

**TECHNICAL EVALUATION OF THE HOLOGIC SELENIA FULL
FIELD DIGITAL MAMMOGRAPHY SYSTEM**

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**KC Young, JM Oduko and L Woolley
National Coordinating Centre for the Physics of Mammography
Guildford**

Enquiries

Enquiries about this report should be addressed to:

Professor KC Young
National Coordinating Centre for the Physics of Mammography
Medical Physics Department
Royal Surrey County Hospital
Guildford
GU2 7XX

Tel: 01483 406738
Fax: 01483 406742
Email: ken.young@nhs.net

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NHS Cancer Screening Programmes
Fulwood House
Old Fulwood Road
Sheffield
S10 3TH

Tel: 0114 271 1060
Fax: 0114 271 1089
Email: info@cancerscreening.nhs.uk
Website: www.cancerscreening.nhs.uk

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CONTENTS

	Page No
1. INTRODUCTION	1
1.1 Testing procedures and performance standards for digital mammography	1
1.2 Objectives	1
2. METHODS	2
2.1 System tested	2
2.2 Detector response and noise analysis	2
2.3 Dose measurement	2
2.4 Contrast to noise ratio	2
2.5 Image quality measurements	3
2.6 Optimisation	3
3. RESULTS	5
3.1 Detector response	5
3.2 Noise measurements	5
3.3 AEC performance	6
3.4 Image quality measurements	8
3.5 Comparison with other systems	10
3.6 Optimisation	12
4. DISCUSSION	14
5. CONCLUSIONS	15
REFERENCES	16

1. INTRODUCTION

1.1 Testing procedures and performance standards for digital mammography

The testing methods and standards applied in this report were mainly derived from NHSBSP Equipment Report 0604.¹ This is referred to in this document as the NHSBSP protocol and it has the same image quality and dose standards as those provided in the European protocol.^{2,3} The European protocol was followed where there is a more detailed performance standard, eg for the automatic exposure control (AEC) system.

1.2 Objectives

The purpose of these tests was firstly to determine whether the Hologic Selenia met the main standards in the UK and European protocols, and to provide performance data for comparing this system against other manufacturers' products. Some measurements had been made previously on earlier versions of the Selenia but the manufacturers have since made improvements to the detector design and asked that any published results be based on the latest model. Additional measurements were also undertaken to assess how well the system's AEC was optimised. The method of assessing optimisation has been reported previously.^{4,5} This report is one of a series intended to evaluate all the commercially available digital mammography systems on behalf of the NHS Breast Screening Programme. Clinical evaluations are published separately by the NHSBSP where systems meet the minimum standards in the NHSBSP protocol.

2. METHODS

2.1 System tested

A Hologic Selenia was tested in the Breast Screening Unit at Edgware Community Hospital during July 2006.

2.2 Detector response and noise analysis

The detector response was measured as described in the NHSBSP protocol. A phantom of PMMA with total thickness of 45 mm was positioned at the tube exit port and exposed using a tube voltage of 31 kV and a Mo/Rh target/filter combination. An ion chamber was positioned at the surface of the breast support table with the grid removed – and the entrance surface air kerma measured for a range of tube current-time products. The readings were corrected to the surface of the imaging detector using the inverse square law. It was determined that the imaging detector is at a distance of 66 cm from the tube focus and 2 cm below the surface of the breast support table using data provided by the manufacturer. No correction was made for attenuation by the protective plates above the detector. The images were saved as unprocessed files and transferred to another computer for analysis. A 10 mm square region of interest (ROI) was positioned on the mid-line and 6 cm from the chest wall edge of each image. The average pixel value and the standard deviation of pixel values within that region were measured. The relationship between average pixel values and the detector entrance surface air kerma was determined. The magnitude of the pixel offset at zero air kerma was determined. The standard deviations for the pixel values in the ROI for each image were used to investigate the relationship between dose to the detector and image noise.

2.3 Dose measurement

Doses were measured by using the AEC control to expose different thicknesses of PMMA to simulate breasts. U-shaped expanded polystyrene spacers were added to adjust the total thickness to be equal to the equivalent breast thickness. To measure the contrast-to-noise ratio (CNR) an aluminium square (10 mm × 10 mm) with a 0.2 mm thickness was placed on top of the 20 mm thick block, with one edge on the midline and 6 cm from the chest wall edge. Additional layers of PMMA were added on top to vary the total thickness.

2.4 Contrast to noise ratio

The images of the blocks of PMMA obtained during the dose measurement were analysed to obtain the CNRs. To apply the standards in the European protocol the limiting value for CNR (using 50 mm PMMA) was determined according to equation 1. This equation determines the CNR value ($CNR_{limiting\ value}$) that is necessary to achieve the minimum threshold gold thickness for the 0.1 mm detail (ie $threshold\ gold_{limiting\ value} = 1.68\ \mu m$).

$$Threshold\ gold_{measured} CNR_{measured} = Threshold\ gold_{limiting\ value} CNR_{limiting\ value} \quad (1)$$

The relative CNR was then calculated according to equation 2 and compared with the limiting values provided for relative CNR shown in Table 1.

$$Relative\ CNR = CNR_{measured} / CNR_{limiting\ value} \quad (2)$$

Table 1 Limiting values for relative CNR

Thickness of Perspex (mm)	Equivalent breast thickness (mm)	EUREF limiting values for relative CNR (%)
20	21	> 115
30	32	> 110
40	45	> 105
45	53	> 103
50	60	> 100
60	75	> 95
70	90	> 90

2.5 Image quality measurements

Contrast detail measurements were made using the CDMAM phantom (version 3.4, UMC St Radboud, Nijmegen University, Netherlands). The phantom was positioned with a 20 mm thickness of PMMA blocks above and below, to give a total attenuation approximately equivalent to 50 mm of PMMA or 60 mm thickness of typical breast tissue. This arrangement was imaged using the x-ray set's automatically selected factors normally set for clinical use for a breast of equivalent attenuation, ie 60mm. This procedure was repeated seven times to obtain a representative sample of eight images. Unprocessed images were transferred to disk for subsequent analysis off-site. The digital images had their contrast and density adjusted to optimally display the details in the test object, before scoring on a monitor. These image quality measurements were then repeated at three other dose levels by manually selecting higher and lower mAs values with the same beam quality as selected under AEC control.

For an image quality measurement at each dose level three observers reviewed four of the digital images on a soft copy display and the test object manufacturer's correction scheme was then applied, before determining the threshold gold thickness for each detail diameter.

The average threshold gold thickness for each detail diameter for each dose level (an average for four images and three experienced observers) was fitted with a curve as described in the NHSBSP protocol. The measured threshold gold thicknesses typically have 95% confidence limits of about 10%. The threshold contrasts quoted in the tables of results are derived from the fitted curves, as this has been found to improve the accuracy.⁶

The expected relationship between threshold contrast and dose was plotted with the experimental data and is given by equation 3.

$$\text{Threshold contrast} = \lambda D^{-n} \quad (3)$$

The appropriate value of n was determined from the analysis of the noise as a function of the pixel value. In practice this was done by finding the value of n that provided the best fit to the experimental data. D represents the MGD for a 60 mm thick standard breast equivalent to the test phantom configuration used for the image quality measurement. λ is a constant to be fitted.

An automatic method of reading the CDMAM images was also used. This produces a prediction of the threshold gold thickness for a typical human observer using a method that has been described elsewhere.^{6,7} The main advantage of automatic reading is that it has the potential of eliminating observer error which is a significant problem when using human observers. However it should be noted that at the present time the official protocols still require human reading.

2.6 Optimisation

A method for determining optimal beam qualities and exposure factors for digital mammography systems has been described previously and was used to evaluate this system.^{4,5} CNR and mean glandular dose were measured as described above using blocks of PMMA from 20 to 70 mm thick. For each thickness up to six tube voltage settings were used (25, 28, 31, 34, 37 and 39 kV) with each of the target/filter combinations available (Mo/Mo and Mo/Rh,) and the mAs recorded. The MGDs to typical breasts with attenuation equivalent to each thickness of the PMMA were calculated as described in the NHSBSP protocol. Each exposure was designed to achieve a standard pixel value by using the AEC in automatic mAs mode. The relationship between noise and pixel values in digital mammography systems has been previously⁵ shown to be approximated by

$$\text{Relative noise} = \frac{\sqrt{\frac{sd(bgd)^2 + sd(Al)^2}{2}}}{p} = k_1 p^{-n} \quad (4)$$

where k_1 is a constant, and p is the average background pixel value linearised with absorbed dose to the detector. The value of n was found by fitting this equation to the experimental data. Equation 5 was then used to calculate the dose required to achieve a target CNR, where k is a constant to be fitted

$$\text{CNR} = kD^n \quad (5)$$

The target CNR was that calculated to reach either the minimum or achievable image quality in the NHSBSP and European protocols using the following relationship.

$$\text{Threshold contrast} = \frac{\lambda}{\text{CNR}} \quad (6)$$

where λ is a constant that is independent of dose, beam quality and the thickness of attenuating material. The optimal beam quality for each thickness was selected as that necessary to achieve the target CNR for the minimum dose.

3. RESULTS

3.1 Detector response

The detector was found to have a linear response with a pixel value offset of 63 as shown in Figure 1. The gradient was measured to be 0.236 μGy per pixel value. The AEC typically selected exposures to achieve a pixel value of 360 which corresponds to a detector entrance air kerma of 70.0 μGy . In practice attenuation by protective plates will make the true value somewhat lower than this.

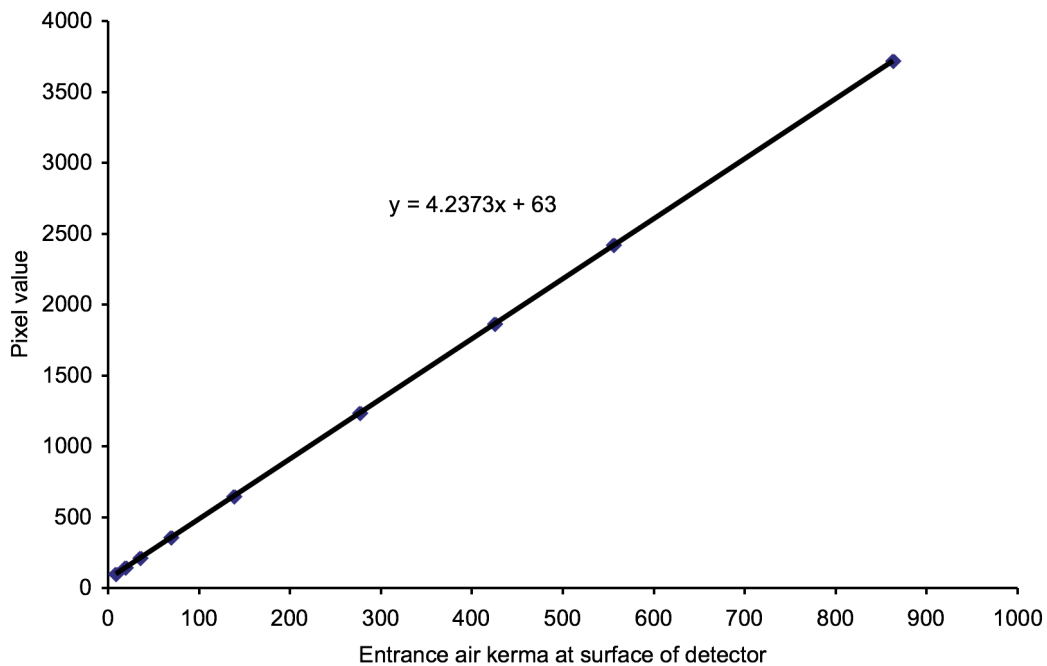


Figure 1 Detector response.

3.2 Noise measurements

The variation in noise with dose was analysed by plotting the detector entrance air kerma against the standard deviation in pixel values as shown in Figure 2. The fitted power curve has an index of 0.47. If only quantum noise sources were present the data would form a straight line with an index of 0.5. The presence of some electronic noise and structural noise has caused the curve to deviate from a straight line. This is normal for such systems and quantum noise was the dominant noise source.

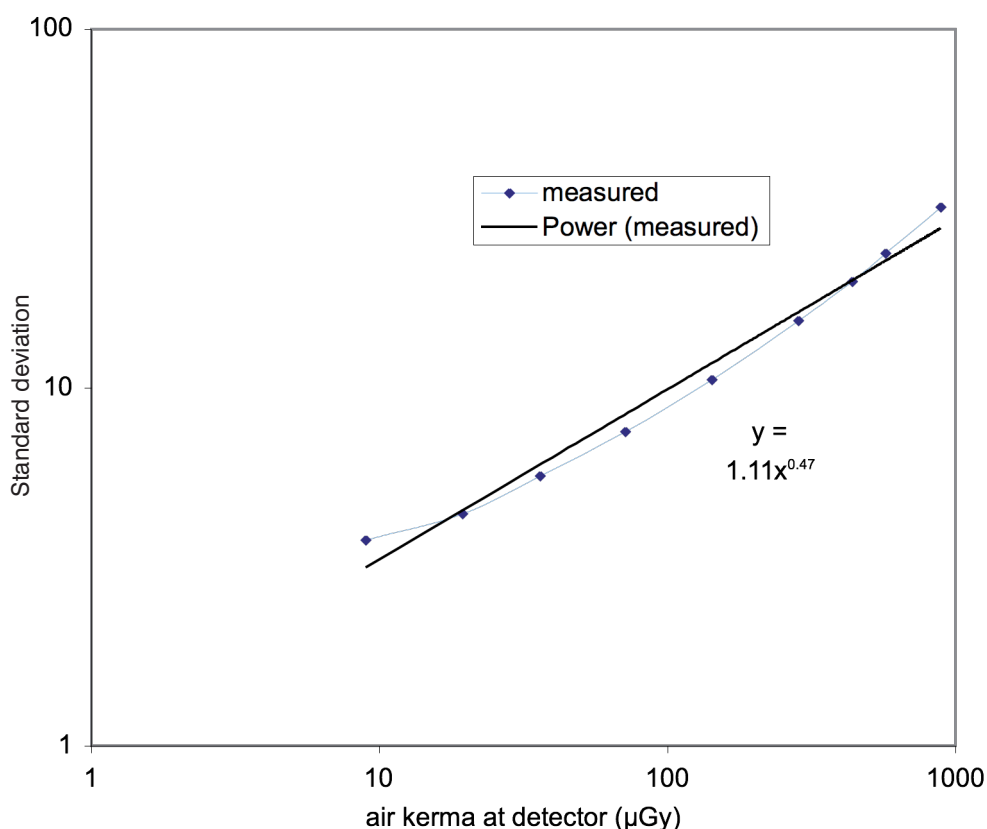


Figure 2 Standard deviation of pixel values versus detector entrance air kerma.

3.3 AEC performance

3.3.1 Dose

The mean glandular doses for breasts simulated with PMMA exposed under AEC control are shown in Table 2 and Figure 3. At all thicknesses the dose was below the remedial level in the NHSBSP protocol which is the same as the maximum acceptable level in the European Protocol.

Table 2 Mean glandular doses for simulated breasts

PMMA thickness (mm)	Equivalent breast thickness (mm)	kV	Target	Filter	mAs	MGD (mGy)	NHSBSP remedial level
20	21	25	Mo	Mo	25.9	0.76	> 1.0
30	32	26	Mo	Mo	41.7	1.07	> 1.5
40	45	29	Mo	Mo	47.9	1.50	> 2.0
45	53	31	Mo	Rh	46.0	1.34	> 2.5
50	60	32	Mo	Rh	52.3	1.58	> 3.0
60	75	33	Mo	Rh	69.1	2.02	> 4.5
70	90	34	Mo	Rh	89.7	2.50	> 6.5

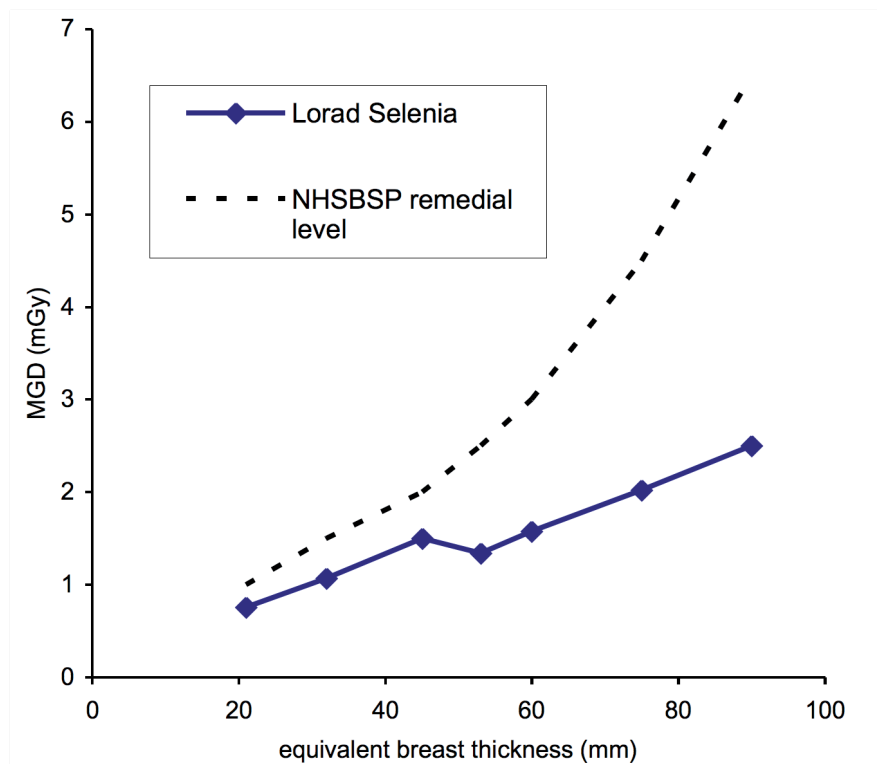


Figure 3 MGD for simulated breasts.

3.3.2 CNR

The results of the contrast and CNR measurements are shown in Table 3 and Figure 4. The CNR required to meet the minimum acceptable and achievable image quality standards at the 60 mm breast thickness have been calculated and are shown in Table 3 and Figure 4. The CNR required at each thickness to meet the limiting values for CNR in the European protocol are also shown.

Table 3 Contrast and CNR measurements using AEC

Equivalent breast thickness (mm)	kV target filter	mAs	Background pixel value	Contrast for 0.2 mm		CNR at minimum acceptable IQ	CNR at achievable IQ	CNR to meet European limiting value	EUREF limiting values for relative CNR
				Al square (%)	Measured CNR				
21	25 Mo/Mo	25.9	410	22.7	11.19	4.26	6.20	4.90	> 115
32	26 Mo/Mo	41.7	402	20.6	9.79	4.26	6.20	4.69	> 110
45	29 Mo/Mo	47.9	399	17.1	7.49	4.26	6.20	4.47	> 105
53	31 Mo/Rh	46	*	15.1	6.09	4.26	6.20	4.39	> 103
60	32 Mo/Rh	52.3	387	13.7	5.60	4.26	6.20	4.26	> 100
75	33 Mo/Rh	69.1	391	11.9	4.70	4.26	6.20	4.05	> 95
90	34 Mo/Rh	89.7	395	10.0	3.81	4.26	6.20	3.83	> 90

*Missing data.

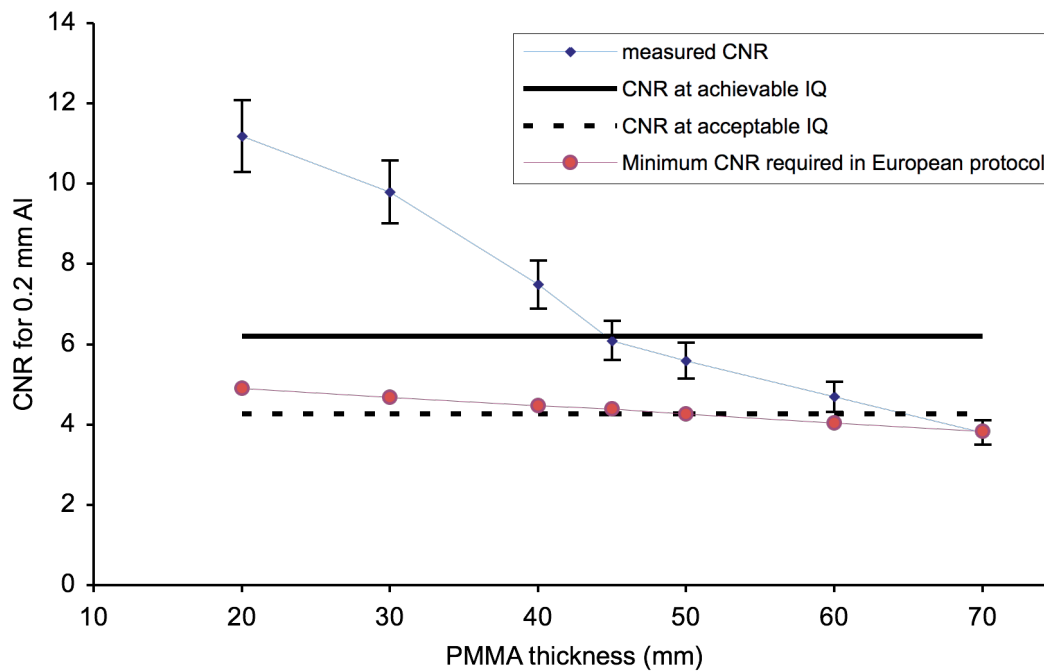


Figure 4 Measured CNR compared with the limiting values in the European protocol (error bars indicate 95% confidence limits).

3.4 Image quality measurements

The first exposures of the image quality phantom were made using the AEC to select the beam quality and exposure factors. This resulted in the selection of 32 kV Mo/Rh and 52.2 mAs and an MGD of 1.56 mGy to an equivalent breast. Subsequent image quality measurements were made at approximately half, double and quadruple this dose by manual selection of the mAs at the same beam quality. The threshold gold thicknesses for different diameters and the four different dose levels are shown in Table 4, along with the minimum and achievable threshold values from the NHSBSP protocol. The contrast detail curves at the four dose levels are shown in Figure 5. The system meets the minimum acceptable standard for all doses except the lowest. The measured threshold gold thicknesses are plotted against the dose for the 0.1 and 0.25 mm detail sizes in Figure 6. This illustrates that when the dose was increased the threshold contrast reduced as expected by the theory. The fitted curves in Figure 6 were used to determine the doses required to meet the minimum acceptable and achievable image quality levels for comparison with other systems in the next section. In practice this is dictated by the threshold contrast for the 0.1 mm detail size as this required the highest dose. Figure 6 also shows the predicted threshold gold thickness using automated reading at each dose level.

Table 4 Average threshold gold thicknesses for different detail diameters for four different doses using 32 kV Mo/Rh

Diameter (mm)	Threshold gold thickness (μm)					
	Acceptable value	Achievable value	MGD = 0.64 mGy	MGD = 1.56 mGy	MGD = 3.21 mGy	MGD = 6.4 mGy
0.1	1.680	1.100	1.869	1.238	0.798	0.614
0.25	0.352	0.244	0.417	0.262	0.168	0.131
0.5	0.150	0.103	0.174	0.122	0.083	0.068
1	0.091	0.056	0.087	0.068	0.051	0.045
2	0.069	0.038	0.051	0.043	0.036	0.036

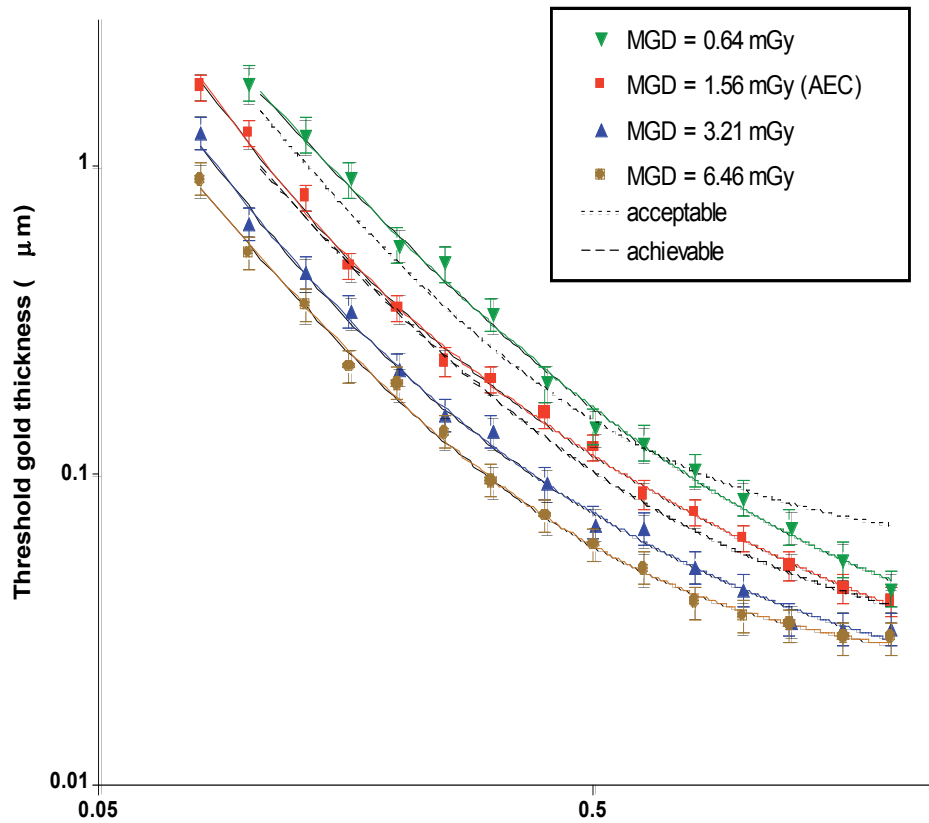


Figure 5 Contrast–detail curves for four different doses at 32 kV Mo/Rh using human readers.

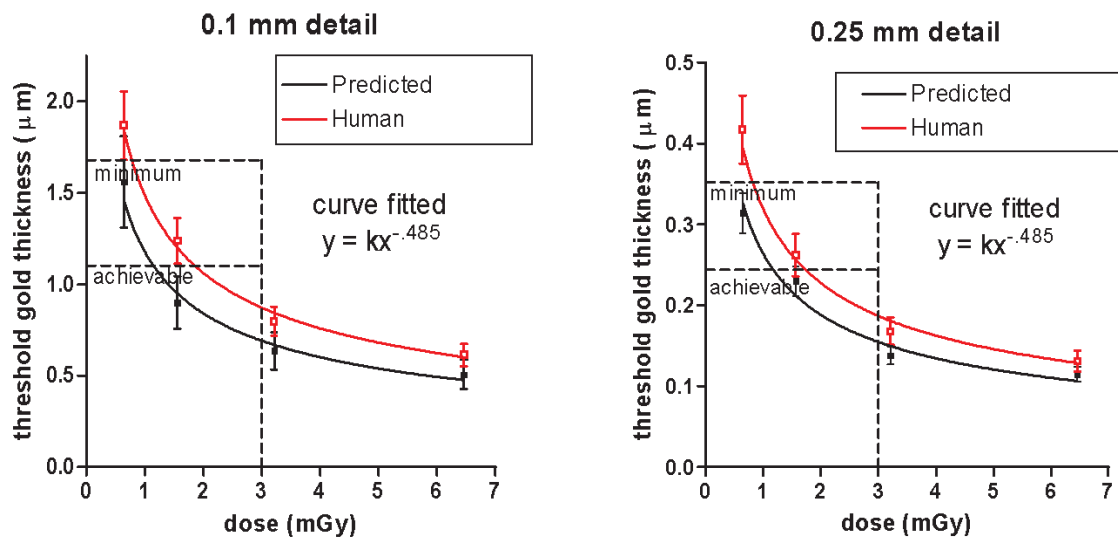


Figure 6 Threshold gold thickness at different doses.

3.5 Comparison with other systems

The mean glandular doses to reach the minimum and achievable image quality standards in the NHSBSP protocol have been estimated from the curves shown in Figure 6. These doses are shown against similar data for other models of digital mammography system in Tables 5 and 6 and Figures 7 and 8. The data for the other systems has been determined in the same way as described here for the Hologic Selenia and the results published previously.^{7,8} The data for film screens represent an average value determined using a variety of film screen systems.

Table 5 The MGD for different systems to reach the minimum threshold gold thickness for 0.1 and 0.25 mm details

System	MGD (mGy) for 0.1 mm		MGD (mGy) for 0.25 mm	
	Human	Predicted	Human	Predicted
Fischer Seno	0.55 ± 0.08	0.42 ± 0.06	0.48 ± 0.07	0.53 ± 0.08
Sectra MDM	0.60 ± 0.09	0.82 ± 0.12	0.67 ± 0.10	0.46 ± 0.07
Siemens Novation	0.63 ± 0.04	0.61 ± 0.17	0.52 ± 0.04	0.63 ± 0.13
Hologic Selenia	0.85 ± 0.10	0.55 ± 0.07	0.80 ± 0.10	0.53 ± 0.09
GE DS	1.01 ± 0.17	0.82 ± 0.07	0.87 ± 0.08	0.83 ± 0.08
Film-screen	1.17 ± 0.09	1.30 ± 0.11	1.07 ± 0.08	1.36 ± 0.065
Fuji Profect CR	1.67 ± 0.12	1.78 ± 0.16	1.45 ± 0.02	1.35 ± 0.07
Kodak CR	3.46 ± 0.29	2.49 ± 0.13	1.49 ± 0.12	1.33 ± 0.12
Test CR	4.52 ± 0.35	4.17 ± 0.14	2.33 ± 0.07	2.12 ± 0.05

Technical Evaluation of the Hologic Selenia Full Field Digital Mammography System

Table 6 The MGD for different systems to reach the achievable threshold gold thickness for 0.1 and 0.25 mm details

System	MGD (mGy) for 0.1 mm		MGD (mGy) for 0.25 mm	
	Human	Predicted	Human	Predicted
Fischer Seno	1.16 ± 0.17	0.90 ± 0.13	0.98 ± 0.15	1.09 ± 0.16
Sectra MDM	1.27 ± 0.19	1.74 ± 0.26	1.37 ± 0.21	0.95 ± 0.14
Siemens Novation	1.56 ± 0.03	1.21 ± 0.07	1.14 ± 0.05	1.27 ± 0.13
Hologic Selenia	1.84 ± 0.10	1.19 ± 0.07	1.68 ± 0.095	1.12 ± 0.09
GE DS	2.35 ± 0.40	1.57 ± 0.07	1.80 ± 0.08	1.87 ± 0.07
Film-screen	2.48 ± 0.18	3.03 ± 0.25	2.19 ± 0.16	2.83 ± 0.13
Fuji Profect CR	4.26 ± 0.66	3.29 ± 0.44	3.52 ± 0.03	2.65 ± 0.03
Kodak CR	7.74 ± 0.71	5.56 ± 0.26	6.28 ± 0.25	5.60 ± 0.17
Test CR	11.5 ± 2.8	9.90 ± 1.10	5.96 ± 0.53	5.63 ± 0.26

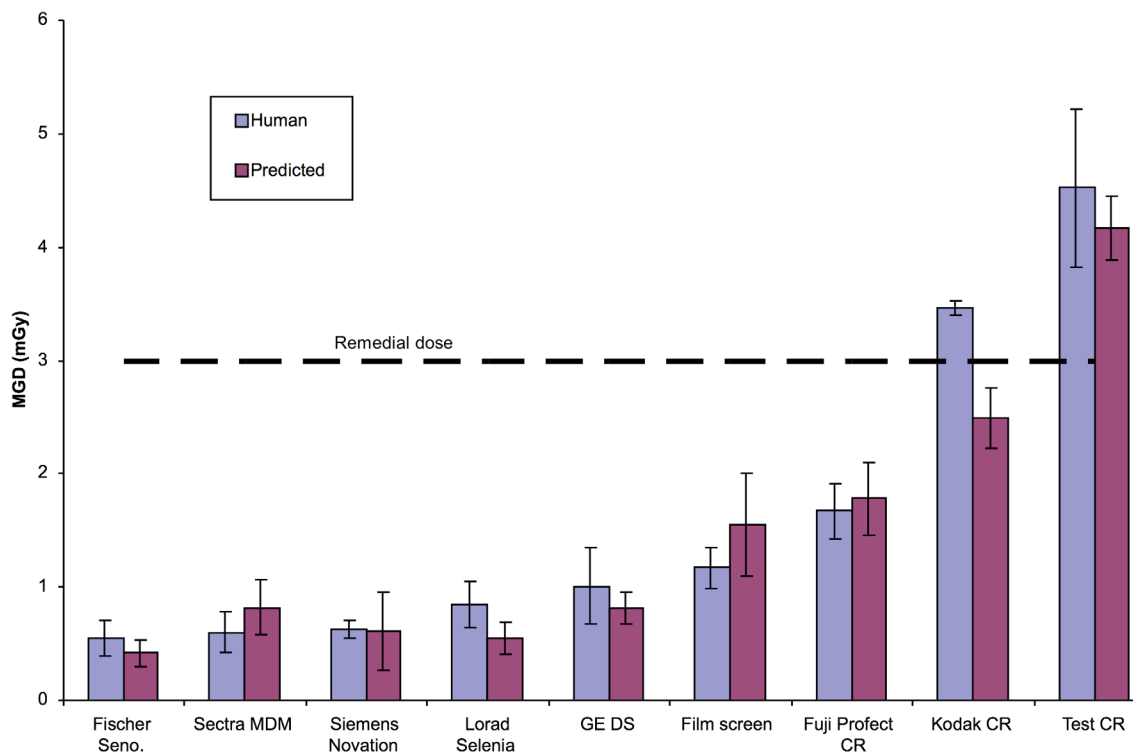


Figure 7 Dose to achieve minimum acceptable image quality standard.

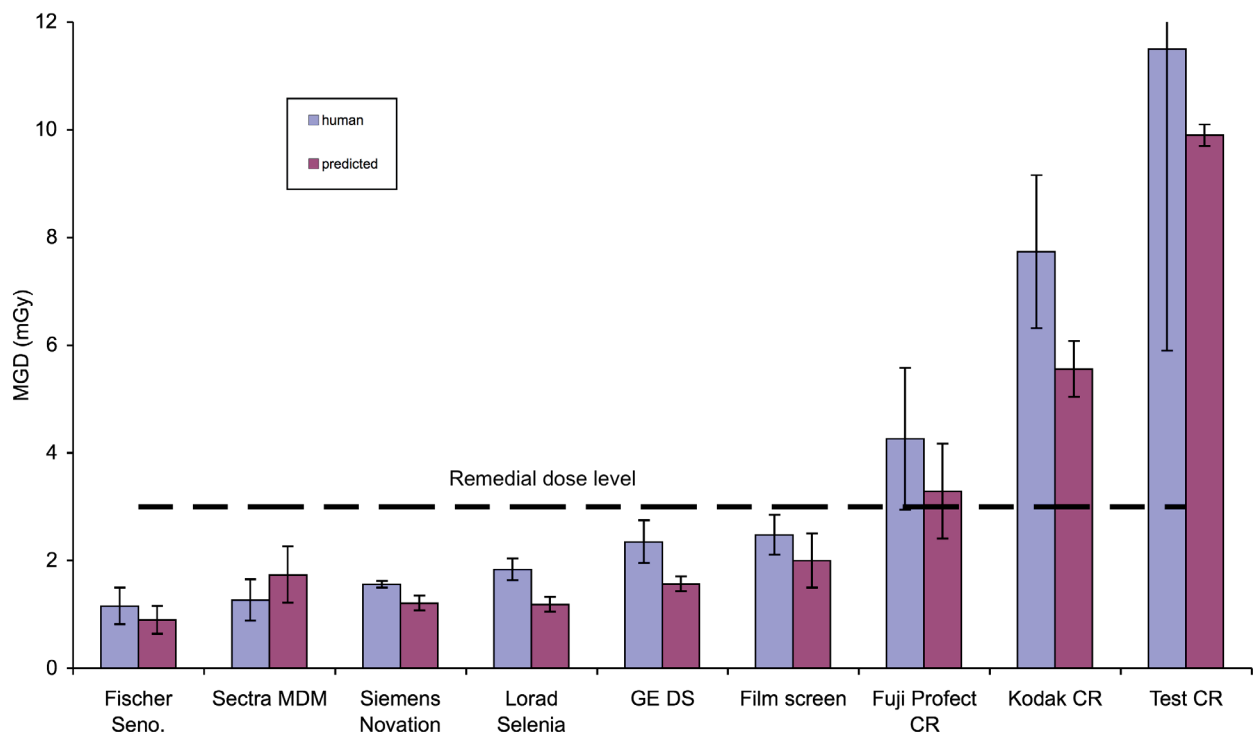


Figure 8 Dose to reach achievable image quality standard.

3.6 Optimisation

The target CNR corresponding to the achievable image quality standard was calculated to be 6.2. The MGD required to reach this target CNR for each beam quality and thicknesses of PMMA are shown in Figure 9. From these data the optimal beam qualities were selected and are shown in Table 7.

Table 7 Optimal factors to produce achievable image quality (where CNR = 6.2)

PMMA Thickness	kV target filter	BGD pixel value	mAs	MGD (mGy)	Dose compared with current beam quality under AEC (%)	Remedial dose level in NHSBSP protocol
20	25 Mo/Mo	170	8	0.23	100	1.0
30	25 Mo/Mo	191	19	0.43	99	1.5
40	25 Mo/Mo	212	46	0.82	80	2.0
45	28 Mo/Rh	315	56	1.15	83	2.5
50	28 Mo/Rh	339	79	1.51	78	3.0
60	28 Mo/Rh	383	157	2.62	74	4.5
70	28 Mo/Rh	447	323	4.71	71	6.5

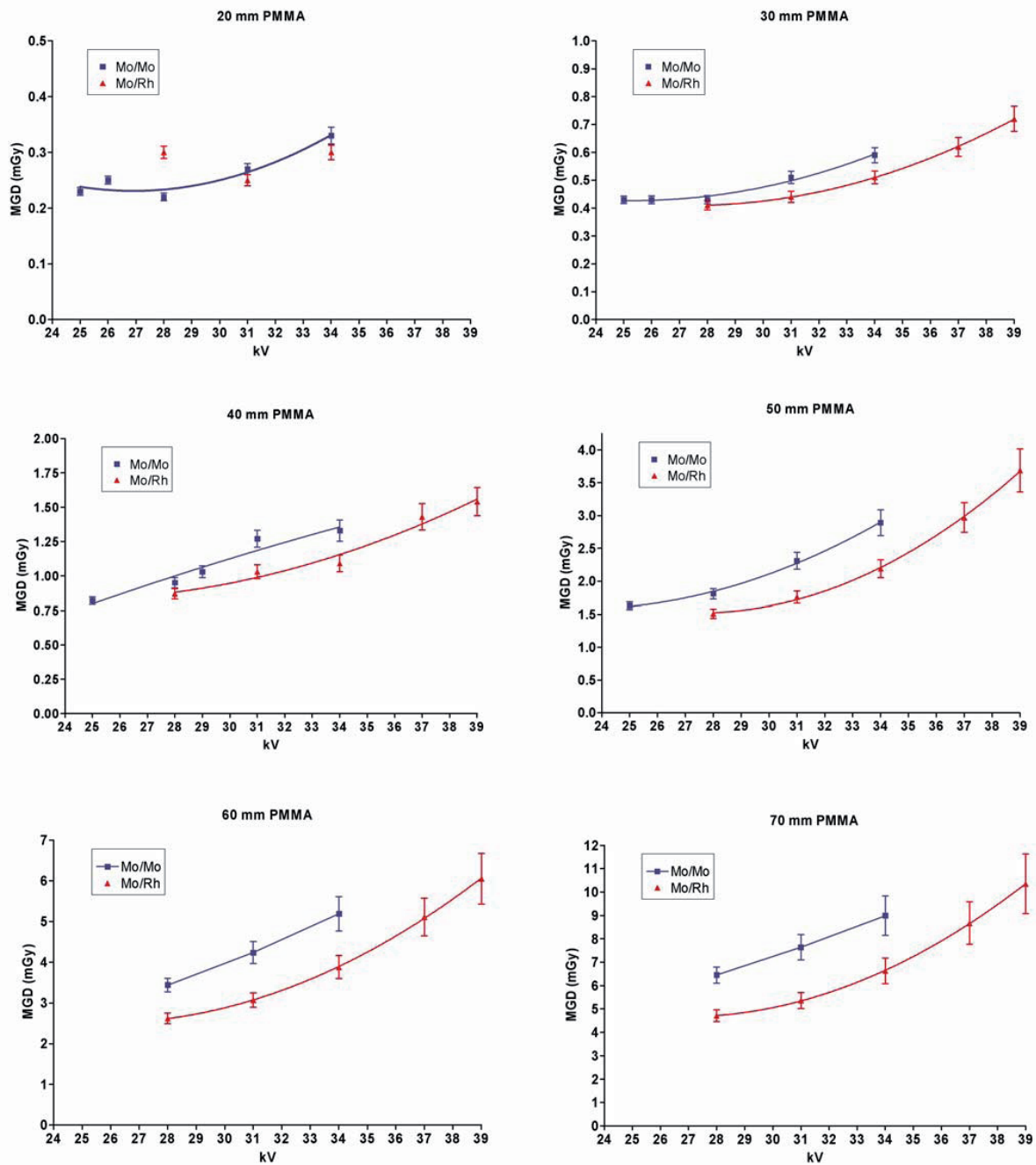


Figure 9 MGD to reach the achievable image quality standard in the NHSBSP protocol (error bars indicate 95% confidence limits).

4. DISCUSSION

The detector response was as expected linear with a pixel value offset of 63. The noise analysis confirmed that quantum noise is the dominant noise source. The AEC resulted in doses to simulated breasts that were within the limits in the NHSBSP protocol. The dose for the standard breast simulated with 45 mm of PMMA was 1.34 mGy which is about half the upper limit of 2.5 mGy applied by the NHSBSP.

The AEC resulted in approximately constant background pixel values. The AEC also chose beam qualities with higher x-ray energy with increasing thickness. The net result of these choices was that the Contrast and CNR declined steeply with increasing thickness. Comparison with the CNR necessary to reach the achievable and minimum acceptable image quality levels showed that while excellent image quality can be expected for breasts with small and medium thicknesses a level close to the minimum acceptable will be achieved for the largest breast thicknesses.

The image quality measurements indicated that for the standard thickness tested (equivalent to 50 mm thickness of PMMA, ie 60 mm of typical breast) the image quality was close to the achievable level at the current AEC setting. The AEC selected a dose of 1.56 mGy using 32 kV Mo/Rh, while a dose of 1.84 ± 0.10 mGy was calculated to be necessary to reach the achievable image quality level.

The doses required to reach the acceptable and achievable image quality levels were similar to other DR systems. The results using the automated image quality assessment were broadly similar to those with human readers. However, the automated method indicated that slightly lower doses might be sufficient to meet the two image quality levels. The reason for this difference could be a systematic error in the automated method or a change in the performance of the human readers since the automated method was calibrated against a panel of human readers.

The optimisation study found that the Rh filter was preferable to the Mo filter for all but the thinnest breasts. A low kV was always preferable to the use of a higher kV. These findings suggest that the current AEC design is not optimal in either the mAs or beam quality selection. Optimal beam quality selection could save up to 30% of the dose for the same image quality (see Table 7) for the large thicknesses of breast. More importantly the selection of higher detector doses to ensure greater CNR at the greater breast thicknesses would ensure good image quality for all thicknesses of breast. It was surprising that low kV seemed preferable to high kV as this has not been observed with other systems and this merits further investigation.^{4,5} It should be noted that the use of lower kV would lead to longer exposure times – and this may ultimately limit the choice available.

5. CONCLUSIONS

This system is capable of producing good image quality for a relatively low radiation dose. As currently set up the AEC will be mostly satisfactory for most types of breast. The system passed the main standards in the NHSBSP protocol. However the system only just passes the additional criteria for AEC performance in the European protocol at 70 mm PMMA. The current design of AEC does not seem optimal and could be improved – especially for larger breasts.

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