

**TECHNICAL EVALUATION OF THE
AGFA CR 85-X MAMMOGRAPHY SYSTEM**

**NHSBSP Equipment Report 0707
May 2007**

**KC Young and JM Oduko
National Coordinating Centre for the Physics of Mammography**

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

Don Valley House

Savile Street

Sheffield

S4 7UQ

Tel: 0114 271 1060

Fax: 0114 271 1089

Email: info@cancerscreening.nhs.uk

Website: www.cancerscreening.nhs.uk

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1. INTRODUCTION

1.1 Testing procedures and performance standards for digital mammography

This report is one of a series evaluating commercially available digital mammography systems on behalf of the NHS Breast Screening Programme (NHSBSP). 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 to determine whether the Agfa CR 85-X system met the main standards in the NHSBSP and European protocols, and to provide performance data for comparison against other manufacturers' products. Additional measurements were also undertaken to determine the optimal exposure factors for this system. The method of assessing optimisation has been reported previously.^{4,5} Clinical evaluations are conducted and published separately by the NHSBSP where systems meet the minimum standards in the NHSBSP protocol.

2. METHODS

2.1 System tested

The CR system described in Table 1 was tested at King's College Hospital, London, on 4 and 5 January 2007. The AEC programme and density setting were chosen on the recommendation of the CR manufacturer.

Table 1 System tested

Imaging plate	CR MM3.0 Mammo Plate
Cassette	CR MM3.0 Mammo Cassette
CR reader	CR85-X
X-ray room	2
Mammography x-ray set	GE Senographe DMR+
AEC programme	DOSE
AEC density setting	0

2.2 Detector response and noise analysis

The detector response was measured broadly as described in the NHSBSP protocol. A Perspex (PMMA) phantom with a total thickness of 45 mm was positioned at the tube exit port and exposed using a tube voltage of 29 kV and a Rh/Rh target/filter combination. A CR cassette was placed on top of the Bucky and an ion chamber was positioned on top of the CR cassette at approximately 6 cm from the chest wall edge. The entrance surface air kerma was measured for a range of tube current-time products. The readings were corrected to the surface of the cassette using the inverse square law. No correction was made for attenuation by the cassette top cover. The images were saved as unprocessed DICOM files and transferred to another computer for analysis. Multiple small (5 mm × 5 mm) square regions of interest (ROI) were positioned on the mid-line and approximately 6 cm from the chest wall edge and adjacent to the image of the ion chamber. The average pixel value and the average standard deviation of pixel values within these ROIs were measured. The relationship between average pixel values and the detector entrance surface air kerma was determined. This was used to linearise all pixel values and their standard deviations against the entrance air kerma. The average standard deviations for the pixel values in the ROIs for each image were used to investigate the relationship between dose to the detector and image noise. A method described previously was used to estimate the relative amounts of electronic, structural and quantum noise.⁵

2.3 Dose measurement

Doses were measured by using the AEC 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. The mean glandular doses (MGDs) for breasts equivalent in attenuation to each thickness of PMMA were calculated as described in the NHSBSP and European protocols.^{2,3}

2.4 Contrast-to-noise ratio

The images of the blocks of PMMA obtained during the dose measurement were analysed to obtain the CNRs. Multiple small ROIs (< 3 mm × 3 mm) were used to determine the average signal and the standard deviations in the signal within the image of the aluminium square and the surrounding background. Small ROIs were used to minimise distortions due to the heel effect. The CNR was calculated for each image as defined in the NHSBSP and European protocols.

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 $threshold\ gold_{limiting\ value} = 1.68\ \mu m$ which is equivalent to $threshold\ contrast_{limiting\ value} = 23.0\%$ using 28 kV Mo/Mo). Threshold contrasts were calculated as described in the European protocol and used in equation 1.

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

The relative CNR was then calculated according to equation 2 and compared with the limiting values provided for relative CNR shown in Table 2. The minimum CNR required to meet this criterion was then calculated.

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

Table 2 Limiting values for relative CNR

Thickness of PMMA (mm)	Equivalent breast thickness (mm)	Limiting values for relative CNR (%) in European protocol
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 a 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 60 mm. This procedure was repeated 15 times to obtain a representative sample of 16 images. (Using a large number of images increases the accuracy of the automated image quality measurements.) 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 DICOM calibrated monitor. These image quality measurements were then repeated using eight exposures at 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 medical grade DICOM calibrated soft copy display. The contrast and brightness of each image was adjusted by the observer to optimally display the details in the test object, before scoring. 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%.⁶

The expected relationship between threshold contrast and dose was plotted with the experimental data for the 0.1 and 0.25 mm details and is given by equation 3.

$$\text{Threshold contrast} = \lambda D^{-n} \tag{3}$$

The appropriate value of n was determined from analysis of the noise as a function of the background pixel value (linearised). 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. 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 with this system.^{4,5} CNR and MGD were measured as described above using blocks of PMMA from 20 to 70 mm thick. For each thickness up to five tube voltage settings were used (25, 28, 31, 34, and 37 kV) with each of the target/filter combinations available (Mo/Mo, Mo/Rh and Rh/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. $sd(bgd)$ is the average standard deviation of pixel values in the ROIs over the background. $sd(Al)$ is the average standard deviation of pixel values in an ROI over a 0.2 mm × 10 mm × 10 mm piece of aluminium. 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, and D is the MGD for a breast of equivalent thickness.

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

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 pixel values in the unprocessed images were found as expected to have a square root response to entrance air kerma as shown in Figure 1. (Note that it is also possible to save unprocessed images with a logarithmic response using this system.) The AEC had been adjusted to have the values proposed for clinical use with a typical pixel value of 975 which corresponds to a detector entrance air kerma of 164 μGy. All the measured pixel values were linearised against entrance air kerma as shown in Figure 2.

3.2 Noise measurements

The variation in noise with dose was analysed by plotting the standard deviation in the linearised pixel values against detector entrance air kerma as shown in Figure 3. The fitted power curve has an index of 0.53. If only quantum noise sources were present the data would form a straight line with an index of 0.5. The presence of

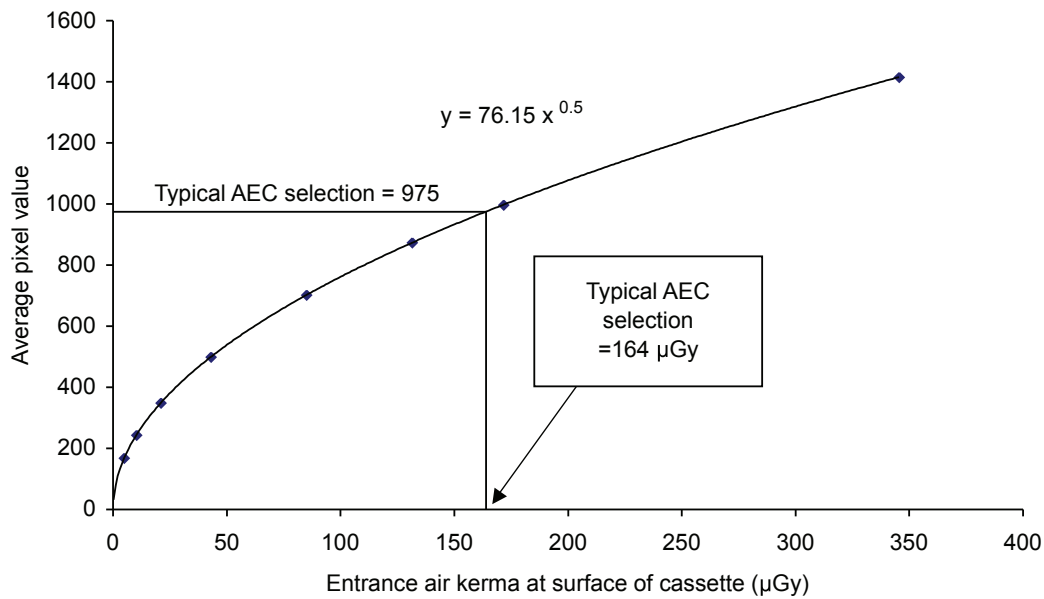


Figure 1 Detector response using 29 kV Rh/Rh.

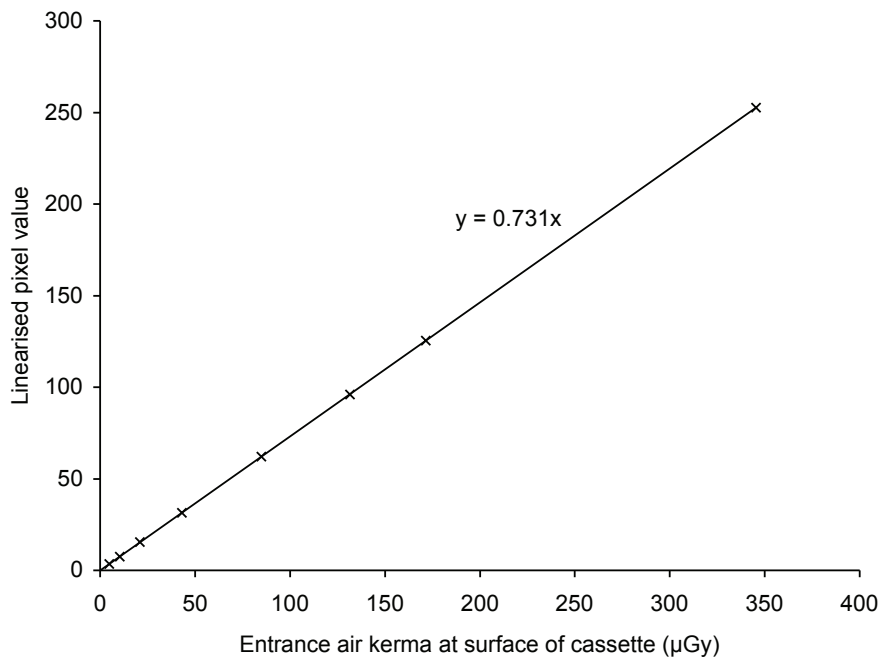


Figure 2 Linearisation of pixel values.

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 4 is an alternative way of presenting the data and shows the relative noise at different entrance air kerma. The estimated relative contributions of electronic, structural and quantum noise are shown and the quadratic sum of these contributions fitted to the measured noise. These measured data were also fitted with a power curve described by equation 4 (not shown in the figure) with an index of -0.41 in the clinically used dose range. If only quantum noise were present the curve would fit perfectly and the index would be -0.5 .

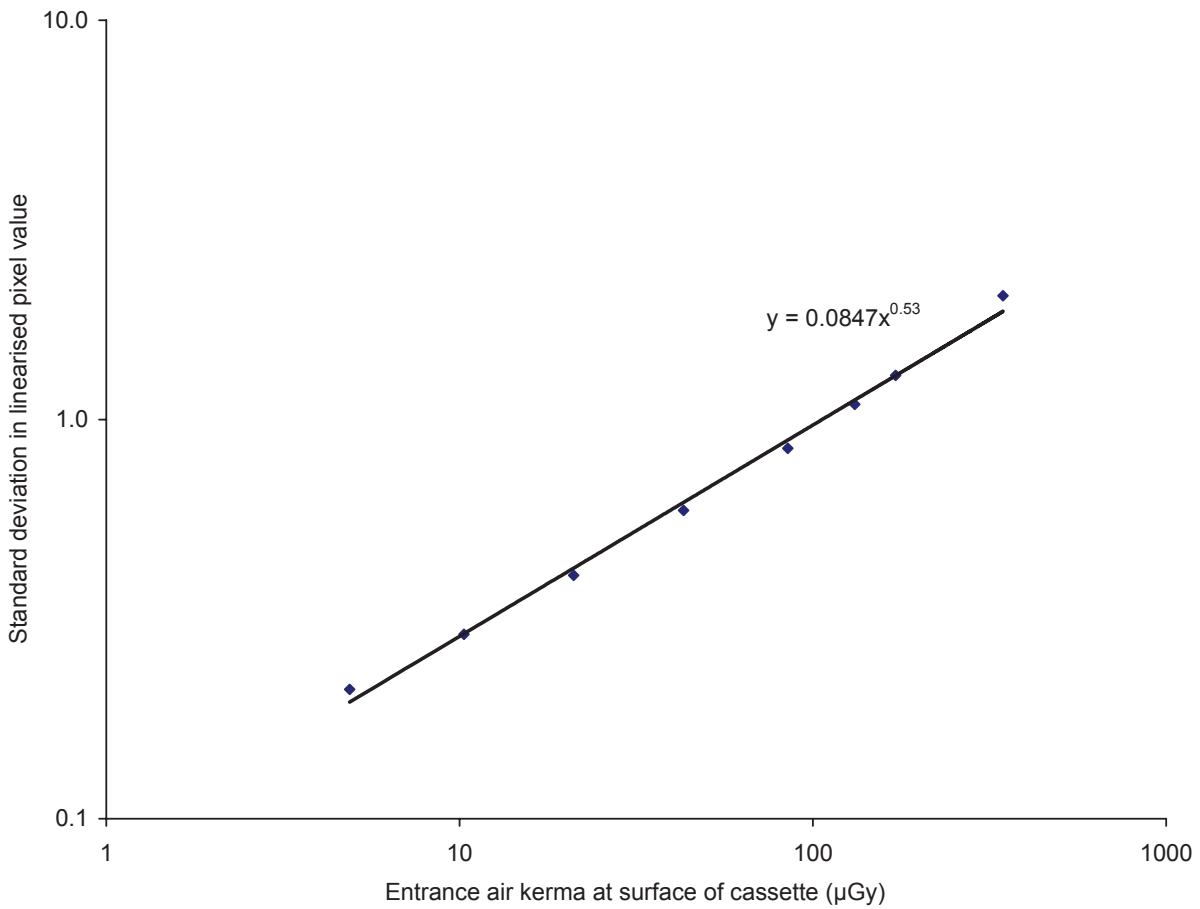


Figure 3 Standard deviation of linearised pixel values versus detector entrance air kerma.

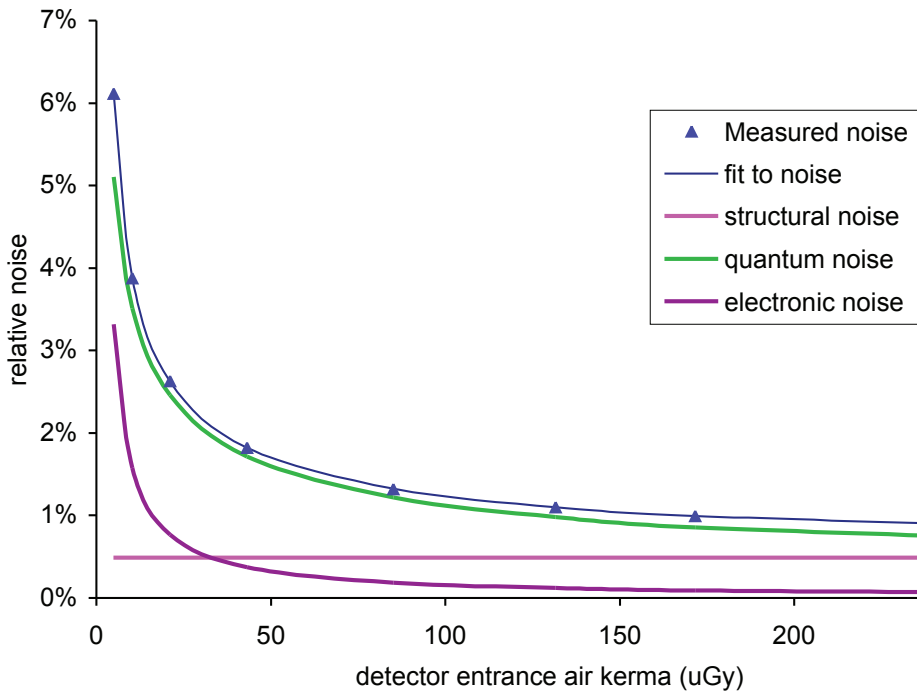


Figure 4 Relative noise and entrance air kerma at cassette surface.

3.3 AEC performance

3.3.1 Dose

The MGDs for breasts simulated with PMMA exposed under AEC control are shown in Table 3 and Figure 5. At all thicknesses the dose was below the remedial level in the NHSBSP protocol except for the 7 cm PMMA measurement. Using the 7 cm thickness of PMMA the dose was 2.7% above the NHSBSP remedial level.

Table 3 Mean glandular dose for simulated breasts

PMMA thickness (mm)	Equivalent breast thickness (mm)	kV	Target	Filter	mAs	MGD (mGy)	NHSBSP remedial level (mGy)
20	21	26	Mo	Mo	35	0.86	> 1.0
30	32	28	Mo	Mo	57	1.39	> 1.5
40	45	31	Mo	Rh	58	1.58	> 2.0
45	53	30	Mo	Rh	96	2.14	> 2.5
50	60	29	Rh	Rh	134	2.62	> 3.0
60	75	32	Rh	Rh	155	3.89	> 4.5
70	90	32	Rh	Rh	302	6.68	> 6.5

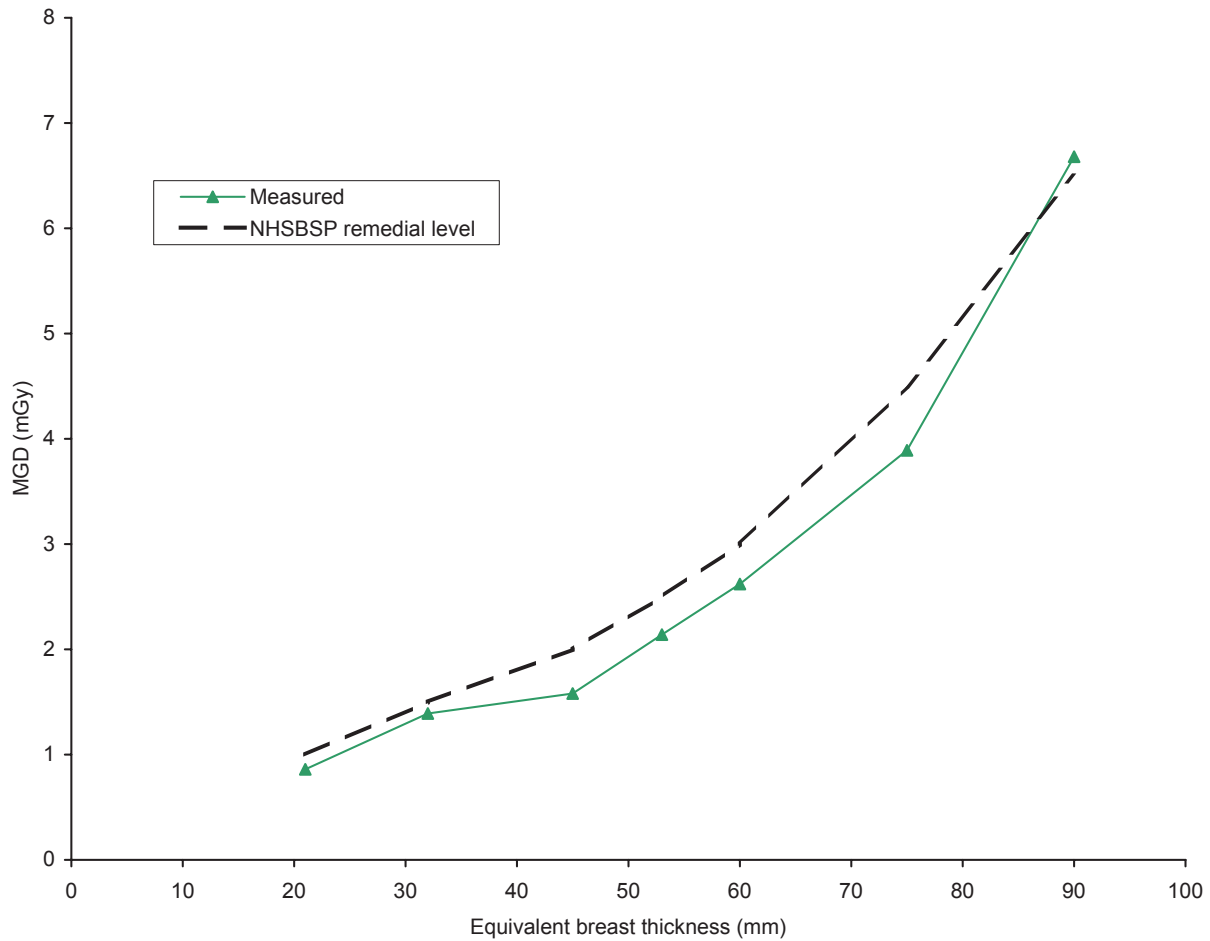


Figure 5 MGD for simulated breasts.

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3.3.2 CNR

The results of the contrast and CNR measurements are shown in Table 4 and Figure 6. The CNR required to meet the minimum acceptable and achievable image quality standards at the 60 mm breast thickness have been calculated and are also shown in Table 4 and Figure 6. The CNR required at each thickness to meet the limiting values in the European protocol are also shown.

Table 4 Contrast and CNR measurements using AEC in dose mode

PMMA thickness (mm)	kV target/filter	mAs	Back-ground pixel value ^a	% contrast	Measured CNR	CNR at minimum acceptable IQ	CNR at achievable IQ	CNR to meet European limiting value	Relative CNR (%)	European limiting values for relative CNR (%)
				for 0.2 mm Al						
20	26 Mo/Mo	35	91	20.8%	19.2	12.0	17.5	13.8	160	> 115
30	28 Mo/Mo	57	96	18.8%	17.6	12.0	17.5	13.2	147	> 110
40	31 Mo/Rh	58	89	15.1%	13.3	12.0	17.5	12.6	111	> 105
45	30 Mo/Rh	96	96	14.9%	13.6	12.0	17.5	12.4	113	> 103
50	29 Rh/Rh	134	123	13.4%	13.6	12.0	17.5	12.0	113	> 100
60	32 Rh/Rh	155	135	11.9%	12.4	12.0	17.5	11.4	103	> 95
70	32 Rh/Rh	302	157	11.0%	12.1	12.0	17.5	10.8	101	> 90

a Background pixel value has been linearised with respect to dose absorbed by the detector.

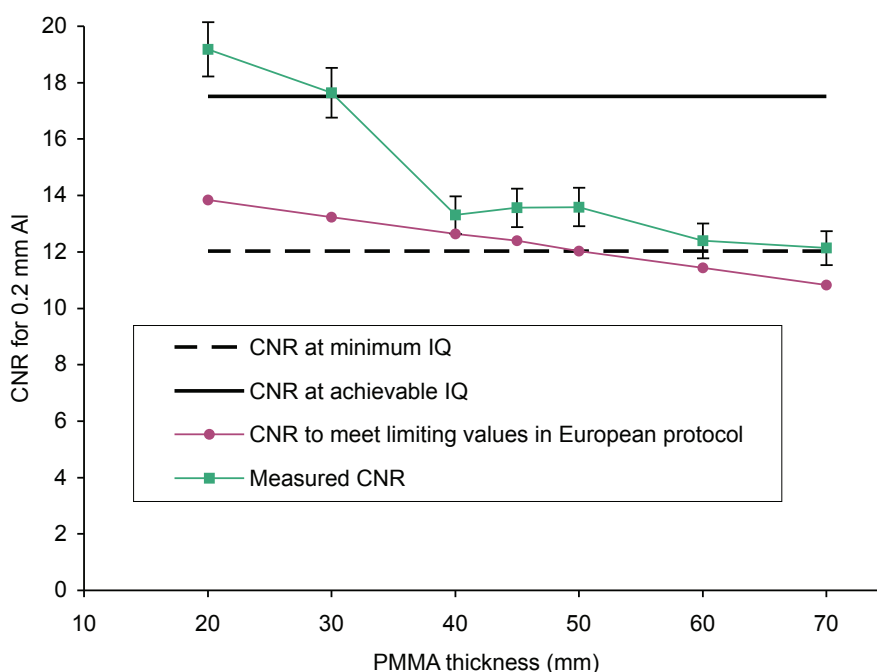


Figure 6 Measured CNR compared to the limiting values in the European Protocol (error bars indicate 95% confidence limits).

3.4 Image quality measurements

The first exposures of the image quality phantom were made under automatic exposure control (DOSE mode) which selected 29 kV Rh/Rh and an average tube current-time product of 129 mAs. This resulted in an MGD of 2.53 mGy to an equivalent breast. Subsequent image quality measurements were made at approximately half and double this dose by manual selection of the mAs at the same beam quality. The threshold gold thicknesses for different diameters and the three different dose levels are shown in Table 5, along with the minimum and achievable threshold values from the NHSBSP protocol. The contrast detail curves at these three dose levels are shown in Figure 7. The measured threshold gold thicknesses are plotted against the dose for the 0.1 and 0.25 mm detail sizes in Figure 8. This illustrates that when the dose was increased the threshold contrast reduced as expected by the theory, within the measurement error. The fitted curves in Figure 8 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 was dictated by the threshold contrast for the 0.1 mm detail size as this required the highest dose.

Table 5a Threshold gold thicknesses for different detail diameters for three different doses using 29 kV Rh/Rh

Threshold gold thickness (μm)					
Diameter (mm)	Acceptable value	Achievable value	MGD = 1.23 mGy	MGD = 2.53 mGy (AEC)	MGD = 4.89 mGy
0.1	1.680	1.100	2.24	1.41	1.14
0.25	0.352	0.244	0.333	0.203	0.196
0.5	0.150	0.103	0.111	0.091	0.086
1	0.091	0.056	0.056	0.055	0.050
2	0.069	0.038	0.041	0.039	0.036

Table 5b Predicted threshold gold thicknesses for different detail diameters for three different doses using 29 kV Rh/Rh

Threshold gold thickness (μm)					
Diameter (mm)	Acceptable value	Achievable value	MGD = 1.23 mGy	MGD = 2.53 mGy (AEC)	MGD = 4.89 mGy
0.1	1.680	1.100	1.85	1.57	1.07
0.25	0.352	0.244	0.378	0.249	0.201
0.5	0.150	0.103	0.153	0.105	0.090
1	0.091	0.056	0.075	0.058	0.060

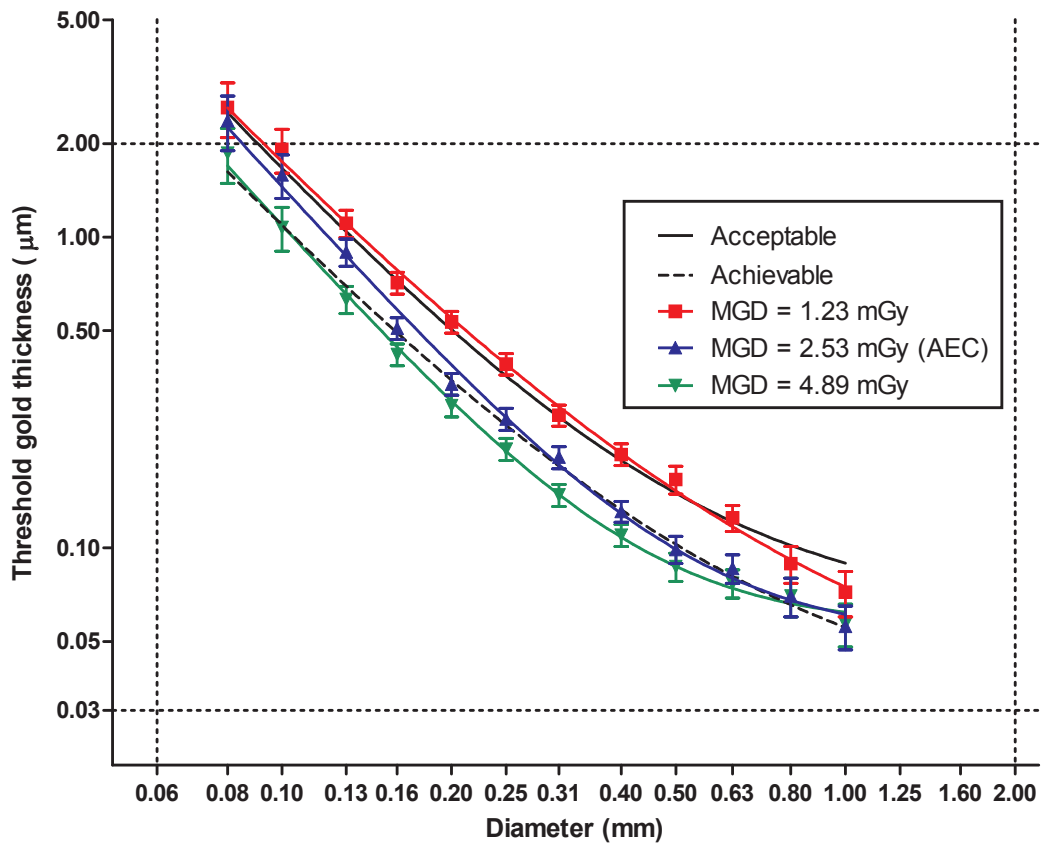


Figure 7 Predicted contrast-detail curves using log-log scales for three different doses at 29 kV Rh/Rh and automatic reading. Error bars indicate 95% confidence limits. The straight dashed lines indicate the minimum and maximum detail diameters and gold thicknesses within the test object.

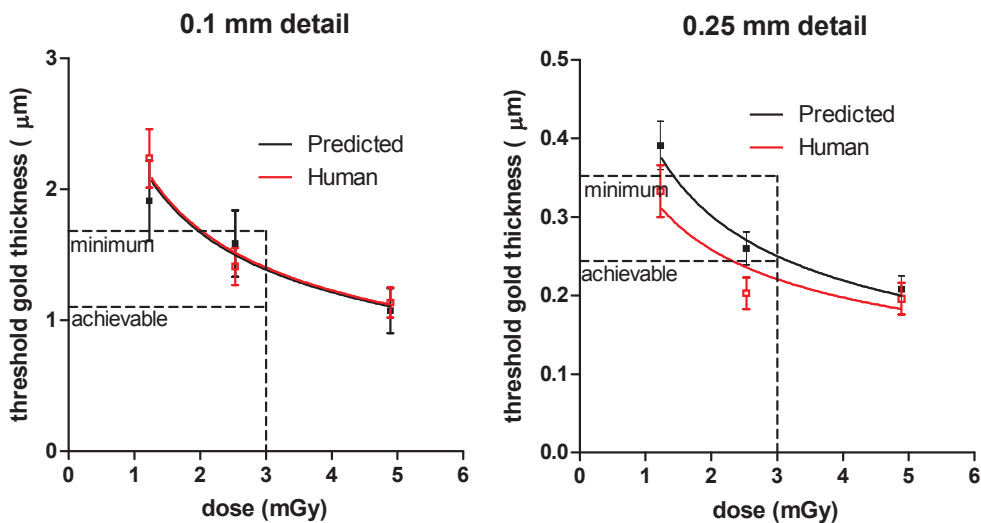


Figure 8 Threshold gold thickness at different doses using 29 kV Rh/Rh using human and automatic reading.

3.5 Comparison with other systems

The MGDs to reach the minimum and achievable image quality standards in the NHSBSP protocol have been estimated from the curves shown in Figure 8. (The error in estimating these doses depends on the accuracy of the curve fitting procedure and pooled data for several systems has been used here to estimate 95% confidence limits of about 20%.) These doses are shown against similar data for other models of digital mammography system in Tables 6 and 7 and Figures 9–12. The data for the other systems has been determined in the same way as described in this report and the results published previously.^{7–10} The data for film screens represent an average value determined using a variety of modern film screen systems.

Table 6 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 Senoscan	0.55	0.42	0.48	0.53
Sectra MDM	0.60	0.82	0.67	0.46
Siemens Novation	0.63	0.61	0.52	0.63
Hologic Selenia	0.85	0.55	0.80	0.53
GE DS	1.01	0.82	0.87	0.83
Film-screen	1.17	1.30	1.07	1.36
Fuji Profect CR	1.67	1.78	1.45	1.35
Agfa CR 85-X	2.00	1.94	0.86	1.42
Kodak CR (EHR-M2)	2.29	2.34	1.45	1.80
Test CR	4.52	4.17	2.33	2.12

Table 7 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 Senoscan	1.16	0.90	0.98	1.09
Sectra MDM	1.27	1.74	1.37	0.95
Siemens Novation	1.56	1.21	1.14	1.27
Hologic Selenia	1.84	1.19	1.68	1.12
GE DS	2.35	1.57	1.80	1.87
Film-screen	2.48	3.03	2.19	2.83
Fuji Profect CR	4.26	3.29	3.52	2.65
Agfa CR 85-X	5.03	4.88	2.20	3.15
Kodak CR (EHR-M2)	5.34	5.45	3.03	3.74
Test CR	11.5	9.90	5.96	5.63

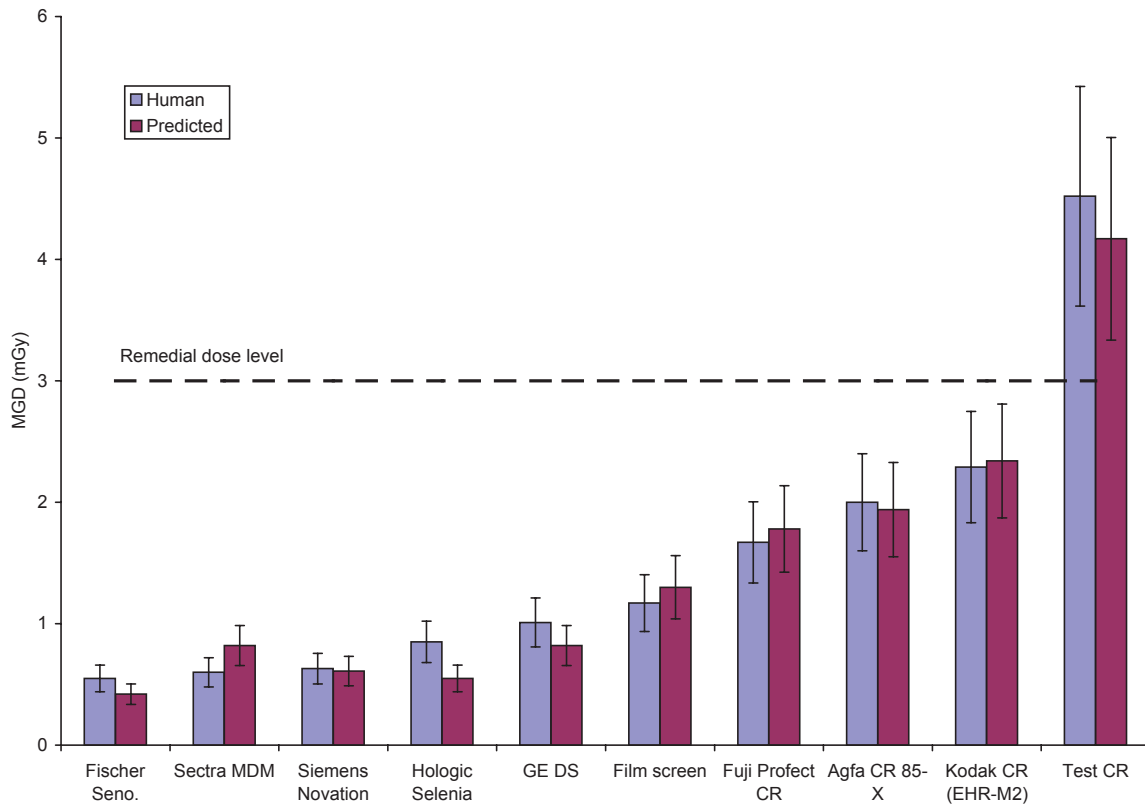


Figure 9 Dose to achieve minimum acceptable image quality standard for 0.1 mm detail (error bars represent 95% confidence limits).

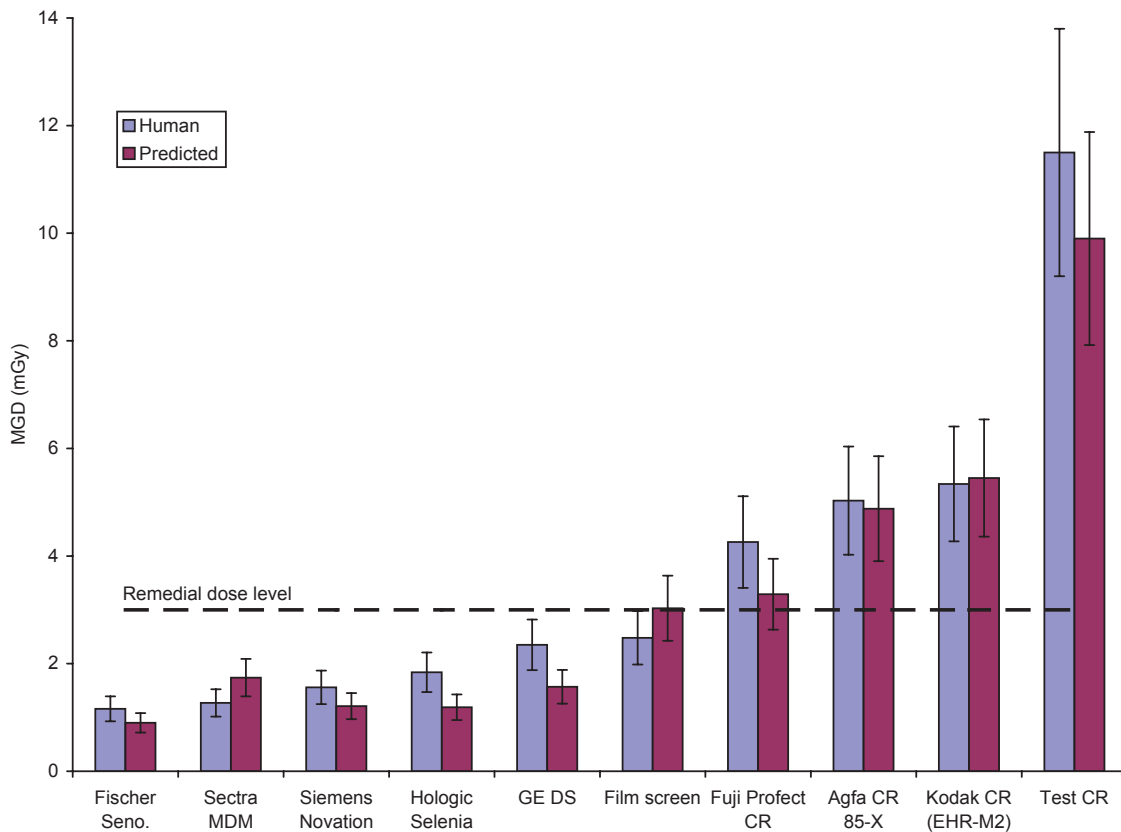


Figure 10 Dose to reach achievable image quality standard for 0.1 mm detail (error bars represent 95% confidence limits).

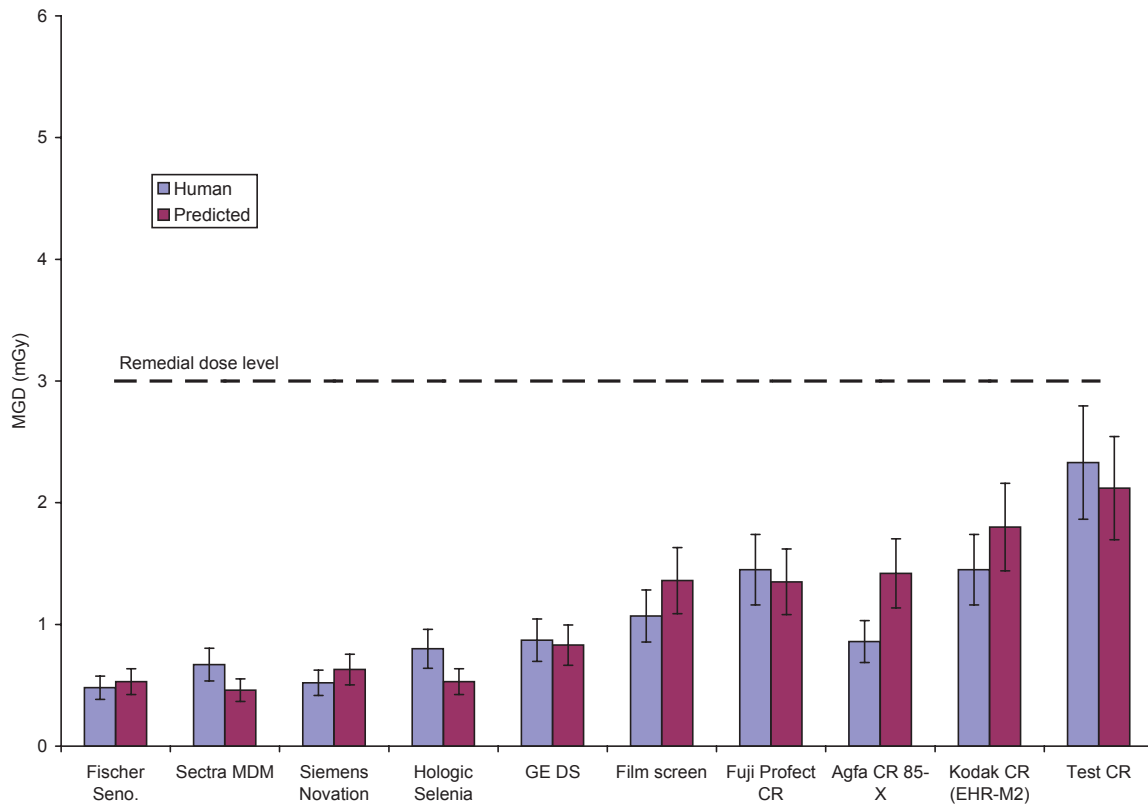


Figure 11 Dose to achieve minimum acceptable image quality standard for 0.25 mm detail (error bars represent 95% confidence limits).

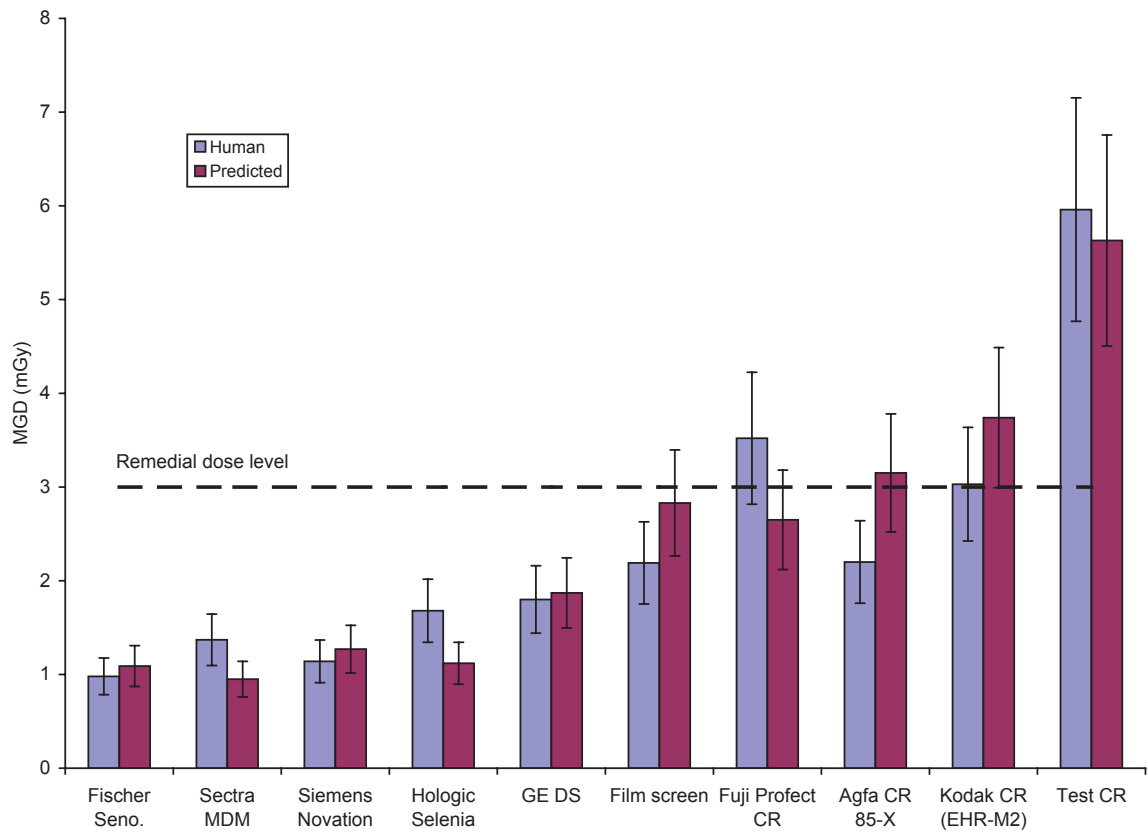


Figure 12 Dose to reach achievable image quality standard for 0.25 mm detail (error bars indicate 95% represent limits).

3.6 Optimisation

The target CNR corresponding to the minimum image quality standard was calculated to be 12.0. The MGDs required to reach this target CNR for each beam quality and thicknesses of PMMA are shown in Figure 13. From these data the beam qualities and mAs necessary to achieve the minimum image quality standard at the lowest dose were selected and are shown in Table 8. When using the 6 and 7 cm thicknesses of PMMA only certain target/filter combinations were possible. For the 7 cm thickness of PMMA the x-ray set refused to complete the exposure at some settings (28–37 kV Mo/Mo; 28, 31, 37 kV Mo/Rh; and 28 kV Rh/Rh), presumably because there was an insufficient dose rate at the AEC detector.

Table 8 Factors to produce the minimum acceptable image quality (where CNR = 12.0) at the lowest dose

PMMA thickness (mm)	kV target/filter	BGD pixel value (linearised)	mAs	MGD (mGy)	Dose compared with current AEC settings	Remedial dose level in NHSBSP protocol (mGy)
20	25 Mo/Mo	26	13	0.27	31%	1.0
30	25 Mo/Mo	32	34	0.55	39%	1.5
40	25 Mo/Rh	46	82	1.04	66%	2.0
50	28 Rh/Rh	84	116	1.95	75%	3.0
60	28 Rh/Rh	93	228	3.37	87%	4.5
70	31 Rh/Rh	133	315	6.14	92%	6.5

4. DISCUSSION

The AEC settings resulted in doses to simulated breasts that were generally just below the limits in the NHSBSP protocol. The dose for the standard breast simulated with 45 mm of PMMA was 2.14 mGy which is 86% of the upper limit of 2.5 mGy applied by the NHSBSP.

The AEC was set up by the GE engineer with Agfa's guidance to select relatively high energy spectra and sufficient dose to exceed the minimum image quality standard within the acceptable dose limits. The doses were below the remedial level for all thicknesses of PMMA except 7 cm where the limit was exceeded by 2.7% which is probably within the measurement error and reproducibility of the AEC system.

The image quality measurements indicated that for the standard thickness tested (equivalent to a 50 mm thickness of PMMA, ie 60 mm of typical breast) the image quality was better than the minimum standard for the smallest detail size (0.1 mm). The AEC selected a dose of 2.53 mGy using 29 kV Rh/Rh, while a dose of 2.0 ± 0.4 mGy was calculated to be necessary to reach the minimum image quality level. This dose level is well below the acceptable dose value of 3.0 mGy for this thickness. At the larger detail diameters the system reached the achievable image quality level at the doses used clinically. This difference in performance between large and small detail sizes can be explained by the relatively low MTF at high spatial frequencies which is typical of CR systems.

The system met the CNR criteria in the European protocol at all thicknesses of PMMA as shown in Figure 6.

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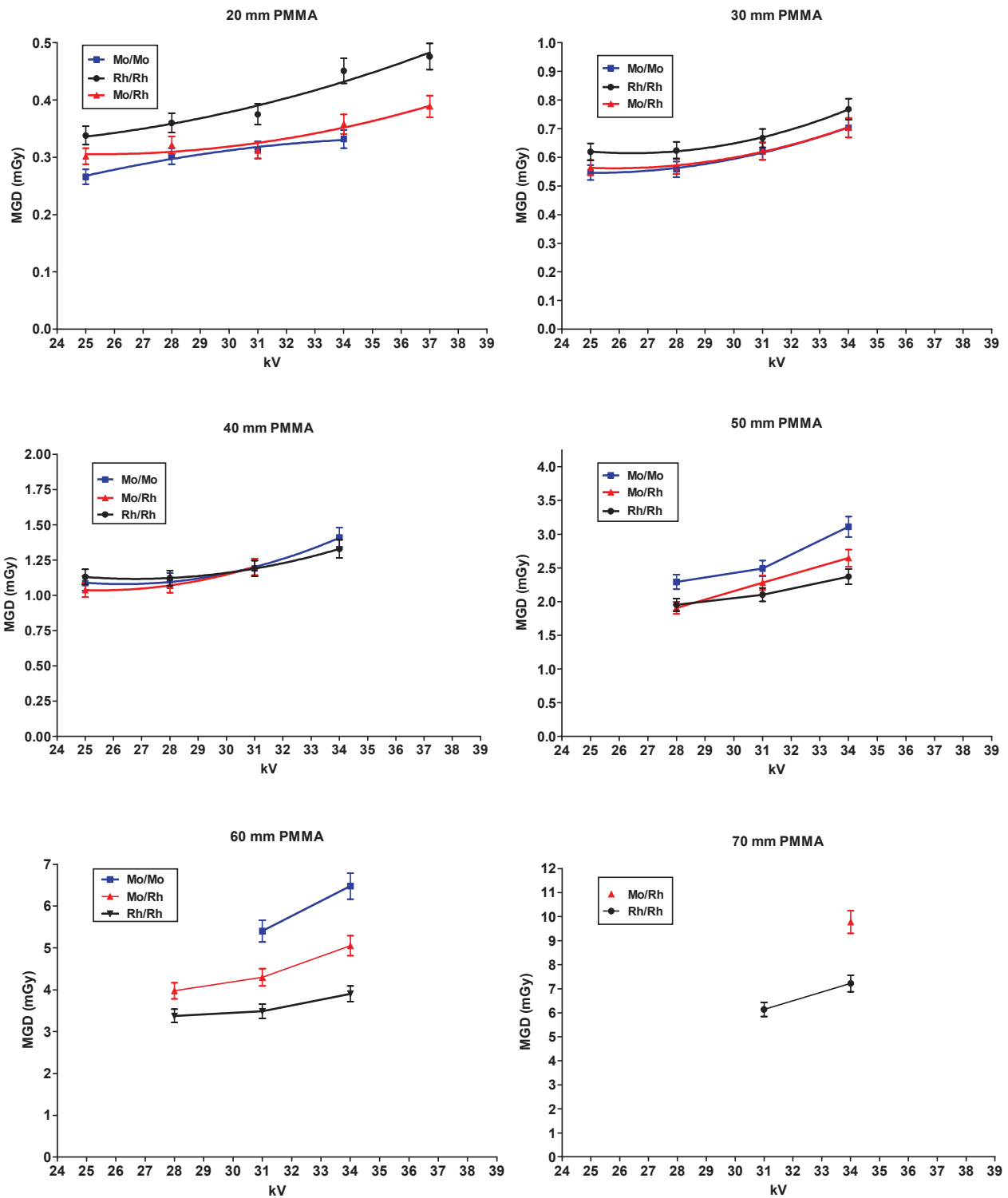


Figure 13 MGD to reach a CNR of 12, corresponding to minimum acceptable image quality. Error bars indicate 95% confidence limits.

The optimisation study indicated that the current choice of beam qualities is close to the optimal. For x-ray sets that have only Mo/Mo or Mo/Rh target/filter combinations the dose for the larger breast thicknesses to achieve the minimum image quality requirements would be somewhat higher (Figure 13).

Relatively high dose levels are selected by the AEC to ensure that the minimum image quality requirements in the UK and European protocols are exceeded. Although these doses are within accepted limits they are rather higher than would be necessary with either a film-screen system or a modern DR system (Figures 9–12).

The noise analysis showed the presence of some structural noise in the detector. However, this does not seem excessive and the total relative noise level is only about 1% at the exposures used clinically. This is rather lower than found with DR systems and may be compensating for the relatively poor MTF typical of CR systems.

Methods for evaluating the effect of the image processing on clinical images were not available at the time of this technical evaluation.

5. CONCLUSIONS

The system tested meets the minimum dose and image quality criteria applied by the NHSBSP except for the dose tested using a 7 cm thickness of PMMA which was exceeded by 2.7%. A small dose reduction at this thickness could correct this. Clinical evaluation of this system by the NHSBSP at this site is appropriate. It will be particularly important to assess whether small details such as fine microcalcifications are adequately displayed, eg by comparison with corresponding film screen images on the same patient. It will also be important to assess whether the image processing used clinically is effective as this has not been assessed technically. A final decision on the suitability of this system for use in the NHSBSP will depend on a review of both the technical and clinical evaluations.

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