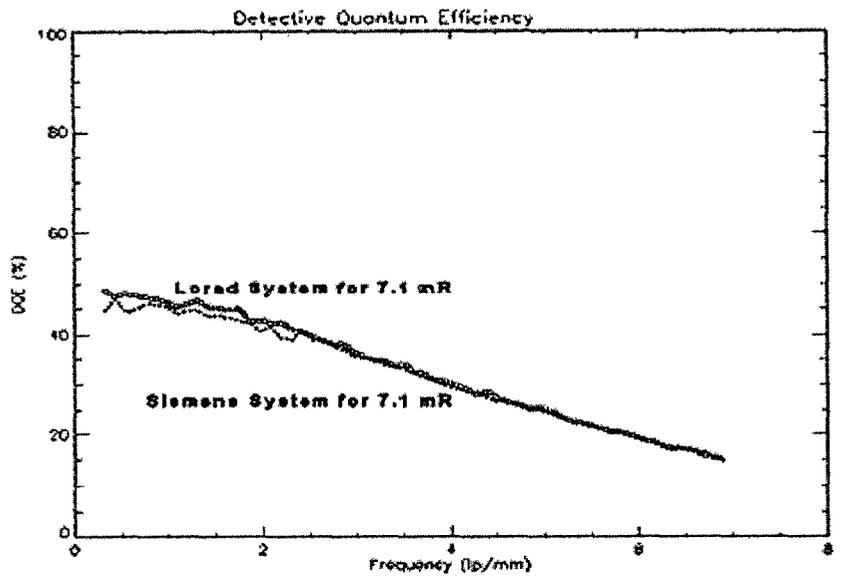


Figure 4.1 DQE at exposure of 7.1 mR for both the Selenia and *Novation*^{DR} systems.

5. Signal-to-Noise Ratio (SNR)

The signal-to-noise ratio (SNR) is the ratio of the signal level relative to the noise level (standard deviation) and can be expressed as:

$$SNR = \frac{S}{\sigma}, \text{ where } S = \text{ADU Value}; \sigma = \text{Standard Deviation.}$$

SNR images were acquired at varying techniques (kVs ranging from 25 to 32 and mAs ranging from 26 to 75) using different acrylic phantom thicknesses for the anode filter combinations of Mo/Mo and Mo/Rh. All exposures were normalized to the same ADU at the detector surface of the *Novation*^{DR} system. The entrance surface air kerma (ESAK) was measured for the *Novation*^{DR} system and then applied to the SeleniaTM system. With deviations less than +/- 10%, both systems demonstrate equivalence as illustrated in Figure 5.1

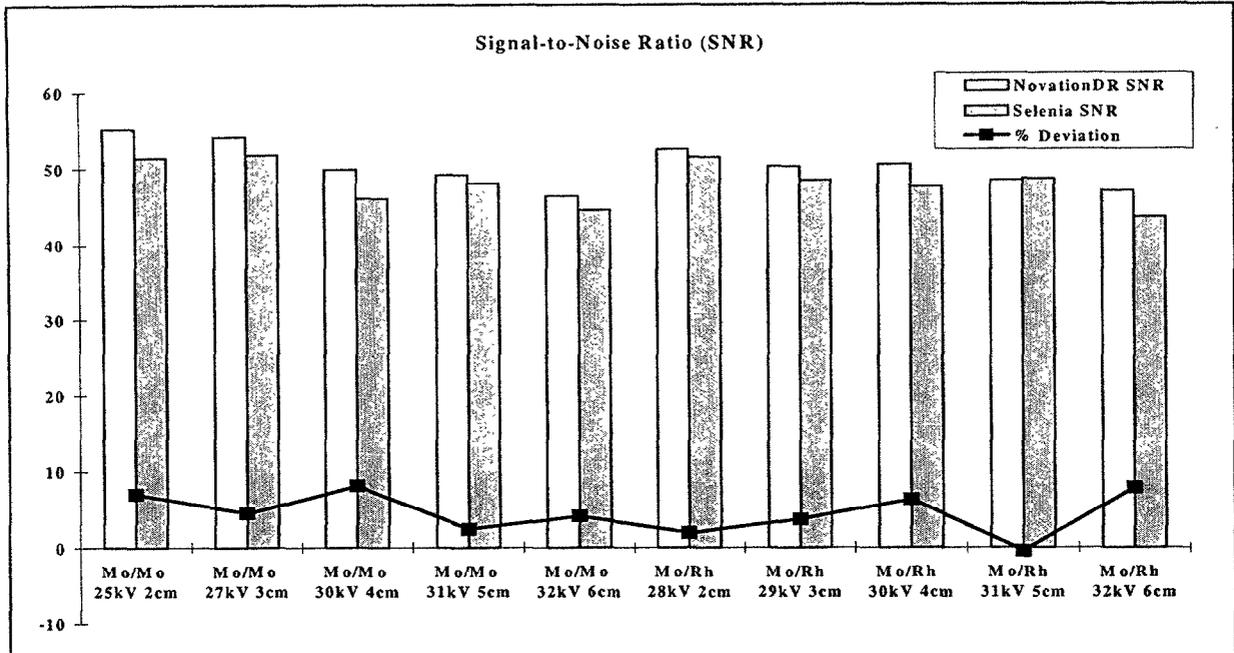


Figure 5.1 Comparison of SNR and percent deviation between the Selenia and *Novation^{DR}* using the anode/filter combination Mo/Mo and Mo/Rh.

6. Noise Power Spectrum (NPS)

Noise power spectrum (NPS) is a characterization of the noise distribution over the spatial frequency which is important for assessing image degradation. The NPS was determined using the synthesized slit method (Dainty and Shaw 1974) and plotted as a function of frequency (lp/mm) for four exposure levels. Figure 6.1 shows the relative differences in NPS of the *Novation^{DR}* and *SeleniaTM* systems for an entrance exposure of 7.1 mR. The relative differences in NPS for these systems are a reflection of the gain factor utilized by each system, and a more accurate comparison should be based on the DQE values.

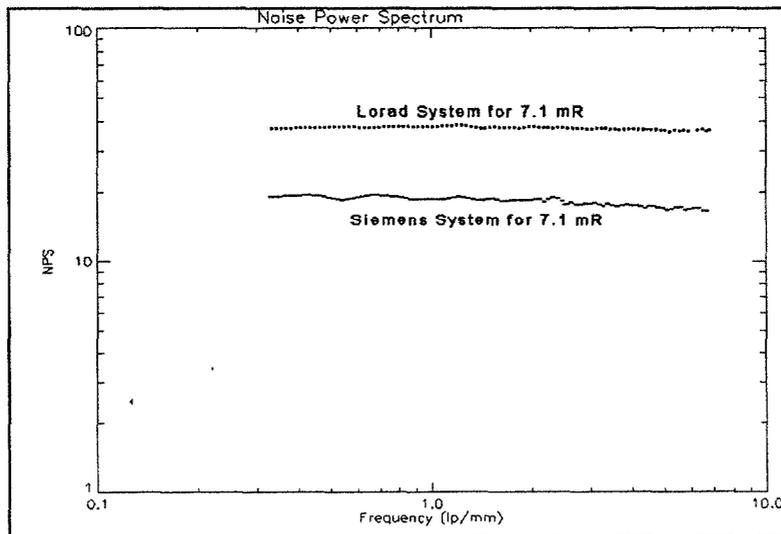


Figure 6.1 Measured NPS of the *Novation^{DR}* and *Selenia* image receptor for an entrance exposure of 7.1 mR.

7. System Sensitivity

Sensitivity is plotted as a function of the exposure level (mR). The formula used is:

$$\text{Sensitivity} = \frac{\text{Counts}}{\text{mR}} \cdot \frac{S}{\sigma^2},$$

where S is the ADU value, σ the standard deviation and the counts/mR is the slope of the characteristic curve. Figure 7.1 compares the relative sensitivity for the *Novation*^{DR} and the *Selenia*TM systems. The maximum deviation of these two systems for different exposure levels is 9%.

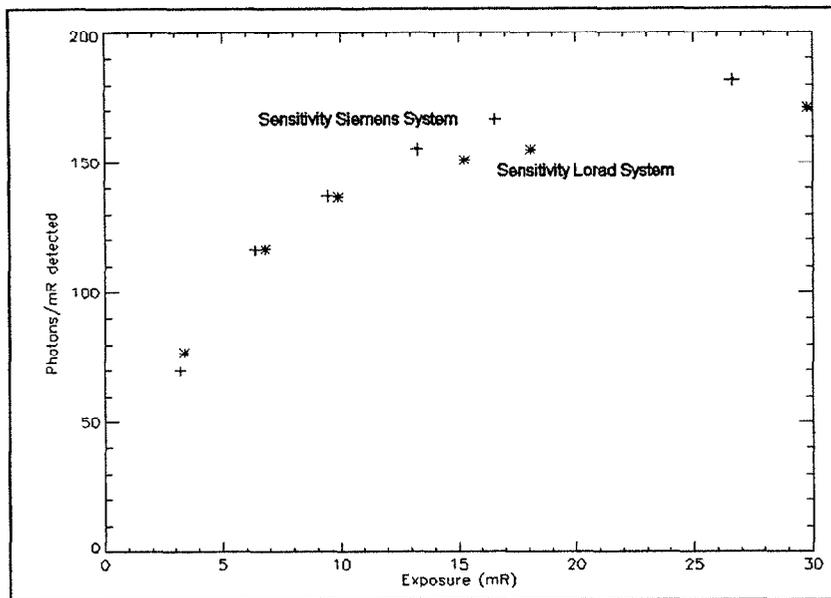


Figure 7.1 Relative Sensitivity of the *Novation*^{DR} (+) and *Selenia* (*) systems.

8. Image Ghosting

Image ghosting is a phenomenon whereby residual images are visible in subsequent images as a result of trapped bulk charges. The *Novation*^{DR} image receptor utilizes an erasing and conditioning process to eliminate or reduce the trapped bulk charges sufficiently so image ghosting is not a problem. To quantify the effectiveness of the erasing and conditioning process two test cases were set up using a 50/50 (glandular/adipose tissue) phantom of tissue-equivalent (TE) breast material in such a way that a first exposure delivered a normal dose to the area under the breast phantom while the area adjacent to the breast phantom received an X-ray flux which saturated the detector. The specifics of the two test cases are described below.

In Test Case 1, a 6 cm thick 50/50 tissue equivalent phantom was positioned on the *Novation*^{DR} image receptor and exposed at 30kV, 80mAs using the Mo/Mo anode/filter combination. This technique produced an exposure level under the breast of approximately

70 μ Gy which is a typical x-ray exposure level for a screen film system using a Kodak Min-R 2000 film. The 6 cm phantom was subsequently replaced by a 2 cm thick 50/50 tissue equivalent phantom that was smaller in breadth and width. Another image was taken at 28 kV, 7.1mAs and Mo/Mo anode/filter combination 1 minute after the first image. This technique also produced an exposure level under the breast of approximately 70 μ Gy.

In Test Case 2, a lead bar was positioned on the *Novation*^{DR} image receptor and exposed at 23kV, 2 mAs for the Mo/Mo anode/filter combination. This technique produced an exposure level under the lead bar corresponding to a zero exposure level. The lead bar phantom was replaced with a 4 cm thick 50/50 tissue equivalent phantom which was sufficiently large that it overlapped the lead bar. A second exposure was made after 3 minutes at 28 kV, 32 mAs and Mo/Mo anode/filter combination. This technique produced an exposure level under the breast of approximately 70 μ Gy.

In the saturated area of the detector many electron-hole pairs are generated and transported in the applied field although some of the electrons can be trapped. During subsequent image acquisition some of the trapped charges that would normally be collected by the charge collection electrodes recombine with trapped electrons/holes and do not contribute to the signal charge. This especially occurs with low exposure X-ray images.

For both test cases signal levels inside the smaller of the phantoms and in the overlap region were measured in digital counts over a 128x128 region of interest. For test case 1 the saturation area received about 3 counts lower than the area directly under the TE breast phantom. This represents a 1.5% difference that will not affect the quality of a clinical image. Similarly, for test case 2 the area under the lead bar receiving a zero exposure level had about 4 counts lower than the saturation area beyond. This represents a 2.9% difference which would not degrade the quality of a clinical image although this test case does not represent normal clinical conditions.

9. Phantom Imaging and Blinded Read

9.1 Study Procedures

Two mammography phantoms, the RMI 156 and the CDMAM 3.4, were used in this non-clinical study to acquire images according to the manufacturer's recommendation. The RMI 156 phantom consists of 6 different size nylon fibers which simulate fibrous structures, 5 groups of simulated microcalcifications, and 5 different sized tumor-like masses.

The CDMAM 3.4 consists of an aluminum base containing gold discs of various thicknesses and diameters which are arranged in a matrix of 16 rows and 16 columns. Each square contains two identical discs (same diameter and thickness), one in the center and one in a randomly chosen corner.

9.2 Image Acquisition

A range of sample imaging configurations was used for this study based on varying phantom thicknesses, kV settings, and target-filter combinations. These were selected based on the settings where the device would be expected to be used.

9.3 Blinded Read

Three (3) independent physicists experienced in scoring mammography phantoms evaluated the phantom images. The readers were not aware of any information regarding the protocol-specific image parameters or the type of system on which the images were acquired. Images were viewed as both hardcopy and softcopy display and the three readers, with normal or corrected vision, scored the images independently. There were no restrictions on viewing distance or the use of magnification while reading the image.

9.4 Overall Results for the RMI 156 Phantom

The differences in blinded read results between Selenia™ and the Novation^{DR} were evaluated through confidence bounds and statistical analyses. Figure 9.1 presents the mean scores by each feature type and device, and Table 1 contains a summary of the overall scores by device and display mode.

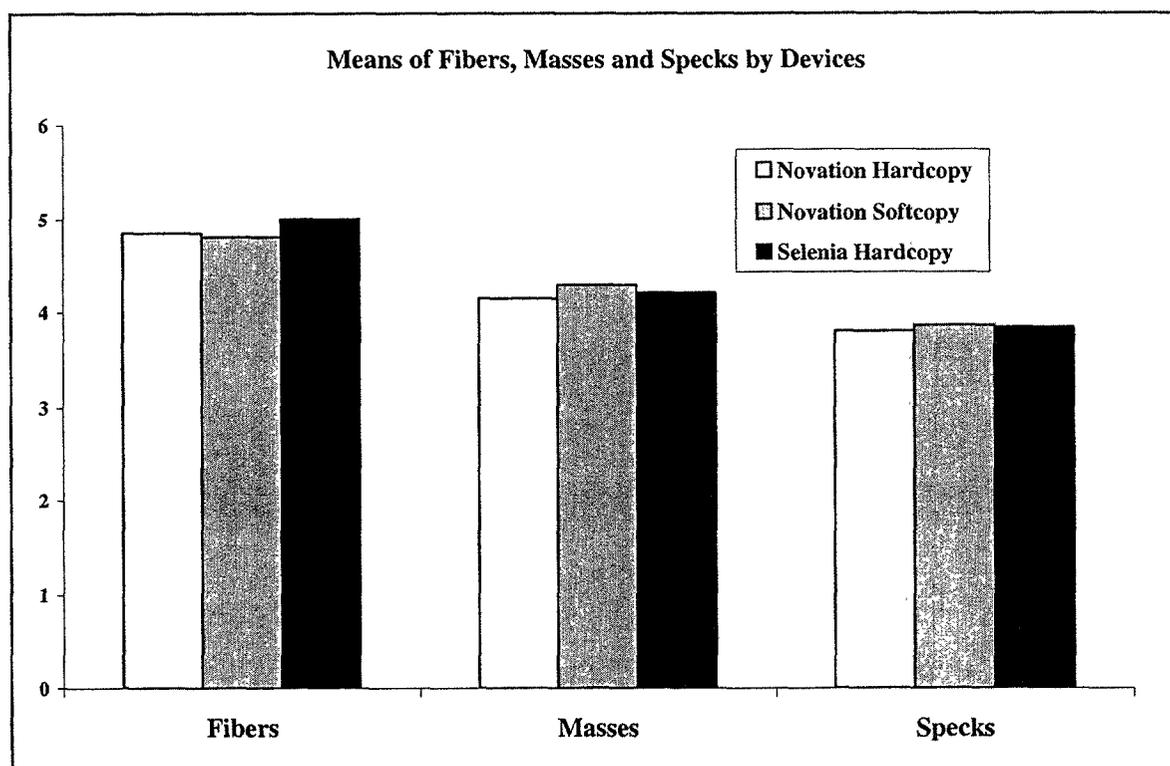


Figure 9.1 Mean of fibers, masses and specks by device.

Table 9.1 Summary of Overall Results for the RMI 156 Phantom by Device and Display Mode						
Overall	<i>Novation</i> ^{DR} Hardcopy		<i>Novation</i> ^{DR} Softcopy		Selenia Hardcopy	
	Mean	Std	Mean	Std	Mean	Std
	12.81	1.03	12.97	0.96	13.06	0.73

9.5 Overall Results for the CDMAM 3.4 Phantom

For each diameter size of gold disc in the phantom, the minimally visualized disc thickness was also determined to obtain a response curve. Figure 9.2 shows the contrast-detail curve.

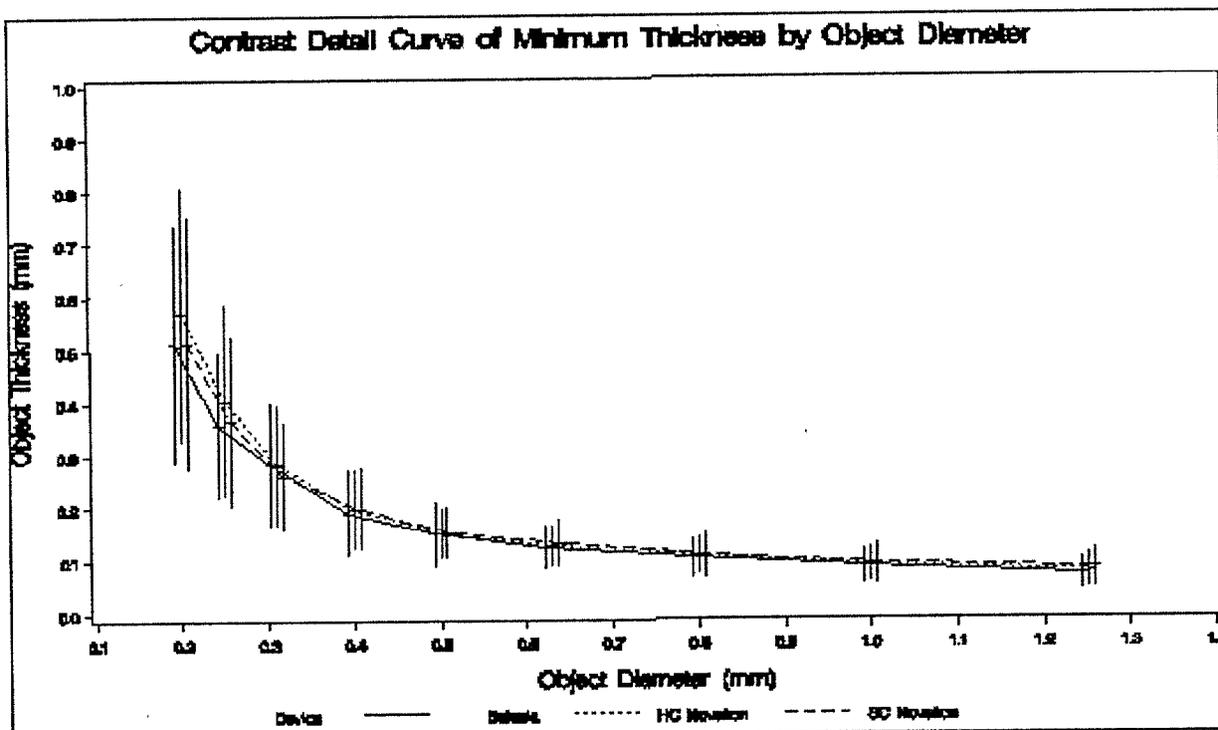


Figure 9.2 Contrast detail curve of minimum thickness by object diameter.

The total percent correct indicates the number of correctly identified cells noted on the phantom image. Table 9.2 lists the mean scores of all 3 readers by device.

Table 9.2 Summary of Correct Cells Identified on CDMAM Phantom by Device						
Overall	<i>Novation</i> ^{DR} Hardcopy		<i>Novation</i> ^{DR} Softcopy		Selenia Hardcopy	
	Mean	Std	Mean	Std	Mean	Std
	43.48	7.60	43.90	8.80	44.93	8.02

CONCLUSION:

This study has demonstrated that the imaging performance of the *Novation*^{DR} is equivalent to that of the SeleniaTM system. The inclusion of the CDMAM phantom improved the

evaluation of both systems and added a second level of confirmation to the study. Overall imaging performance of both systems was affected by phantom thickness in a similar fashion.

Equivalence was supported for all mean comparisons across both phantoms, and the results of this study provide good support for the use of the *Novation*^{DR} system in both hardcopy and softcopy display. With the establishment of technical equivalence in terms of imaging performance between the *Novation*^{DR} and *Selenia*TM systems through the generation of data from objective testing and the blinded read of hardcopy and softcopy phantom images, utilization of the clinical data obtained by Hologic is valid for the *Novation*^{DR} system.

X. SUMMARY OF CLINICAL STUDIES

The Mammomat *Novation*^{DR} is based on the Siemens Mammomat 3000 Nova mammography x-ray system cleared in Pre-Market Notification, K932672. It uses the same image acquisition subsystem and image display subsystem as the Hologic *Selenia*TM system for mammography screening and diagnosis approved in Pre-Market Application, P010025. The conclusions based on data from the objective testing and blinded reads of phantom images in Section IX Summary of Nonclinical Studies demonstrates that the imaging performance characteristics of these systems are sufficiently equivalent to justify the use of data collected during a clinical study conducted by Hologic for PMA P010025. FDA and Hologic agreed that Siemens could reference the clinical studies performed by Hologic, Inc. (PMA Number P010025 and PMA supplement P010025/S1).

XI. CONCLUSIONS DRAWN FROM NONCLINICAL AND CLINICAL STUDIES

The results of the nonclinical study conducted by Siemens and described above demonstrate equivalence between the *Novation*^{DR} and the *Selenia*TM digital mammography systems and provide reasonable assurance of the safety and effectiveness of the *Novation*^{DR} for screening and diagnostic breast imaging.

XII. PANEL RECOMMENDATIONS

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

XIII. REGULATORY REQUIREMENTS

In compliance with the Mammography Quality Standards Act of 1992 (MQSA), Siemens has developed a comprehensive quality control program which will be the responsibility of the

user to conduct and review once acceptance testing has been completed. Use of the *Novation*^{DR} will only be permissible in MQSA certified facilities.

Users must ensure that they have completed the Siemens *Novation*^{DR} training program prior to conducting patient exams. The Siemens training program will address the personnel training requirements under MQSA regulations in product labeling to assure that the prospective users are aware of the required eight hours of training for any medical physicist, technologist, or interpreting physician.

XIV. FDA DECISION

The applicant's manufacturing was inspected during June 1 to June 4, 2004 and was not found to be completely in compliance with the Quality Systems Regulations. FDA issued an approval on XXXXXX XX, 2004.

XIV. APPROVAL SPECIFICATIONS

Directions for Use: See the attached labeling.

Hazards to Health from Use of the Device: See Warnings and Precautions in Essential Prescribing Information (Tab 2), and Potential Adverse Effects of the Device on Health in Section VI.

Post-Approval Requirements and Restrictions: see Approval order