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Cancer Screening Programmes

Technical evaluation of Hologic Selenia Dimensions digital breast tomosynthesis system

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Contents

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Executive summary

The purpose of this evaluation was to measure the technical performance of the Hologic Dimensions digital breast tomosynthesis system. The technical performance was tested in both 2D and tomosynthesis modes. 2D performance met current NHSBSP standards for digital mammography, with 2D image quality better than the achievable level. No performance standards have yet been set for digital breast tomosynthesis systems.

The mean glandular dose to the standard breast was measured in tomosynthesis mode and found to be well within the dose limits for 2D mammography. This report also provides baseline measurements on other aspects of the equipment performance, including image quality, noise, spatial distortion and alignment.

1. Introduction

1.1 Testing procedures and performance standards for digital mammography

Testing procedures and performance standards for two dimensional (2D) mammography are well established and documented[1,2] but there are not as yet any nationally agreed procedures and standards for digital breast tomosynthesis (DBT) systems. The tests of tomosynthesis performance employed for this evaluation were based on those used for the TOMMY trial.[3]

The technical performance of 2D Hologic Selenia Dimensions systems with the original and more recently updated automatic exposure control (AEC) software has previously been evaluated and reported.[4,5] For this evaluation, some of the tests in 2D mode were repeated.

Research to assess the clinical effectiveness of tomosynthesis is ongoing and further work will be required to establish measures of technical performance which indicate acceptable clinical performance. The results of these tomosynthesis performance tests may allow comparisons between different systems to be made, but should be interpreted with caution until further experience in the evaluation of tomosynthesis performance has been gained.

1.2 Objectives

This evaluation of the Hologic Selenia Dimensions tomosynthesis system had two objectives. The first was to establish whether its 2D performance met the main standards in the NHSBSP and European protocols. The second was to provide baseline measurements on the performance of the system in tomosynthesis mode.

2. Methods

2.1 System tested

The Dimensions system employs a tungsten target with a rhodium or silver filter for 2D imaging, and an aluminium filter for tomosynthesis imaging. The same 18cm x 24cm and 24cm x 29cm compression paddles are used for tomosynthesis and 2D imaging. Three AEC automatic modes are available for both 2D and tomosynthesis:

- *AutoFilter*, where the system selects kV, filter and mAs. (The choice of kV and filter is based on compressed breast thickness (CBT))
- *AutokV*, in which the user selects the filter and the system selects kV and mAs
- *AutoTime*, where the user selects both filter and kV while the system selects mAs

For all three automatic modes, a pre-exposure pulse is used, which contributes to patient dose but does not contribute to the formation of the image. There is, in addition, a manual mode, which allows the user to select all the exposure parameters.

During a tomosynthesis acquisition the X-ray tube rotates about a centre of rotation which is at the height of the detector surface, 25mm below the surface of the breast support table. The tube moves to the starting position at an angle of approximately -7.5 degrees, the pre-pulse is performed while the tube is stationary, and then 15 projections are acquired at approximately one degree intervals while the tube is in motion. Collimation is fixed during the tomosynthesis acquisition and the breast support is stationary, but the detector rotates slightly as the tube moves. The grid is not used in tomosynthesis.

As well as acquiring 2D images or tomosynthesis images separately, the system can perform a “combo” exposure. This consists of a tomosynthesis exposure which is automatically followed by a 2D view during the same compression.

To assist in the measurement of tube output and beam quality using the aluminium filter, a *Zero Degree Tomo* mode is available. This provides a pulsed X-ray exposure, which is the same as a tomosynthesis exposure, but with the tube remaining stationary.

Hologic recommend that quality control (QC) images are acquired using the *Flatfield Tomo* views. These were used for all of the tomosynthesis tests included in this report. They are reconstructed using raw projections to which no scatter corrections have been applied. The reconstructed tomosynthesis planes, therefore, have a noticeable low frequency variation which is not evident in the clinical tomosynthesis views.

Details of the system tested are given in Table 1.

Table 1. System description

Manufacturer	Hologic
Model	Dimensions
System serial number	81009111024
Target material	Tungsten
Added filtration	2D: 50µm rhodium 50µm silver Tomosynthesis: 700µm aluminium
Detector type	Amorphous selenium
Detector serial number	MM604072
Pixel size	See Table 2 below
Detector area	Small: 179mm x 233mm Large: 233mm x 287mm
Pixel array	Small: 2560 x 3328 Large: 3328 x 4096
Pixel value offset	50
AEC Modes	AutoFilter, AutokV, AutoTime
AEC pre-exposure pulse	2D: 5mAs for CBT < 50mm; 10mAs for CBT ≥ 50mm Tomosynthesis: 5mAs
Tomosynthesis projections	15 equal dose projections at approximately one degree intervals from -7.5 to +7.5 degrees
Reconstructed focal planes	Vertical intervals: 1mm No of planes : CBT in mm plus 5 Maximum CBT for tomosynthesis exposure: 244mm
Software version	AWS: 1.4.2

Table 2. 2D and tomosynthesis image file sizes for large (24cm x 29cm) format, for a range of breast thicknesses of 20-90mm

	Pixel size	File downloaded from acquisition workstation	File containing extracted projections/ focal planes
2D	70µm	27MB	
Tomosynthesis projections	140µm	30–40MB*	98MB
Tomosynthesis reconstructed focal planes	Approx. 100µm**	33–80MB*	243 – 889MB*

*For a range of compressed breast thicknesses from 20-90mm. **The pixel size varies with height of the reconstructed focal plane above the breast support table.

QC images can be downloaded from the acquisition workstation via a USB port or written to a DVD. The tomosynthesis images acquired in this evaluation were in the DICOM[6] secondary capture (SC) format. Each *Flatfield Tomo* image comprises two SC files, one containing the projections and the other containing the reconstructed focal planes. A proprietary tool from Hologic, which has not yet been made generally available, was used to extract the focal planes and projections from the SC files.

Typical image file sizes for large (24cm x 29cm) format images, for a range of breast thicknesses of 20-90mm, are shown in Table 2.

2.2 Dose and contrast to noise ratio under AEC

Dose and contrast to noise ratio (CNR) were measured using the X-ray set's AEC to expose different thicknesses of Perspex (polymethylmethacrylate or PMMA). The mean glandular dose (MGD) to the standard breast was calculated for the equivalent breast thicknesses. For CNR measurements, a square of aluminium 0.2mm thick was included in the phantom.

2.2.1 Dose measurement

To calculate MGD to the standard breast, measurements were made of half value layer (HVL) and tube output, over the clinically relevant range of kV and target filter combinations. They were made on the midline at the standard position of 40mm from the chest wall edge (CWE) of the breast support platform. The output measurements were made both with the compression paddle in contact with the ion chamber and with the paddle raised well above the ion chamber.

In both 2D and tomosynthesis modes, exposures of a range of thicknesses of PMMA were made under AEC (*AutoFilter*). For each thickness, the paddle was positioned so that the correct equivalent breast thickness was displayed by the compressed breast thickness indicator, leaving an air gap between the PMMA and the paddle. (Spacers are not needed to maintain an air gap for the Dimensions system, as compression is not required for QC images.)

2D doses were calculated as described in the UK protocol. Tomosynthesis doses were calculated using the method described by Dance et al.[7] This is an extension of the established 2D method, using the equation:

$$D = KgcsT \qquad (1)$$

where K is the incident air kerma at the top surface of the breast, and g, c and s are conversion factors. The additional factor, T, is derived by summing weighted correction factors for each of the tomosynthesis projections. Values of T are tabulated for the Dimensions system for different compressed breast thicknesses.

The Dance method of MGD calculation uses a measured dose at the surface of the breast with the paddle in place, but the method described in the UK protocol differs in that dose is measured with the paddle raised well above the ion chamber. To allow comparisons to be made between systems, MGD results in this report are calculated with the paddle raised. A correction factor is provided, which may be used to obtain a more accurate calculation of MGD.

2.2.2 Contrast to noise ratio

For CNR measurements a 10mm x 10mm square of 0.2mm thick aluminium foil was included in the phantom, positioned 10mm above the table on the midline, 60mm from the chest wall edge.

2D CNR was measured using 5mm x 5mm regions of interest (ROIs) positioned in the centre of the aluminium square and at two background positions on the chest wall and nipple sides of the square.

CNR in the tomosynthesis focal plane was measured using 5mm x 5mm ROIs at the same positions as for the 2D image but subdivided into 1mm x 1mm elements, as shown in Figure 1. The ROIs were subdivided to reduce the effect of image non-uniformity on the CNR result. (The non-uniformity is due to the use of *Flatfield Tomo* images for QC, which are reconstructed without processing.) The CNR was measured in the focal plane containing the aluminium square and in two planes above and two further planes below. The result quoted is the average of the measurements from all five planes.

CNR was also measured in the unprocessed tomosynthesis projections acquired for the above images, using a 5mm x 5mm ROI (not subdivided).

Variation of CNR with dose in tomosynthesis mode was assessed both in the projections and in the reconstructed images, for an equivalent breast thickness of 53mm (i.e. using a 45mm thickness of PMMA).

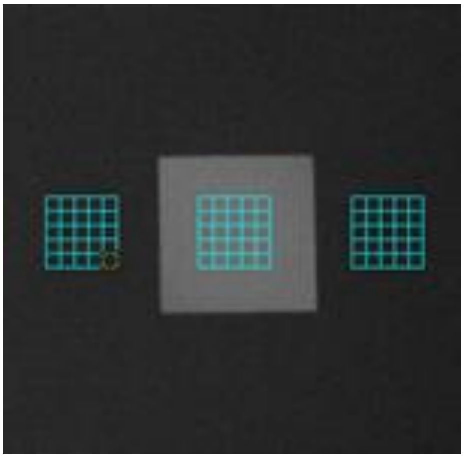

Figure 1. The positions of 5mm x 5mm ROIs subdivided into 1mm x 1mm elements for measurement of CNR in tomosynthesis

2.3 Image quality measurements

Image quality was measured in 2D mode using a CDMAM phantom. In the absence of a suitable test object for assessing tomosynthesis imaging performance, images of the CDMAM in tomosynthesis mode were also acquired. The CDMAM phantom (Version 3.4, serial number 1022)[*] was positioned between two blocks of PMMA, each 20mm thick. The exposure factors used were the same as those selected by the AEC for an equivalent breast thickness of 60mm. One set of sixteen images was acquired in 2D mode at the AEC selected dose. In tomosynthesis mode, one set of sixteen images was acquired at the AEC selected dose and two further sets at approximately half and double this dose.

From the tomosynthesis images, the focal plane in best focus was selected. This corresponded to the actual height of the CDMAM above the breast support table. The set of 2D images and the three sets of tomosynthesis images were read and analysed using two software tools, CDCOM version 1.6[†] and CDMAM Analysis version 1.4[‡]

Due to the non-uniformity of the tomosynthesis focal plane images, it was necessary to flatfield them prior to reading, otherwise CDCOM either failed to read the images or gave poor results. The flatfielding was done by cropping each image close to the useful area of the CDMAM and then padding out to reach an image size with dimensions in pixels equal to a power of two. A Butterworth filter was applied in the frequency domain to remove the higher frequencies, including the grid and contrast details of the CDMAM. The original image was then divided by the filtered image and the pixel values rescaled. This was repeated using the planes immediately above and below the expected plane of best focus to ensure that the CDMAM result quoted corresponded to the best image quality obtained.

It should be noted that the currently available version of CDCOM works with 2D images in the DICOM MG format, but does not work directly with tomosynthesis images in the DICOM BTO format which is available with later versions of the Dimensions software.

2D image quality assessed using the CDMAM is for an equivalent breast thickness of 60mm. This can be related to the image quality at other thicknesses by comparing the CNRs measured for a range of thicknesses. The European protocol gives the relationship between threshold contrast and CNR measurements, enabling calculation of a target CNR value for a particular level of image quality. This can be compared to CNR measurements made at other breast thicknesses. Contrast for a particular gold thickness is calculated using Equation 2, and target CNR is calculated using Equation 3.

$$\mathrm{Contrast} = 1 - \mathrm{e}^{-\mu t} \qquad (2)$$

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[*] UMC St. Radboud, Nijmegen University, Netherlands
[†] CDCOM version 1.6. Available from EUREF website: www.euref.org. Accessed 4 July 2013.
[‡] CDMAM analysis UK v1.4, NCCPM, Guildford, UK

where μ is the effective attenuation coefficient for gold, and t is the gold thickness.

$$\mathrm{CNR}_{\mathrm{target}} = \frac{\mathrm{CNR}_{\mathrm{measured}} \times \mathrm{TC}_{\mathrm{measured}}}{\mathrm{TC}_{\mathrm{target}}} \quad (3)$$

where $\mathrm{CNR}_{\mathrm{measured}}$ is the CNR for a 60mm equivalent breast, $\mathrm{TC}_{\mathrm{measured}}$ is the threshold contrast calculated using the threshold gold thickness for a 0.1mm diameter detail (measured using the CDMAM at the same dose as used for $\mathrm{CNR}_{\mathrm{measured}}$), and $\mathrm{TC}_{\mathrm{target}}$ is the calculated threshold contrast corresponding to the threshold gold thickness required to meet either the minimum acceptable or achievable level of image quality.

The European protocol also defines a limiting value for CNR, which is a percentage of the threshold contrast for minimum acceptable image quality for each thickness. The target CNR values for minimum acceptable and achievable levels of image quality and the European limiting values for CNR were calculated.

2.4 Geometric distortion and reconstruction artefacts

The relationship between reconstructed tomosynthesis focal planes and the geometry of the volume that they represent was assessed. This was done by imaging a geometric test phantom consisting of a rectangular array of 1mm diameter aluminium balls, 50mm apart, in the middle of a 5mm thick sheet of PMMA. The phantom was placed at different heights (7.5, 32.5 and 57.5mm) within a 60mm thick stack of PMMA on the breast support table. The paddle was then raised to 100mm above the table, with the phantom attached to its underside, and an additional tomosynthesis image was acquired.

Reconstructed tomosynthesis planes were analysed to find the height of the focal plane in which each ball was best in focus, the position of the centre of the ball within that plane, the number of adjacent planes in which the ball was also seen, and to quantify the variation in appearance of the ball between focal planes.

This analysis was automated through the use of an ImageJ[§] plug-in, developed at NCCPM for this purpose.

2.4.1 Height of best focus

For each ball, the height of the focal plane in which it was best in focus was identified. Results were compared for all balls within each image to judge whether there was any tilt of the test phantom relative to the reconstructed planes, or any vertical distortion of the focal planes within the image.

[§] http://rsb.info.nih.gov/ij/

2.4.2 Positional accuracy within focal plane

The x and y co-ordinates within the image were found for each ball. (x and y are perpendicular and parallel to the chest wall edge, respectively). The mean distances between adjacent balls were calculated, using the pixel spacing quoted in the DICOM header. This was compared to the physical separation of balls within the phantom, to assess the scaling accuracy in the x and y directions. The maximum deviations from the mean x and y separations were calculated, to indicate whether there was any discernible distortion of the image within the focal plane.

2.4.3 Appearance of the ball in adjacent focal planes

Changes to the appearance of a ball between focal planes were assessed visually.

To quantify the extent of reconstruction artefacts in adjacent focal planes, the reconstructed image was treated as though it were a true three dimensional volume. The ImageJ plug-in was used to find the x, y, and z dimensions of a rectangular volume around each ball which enclosed all pixels with values exceeding 50% of the maximum pixel value. The method used was to create a composite x-y image using the maximum pixel values from all focal planes. A composite x line was created using the maximum pixel value from each column of the x-y composite plane. The full width half maximum (FWHM) measurement in the x direction was made by fitting a polynomial spline. This was repeated in the orthogonal direction to produce the y-FWHM, and again using vertical re-sliced planes to find the z-FWHM. All pixel values were background subtracted, using the mean pixel value from around the ball in the plane of best focus. The composite z-FWHM thus calculated was used as a measure of the inter-plane resolution, or z-resolution. Its value would be different if a ball of different size were used.

The FWHM in the x- and y-directions of the image of the ball were also measured in the plane of best focus, and compared with the composite x- and y-FWHM measurements. This enabled any apparent shift or spread in the appearance of the ball through a series of adjacent focal planes to be quantified.

2.5 Alignment

Alignment measurements were carried out for reconstructed tomosynthesis images.

The alignment of the X-ray beam to the focal plane at the surface of the breast support table was assessed. Self-developing film and graduated markers were positioned on each edge of the X-ray beam. The alignment at the lateral edges was difficult to measure because the movement of the tube during the scan causes the lateral edges of the X-ray beam to move between projections.

The alignment of the imaged volume to the compressed volume was also assessed. Missed tissue at the chest wall edge was assessed at heights of 0, 60, and 100mm above the table, using graduated markers aligned vertically above the chest wall edge of the table. Small high contrast markers were placed on the breast support table and on the underside of the compression paddle to assess vertical alignment. The image planes were then inspected to check whether all markers were brought into focus within the reconstructed tomosynthesis volume.

3. Results

3.1 Output and HVL

The tube output and HVL results are shown in Table 3. The paddle was in the beam and was raised well above the ion chamber. Measurements were also made with the paddle in contact with the upper surface of the ion chamber. The dose measured with the paddle in contact was 3% higher.

Table 3. HVL and tube output measurement

kV	Target	Filter	Tube output (µGy/mAs at 1m)	HVL (mm Al)
25	W	Rh	11.4	0.48
28	W	Rh	16.0	0.52
31	W	Rh	20.4	0.55
31	W	Ag	27.4	0.57
34	W	Ag	33.8	0.59
25	W	Al	20.1	0.44
28	W	Al	29.3	0.50
31	W	Al	39.4	0.55
34	W	Al	50.4	0.60
37	W	Al	62.3	0.65
40	W	Al	75.2	0.70
43	W	Al	89.0	0.74

3.2 Dose and CNR

The 2D and tomosynthesis doses are shown in Tables 4 and 5, and presented graphically in Figure 2. These MGDs were calculated using output measurements made with the paddle raised well above the ion chamber. To correct to a more precise measurement, including scatter from the paddle, a multiplying factor of 1.03 should be applied.

Table 4 shows the 2D CNR measurements for a 0.2mm thickness of aluminium foil. Table 5 shows the measured CNRs for the reconstructed tomosynthesis images and the central (zero degree) 2D projection images. The dose for an individual projection is one fifteenth of the total dose from a tomosynthesis acquisition.

Table 4. Dose measurements for 2D images under AEC

PMMA (mm)	Equivalent breast thickness (mm)	kV	Target / filter	mAs†	MGD† (mGy)	NHSBSP dose limit (mGy)	CNR
20	21	25	W / Rh	50	0.65	1.0	10.9
30	32	26	W / Rh	72	0.86	1.5	9.6
40	45	28	W / Rh	94	1.19	2.0	8.7
45	53	29	W / Rh	115	1.49	2.5	8.2
50	60	31	W / Rh	139	2.04	3.0	8.2
60	75	31	W / Ag	152	2.75	4.5	7.8
70	90	34	W / Ag	146	2.93	6.5	6.1

†The mAs and MGD values quoted here include the pre-exposure pulse (tube load 5mAs for indicated thickness less than 50mm, 10mAs for 50mm or more), which is not included in the image.

Table 5. Dose and CNR for tomosynthesis images under AEC

PMMA (mm)	Equivalent breast thickness (mm)	kV	Target / filter	mAs*	MGD* (mGy)	CNR in reconstructed tomosynthesis image	CNR in central projection
20	21	26	W / Al	36	0.91	29.7	5.07
30	32	28	W / Al	37	1.01	21.6	3.79
40	45	30	W / Al	46	1.37	18.6	3.34
45	53	31	W / Al	58	1.81	18.4	3.34
50	60	33	W / Al	60	2.26	16.7	3.07
60	75	36	W / Al	72	3.30	14.3	2.76
70	90	42	W / Al	64	4.22	10.9	2.16

*The mAs and MGD values quoted include the pre-exposure pulse (tube load 5mAs), which is not included in the reconstructed image.

The 2D and tomosynthesis CNR results are presented graphically in Figures 3 and 4. Figure 3 includes the target levels of CNR required to reach the NHSBSP minimum acceptable and achievable levels of 2D image quality (IQ), 3.4 and 5.0 respectively. These were calculated using an equivalent attenuation coefficient of 0.120 for 31kV W/Rh. The European limiting values of CNR are also shown.

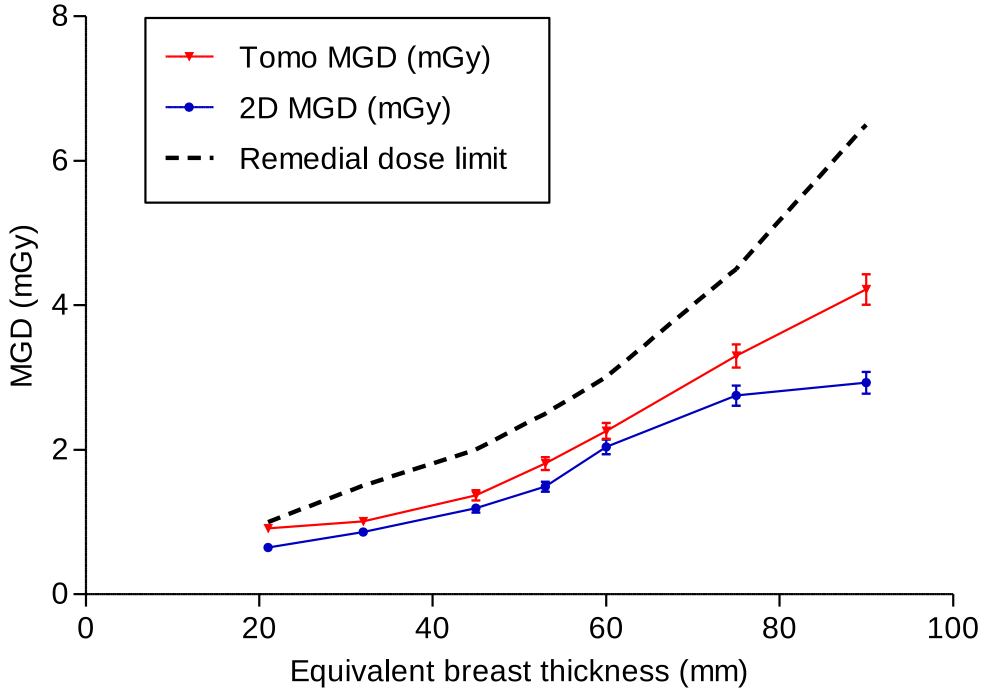

Figure 2. MGD for 2D and tomosynthesis exposures under AEC. (Error bars indicate 95% confidence limits.)

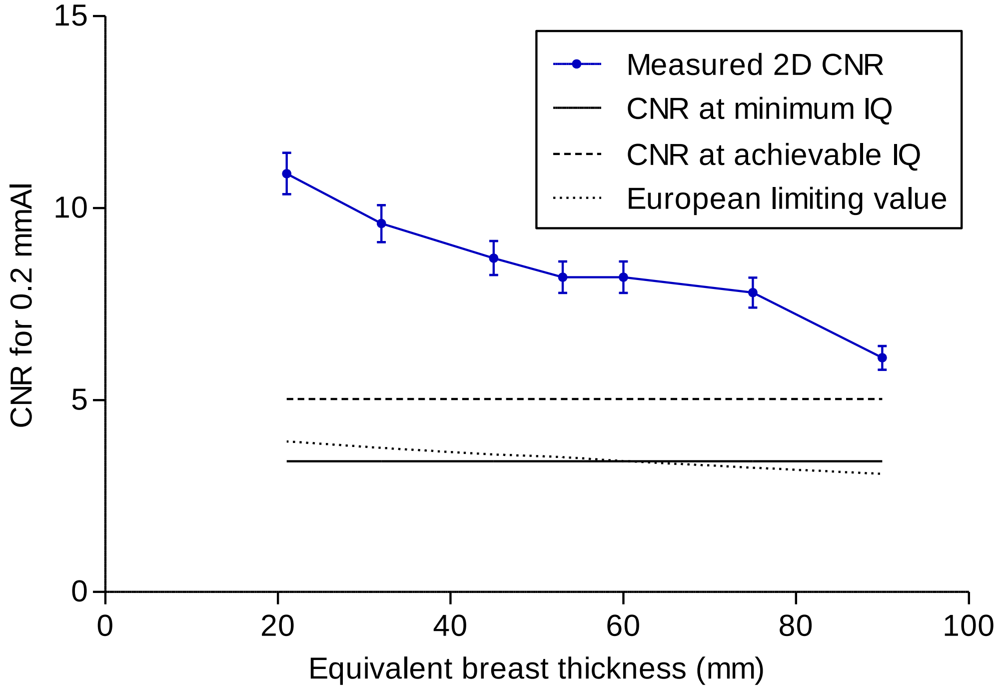

Figure 3. CNR for 2D images obtained under AEC, compared with limiting values from the NHSBSP and European protocols. (Error bars indicate 95% confidence limits.)

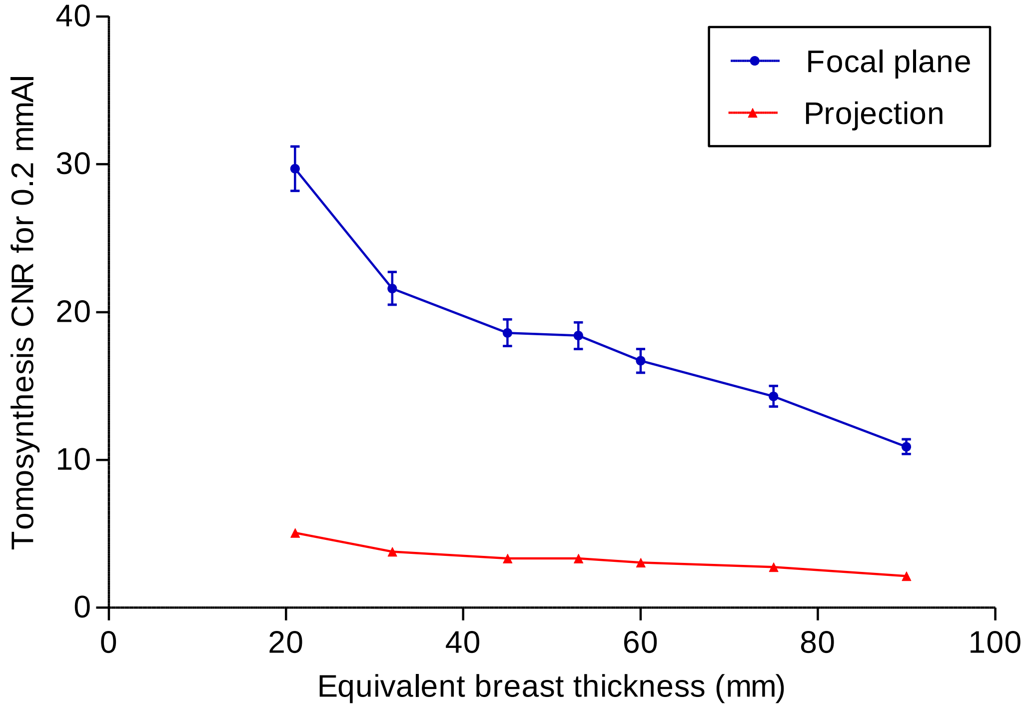

Figure 4. CNR for tomosynthesis images obtained under AEC. (Error bars indicate 95% confidence limits.)

The variation of tomosynthesis CNR with dose is shown in Table 6 and Figure 5. A power fit was applied to the relationship between CNR and dose for reconstructed focal planes and projections.

Figure 6 shows the variation of projection CNR with tube angle for three thicknesses of PMMA.

Table 6. Variation of tomosynthesis CNR with dose

PMMA (mm)	Equivalent breast thickness (mm)	kV	Target / filter	mAs	MGD (mGy)	CNR in reconstructed DBT image	CNR in central projection
45	53	31	W / Al	16	0.50	9.3	1.77
45	53	31	W / Al	30	0.93	12.9	2.48
45	53	31	W / Al	60	1.87	17.9	3.72
45	53	31	W / Al	120	3.74	25.5	5.15

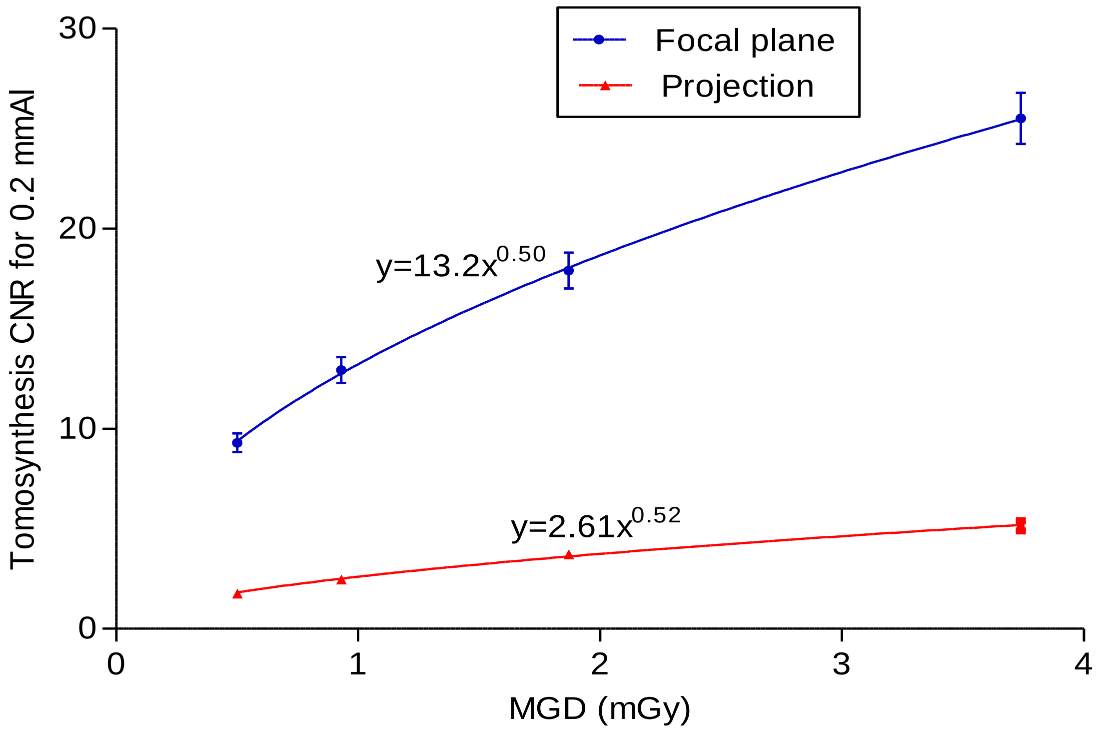

Figure 5. CNR for a 53mm equivalent breast thickness at a range of doses in tomosynthesis mode. (Error bars indicate 95% confidence limits.)

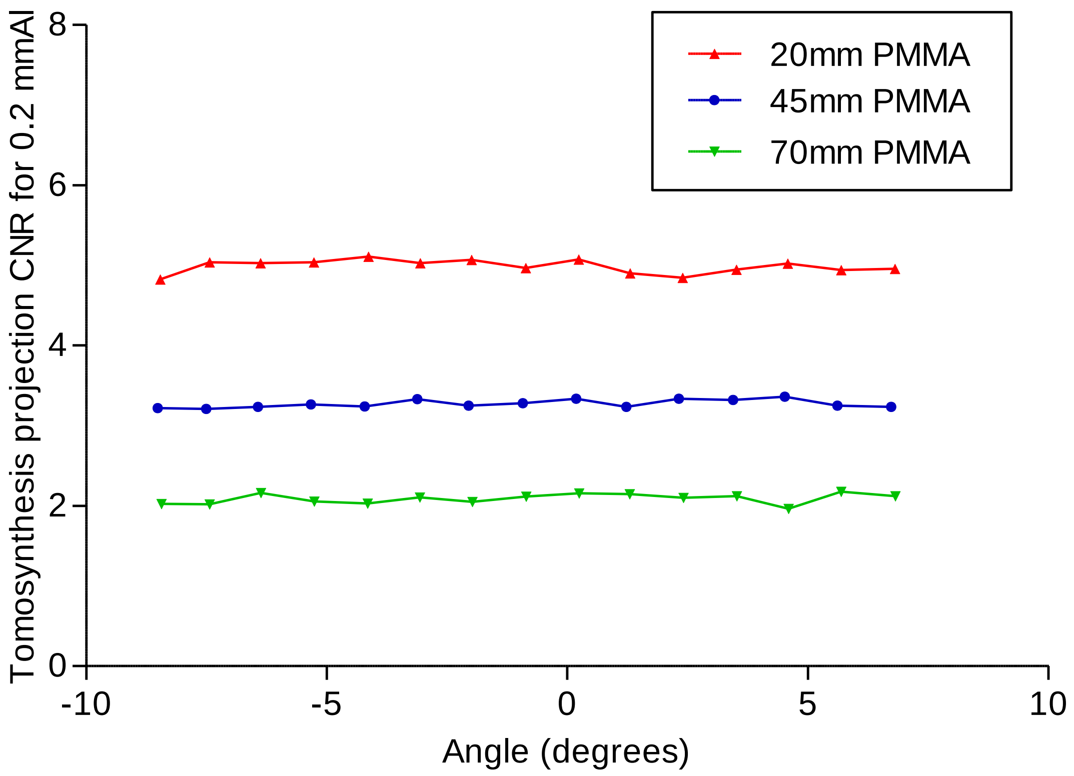

Figure 6. CNR measurements in tomosynthesis projections for three different PMMA thicknesses.

3.3 Image quality measurements

The contrast detail curve for 2D images is shown in Figure 7.

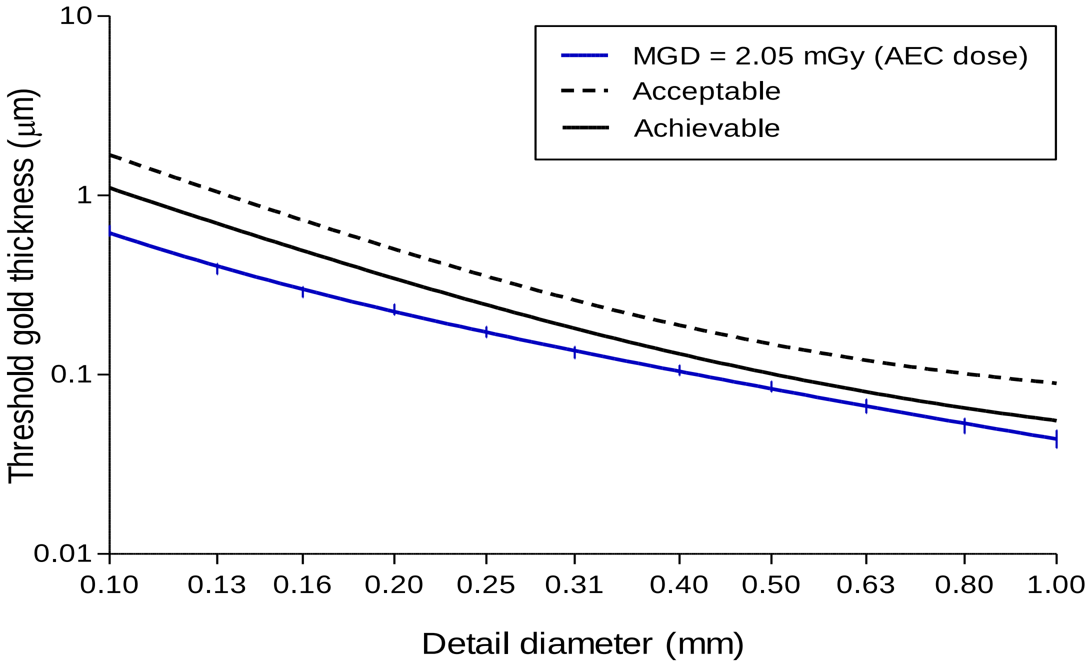

Figure 7. Threshold gold thicknesses for 2D images acquired at 31kV W/Rh. (Error bars indicate 95% confidence limits.)

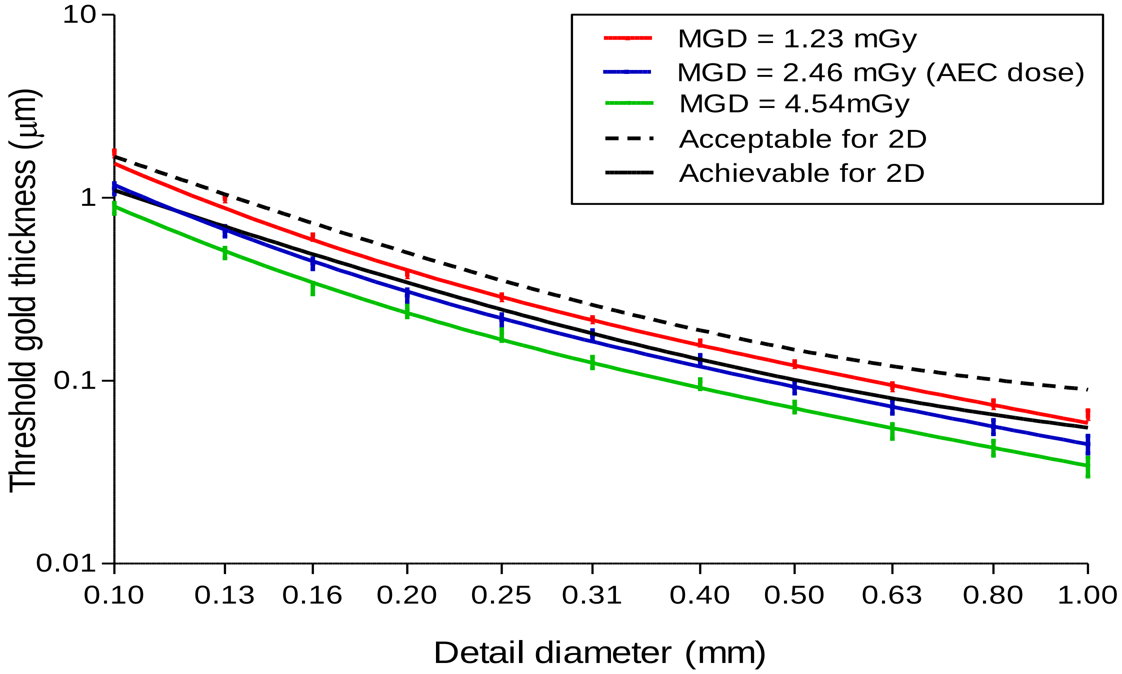

Figure 8. Threshold gold thicknesses for tomosynthesis images for three doses at 33kV W/Al. (Error bars indicate 95% confidence limits.)

In Figure 8, CDMAM curves are shown for sets of sixteen tomosynthesis images, assessed using the flatfielded plane in best focus from each set. Results are for the AEC selected dose, and for half and twice this dose.

The image quality results shown in Figures 7 and 8 are summarised in Table 7.

Table 7. Average threshold gold thicknesses for 2D and tomosynthesis CDMAM images.

	Threshold gold thickness (µm)					
Detail diameter (mm)	2D AEC dose 2.05mGy	DBT AEC dose 2.46mGy	DBT half AEC dose 1.23mGy	DBT double AEC dose 4.54mGy	Minimum standard for 2D	Achievable standard for 2D
0.1	0.635	1.125	1.690	0.879	1.680	1.100
0.25	0.173	0.215	0.276	0.178	0.352	0.244
0.5	0.086	0.092	0.119	0.072	0.150	0.103
1.0	0.044	0.045	0.062	0.034	0.091	0.056

3.4 Geometric distortion and resolution between focal planes

3.4.1 Height of best focus

For the first three images, the height of best focus for each ball was within 1mm of the true height above the table, varying by no more than 1mm across the image. This indicates that the reconstructed focal planes are parallel to the surface of the table, with no vertical distortion.

When the test tool was attached to the bottom of the compression paddle, the paddle sloped down slightly towards the chest wall edge. The height of best focus equalled the nominal height of the balls at the rear of the image, and decreased towards the chest wall edge by 2 to 3mm, due to the tilt of the paddle.

3.4.2 Positional accuracy within focal plane

The mean distances between balls, calculated using the pixel spacings from the DICOM headers, were 52.0mm in both x and y directions. The true separation between balls was 50.0mm, indicating a 4% scaling error. The maximum deviation from the mean separation was 0.2mm in both x and y directions, while the test object's manufacturing specification was a non-cumulative positioning accuracy of +/- 0.1mm. These results indicate that there is no discernible geometric distortion within the focal plane.

3.4.3 Appearance of the ball in adjacent focal planes

The image of a 1mm diameter aluminium ball is well defined in the plane of best focus, with no artefact. In focal planes above and below, the image of the ball becomes fainter, and stretches into a line parallel to the chest wall edge of the image, as shown in Figure 9. The views shown are taken from focal planes at 2mm intervals, from 24mm below to 24mm above the plane at the actual height of the ball.

Figure 10 shows the focal planes re-sliced into vertical planes in the x-z and y-z orientations.

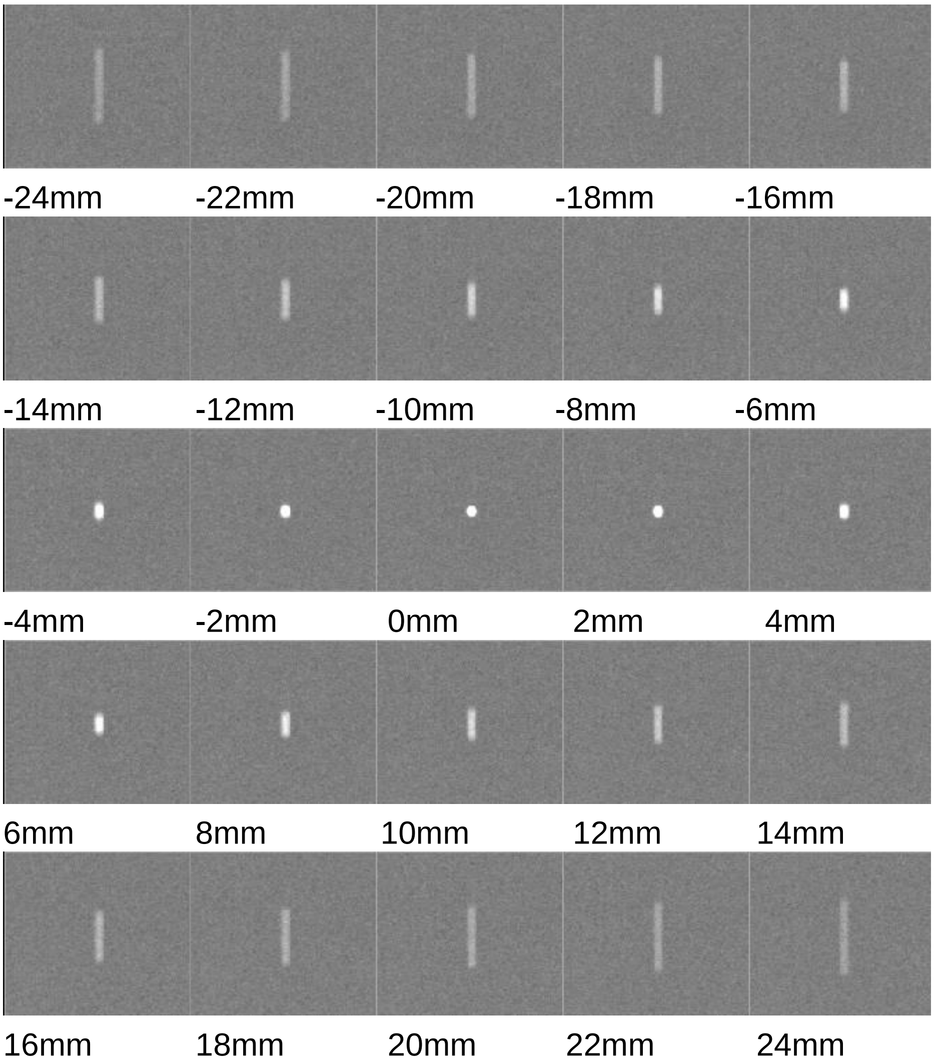

Figure 9. Focal planes at different heights showing a 1mm aluminium ball, 110mm from the chest wall edge in the central area of a tomosynthesis image.

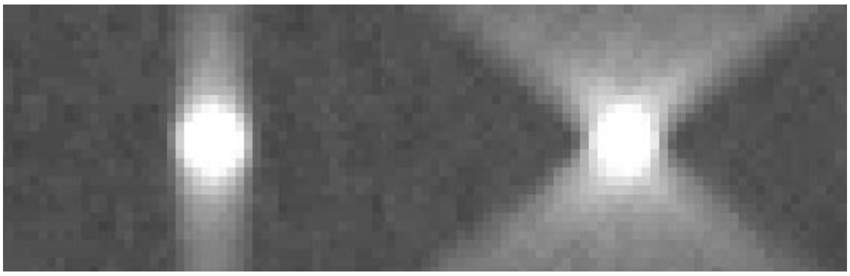

Figure 10. Vertically resliced planes through the centre of a 1mm aluminium ball, 110mm from the chest wall edge in the central area of a tomosynthesis image. The x-z plane is on the left and the y-z plane is on the right.

Table 8 shows the results of the automated analysis of the images. The x and y FWHM, and the composite FWHM (from all planes) are shown. The difference between these quantities indicate the shift or spread of the image between planes.

Figures 11 and 12 show that the composite FWHM in the directions perpendicular and parallel to the chest wall edge have no significant dependence on position within the image.

The composite z-FWHM measurements give a measure of the inter-plane or z-resolution for the tomosynthesis image. Figures 13, 14, and 15 show slight dependence on position within the image. The composite z-FWHM increases very slightly with distance from the centre of the chest wall edge, and decreases slightly with increasing height above the breast support table.

Table 8. Mean values of FWHM for 1mm diameter aluminium balls and their associated reconstruction artefacts, with ranges.

	FWHM within plane of best focus (mm)	Composite FWHM using all planes (mm)	Apparent shift or spread between focal planes (mm)
x (perpendicular to chest wall edge)	0.88 (0.84 to 0.93)	0.89 (0.86 to 0.93)	0.01 (-0.01 to 0.04)
y (parallel to chest wall edge)	0.88 (0.83 to 0.91)	0.94 (0.89 to 0.99)	0.05 (0.01 to 0.09)
z (vertical)		11.0 (9.9 to 12.2)	

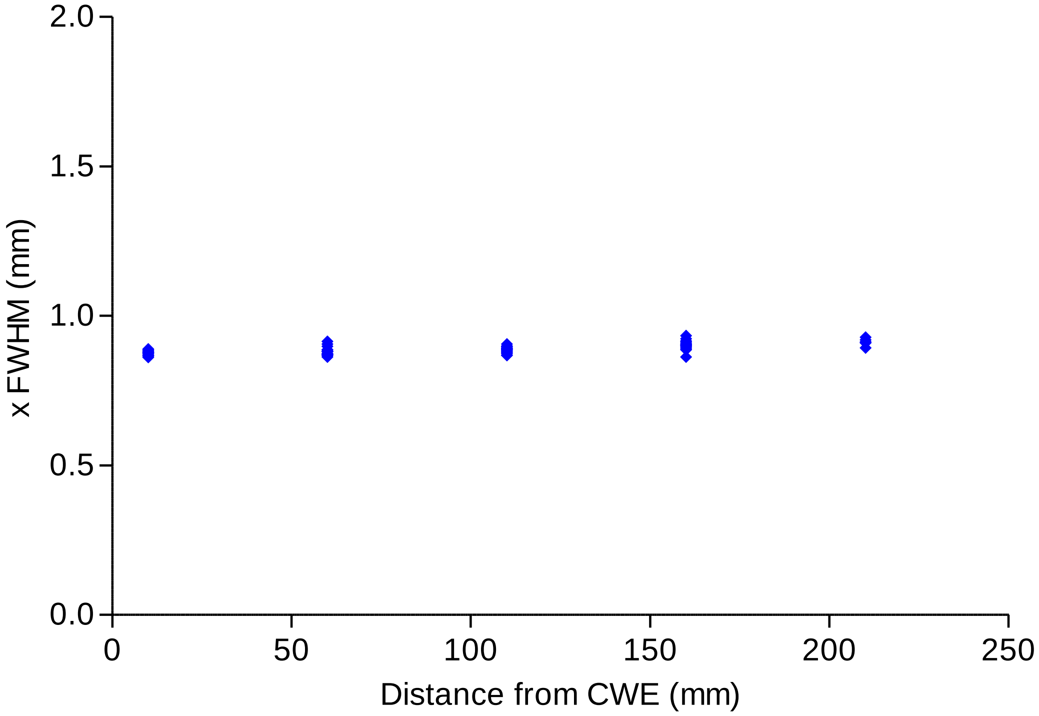

Figure 11. Composite FWHM in the x-direction (perpendicular to the chest wall edge) plotted against distance from the chest wall edge.

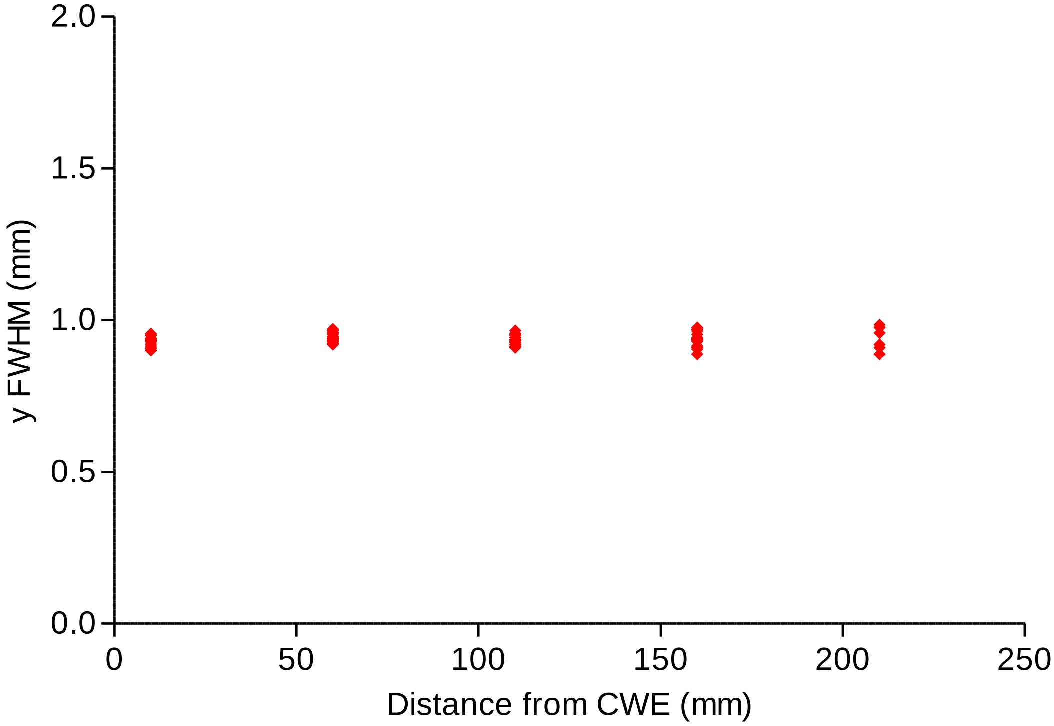

Figure 12. Composite FWHM in the y-direction (parallel to the chest wall edge) plotted against distance from the chest wall edge.

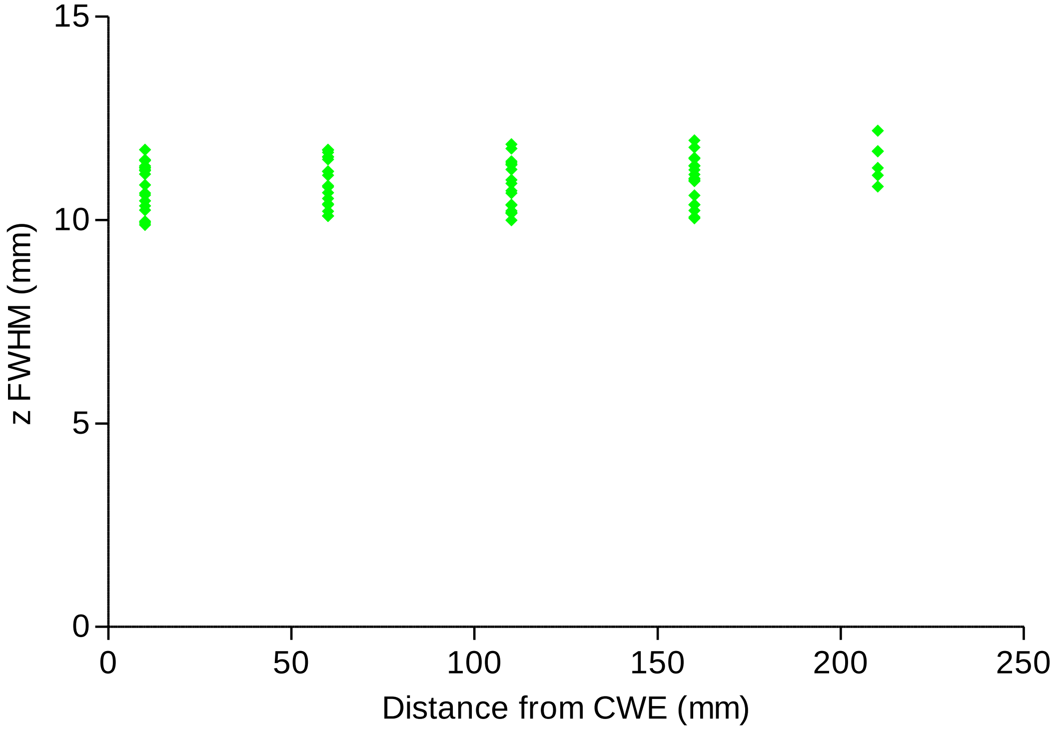

Figure 13. Composite FWHM in the z-direction (vertical) plotted against distance from the chest wall edge.

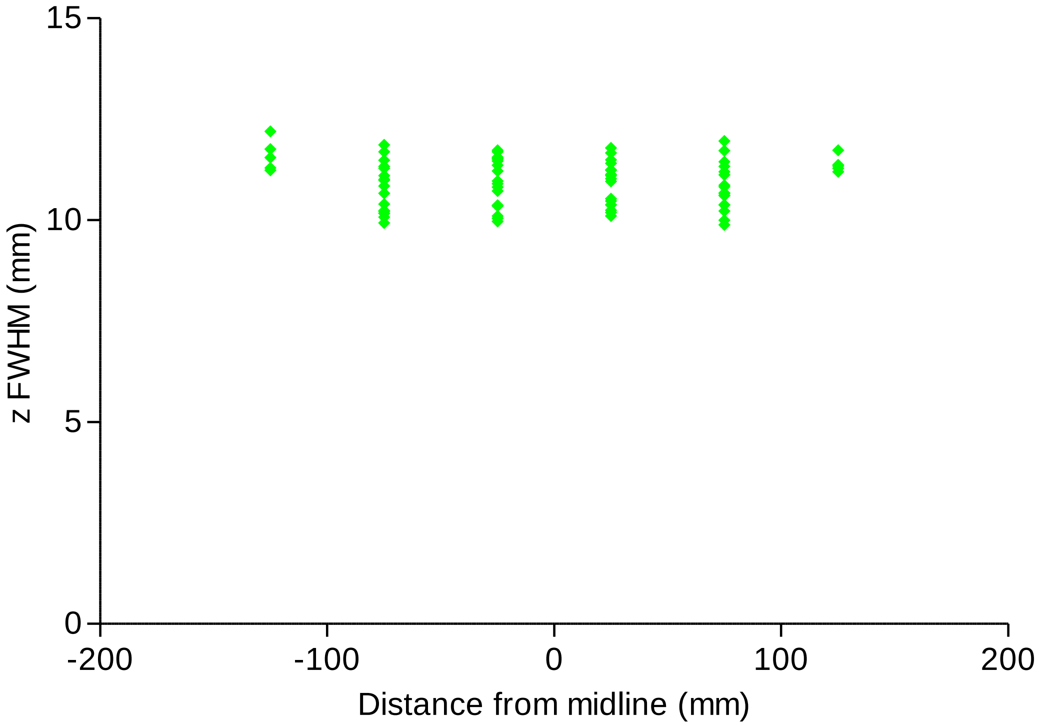

Figure 14. Composite FWHM in the z-direction (vertical) plotted against distance from the midline of the image.

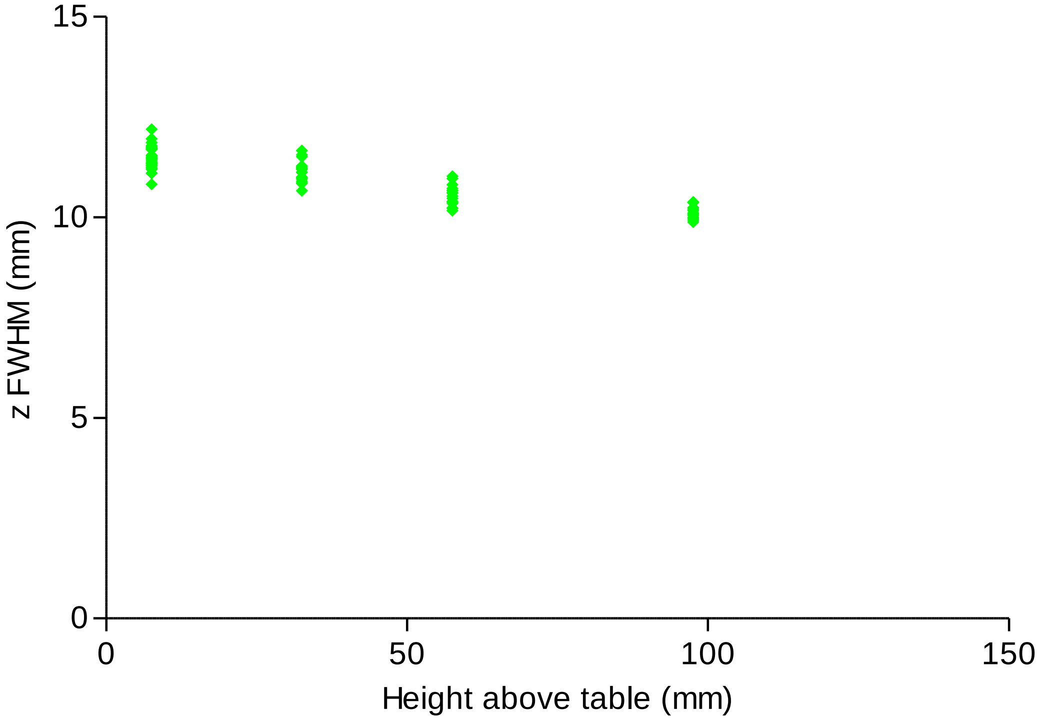

Figure 15. **Composite FWHM in the z-direction (vertical) plotted against height above the table.**

3.5 Alignment

The alignment of the X-ray field to the image in the focal plane at the surface of the breast support table is shown in Table 9. The X-ray field overlaps the edges of the reconstructed focal plane by no more than 5mm, which is the limit applied to 2D mammography.

Table 9. Alignment of X-ray field to reconstructed tomosynthesis image

Height above table (mm)	X-ray field to reconstructed tomosynthesis image* (mm)			
	Front	Back	Left	Right
0	4	5	5	5

*A positive value indicates that the X-ray field extends beyond the edge of the image

The amount of missed tissue at the chest wall edge was 4mm at heights of 0, 60 and 100mm above the breast support table. This is within the 5mm limit which is applied to 2D mammography.

All markers distributed across the surface of the breast support table and the underside of the compression paddle were brought into focus in planes near the bottom or top of the image. This showed that nothing is missed at the base or top of the reconstructed volume.

4. Discussion

4.1 Dose and CNR

The MGDs to the standard breast were calculated for a range of equivalent breast thicknesses from 21 to 90mm. In both 2D and tomosynthesis modes the doses were well within the NHSBSP dose limits for 2D mammography (except for the smallest equivalent breast thickness, where the tomosynthesis dose is close to the limit). The MGD to a 53mm equivalent breast was 1.49mGy and 1.81mGy for 2D and tomosynthesis respectively while the NHSBSP dose limit for 2D mammography of 2.5mGy for this thickness.

In 2D mode under AEC, the CNR for all equivalent breast thicknesses exceeded the value required to meet the NHSBSP standard for achievable image quality. As usual in digital mammography, the CNR in 2D imaging decreased significantly as the breast thickness increased, but remained better than the achievable standard.

CNR values in reconstructed tomosynthesis focal planes are expected to be highly dependent on the degree of smoothing and scaling inherent within the reconstruction algorithm. Any interpretation of absolute CNR values in relation to image quality should therefore be treated with caution. The focal plane CNR is seen to decrease with breast thickness to a greater extent than is the case for 2D CNR. This may be largely due to the greater amount of scatter reaching the detector in the tomosynthesis projections in the absence of a grid.

CNR measurements were also made in the unprocessed tomosynthesis projections. The CNRs are lower because the dose per projection is a fraction (one fifteenth) of the total tomosynthesis dose. The CNR in projections did not change significantly with projection angle within the narrow range of tube angles on this system. Over a greater range of tube angles, some variation in CNR with projection angle would be expected due to changes in contrast and noise.

The variation of tomosynthesis CNR with dose was assessed. A power fit applied to the relationships between CNR and dose had an index close to 0.5 for both reconstructed focal planes and projections. This indicates that quantum noise is the dominant noise source in the tomosynthesis images.

4.2 Image quality

Image quality was assessed in both 2D and tomosynthesis modes using the CDMAM test object under AEC. The 2D threshold gold thickness curve exceeds the achievable level of image quality for all detail sizes.

The threshold gold thickness curve for tomosynthesis is close to the achievable level of image quality that is defined for 2D mammography. However, this result takes no account of the ability of tomosynthesis to remove the obscuring effects of overlying tissue in a clinical image. The degree of this effect in different tomosynthesis systems is expected to vary, depending on the angular range over which projections are acquired. As expected, the threshold gold thickness increases at half the AEC selected dose and decreases when the dose is doubled.

There is no standard test object available yet that would allow a realistic and quantitative comparison of image quality between tomosynthesis systems, or between 2D and tomosynthesis modes. A suitable test object would incorporate simulated breast tissue to show the benefit of removing overlying breast structure in tomosynthesis imaging, as compared to 2D imaging. In the absence of such a test object, an extensive clinical trial would be needed to determine whether the performance of a particular tomosynthesis system is likely to be clinically adequate.

4.3 Geometric distortion and reconstruction artefacts

Assessment of the geometric test phantom images demonstrated that reconstructed tomosynthesis focal planes are parallel to the surface of the breast support table with no vertical distortion. Within the focal plane, comparison of measured and actual separations between imaged details demonstrated that there is no geometric distortion, apart from an overall scaling error of 4%. This is due to inaccuracy in the pixel spacing quoted in the image DICOM headers used in the calculation.

In the tomosynthesis images of 1mm aluminium balls within a PMMA block, the balls were well defined and circular within the plane of best focus, with no artefact. However, in focal planes above and below, the reconstruction artefact associated with each ball persisted and stretched into a faint line parallel to the chest wall edge.

Within focal planes, the spread of reconstruction artefacts associated with the balls did not vary with the position of the ball. The maximum extent of the 50% contour level in background corrected pixel values around each ball did not significantly exceed that in the plane of best focus. The difference was less than the pixel spacing of 0.1mm. Due to the geometry of the diverging primary X-ray beam, the reconstruction artefacts might be expected to extend away from the centre of the chest wall edge of the image with increasing distance from the X-ray tube focal spot. The Dimensions compensates for this magnification effect between focal planes by varying the pixel size with height, such that reconstruction artefacts appear to extend vertically in the plane perpendicular to the chest wall edge (when viewed within the stack of reconstructed focal planes). A spread of the reconstruction artefacts is expected in the direction of tube motion (parallel to the chest wall edge of the image) over a distance which depends on the projection angular range of the system. Although a line is seen parallel to the chest wall edge away from the plane of best focus, the maximum extent of the 50% contour in this direction was no more than 0.1mm greater than in the plane of best focus.

The 50% contour extended vertically between focal planes, giving a mean inter-plane resolution of 11mm for 1mm diameter balls. Balls of different diameter would result in more or less extensive reconstruction artefacts, so the inter-plane resolution would vary accordingly. A tomosynthesis system employing a wider range of projection angles is expected to have improved inter-plane resolution with less persistence between focal planes. Inter-plane resolution did not vary by more than 10% with vertical or horizontal position of the balls.

4.4 Alignment

It is not possible to assess alignment of the irradiated volume to the imaged volume because the lateral parts of the volume are partially irradiated as the X-ray field moves during the tomosynthesis scan. At the breast support table the X-ray beam extended beyond the edges of the reconstructed focal plane by no more than the 5mm limit which is applied to 2D mammography.

Assessment of alignment of the imaged volume in tomosynthesis to the compressed volume indicated that 4mm of tissue is missed at the chest wall edge at heights of 0 -100mm above the breast support table. This is within the 5mm limit for 2D mammography. There was no missed tissue at either the top or bottom of the reconstructed image. The Dimensions system reconstructs five additional 1mm planes above the height of the indicated compressed breast thickness, allowing for any inaccuracy in calibration or tilt of the compression paddle.

5. Conclusions

The technical performance was tested in both 2D and tomosynthesis modes. 2D performance met current NHSBSP standards for digital mammography, with image quality better than the achievable level. No performance standards have yet been set for digital breast tomosynthesis systems and it is not yet possible to predict clinical tomosynthesis performance from these results.

The MGD to the standard breast was found to be approximately 20% higher in tomosynthesis mode than in 2D mode. The tomosynthesis doses are well within the NHSBSP dose limits for 2D mammography.

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Appendix 1: Manufacturer's comments

The manufacturer has added the following comments which are not part of the current evaluation, but provide further information about the equipment.

- The evaluation was carried out on a system with AWS version 1.4.2. More recent Dimensions AWS software versions make images available in the DICOM Breast Tomosynthesis Object (BTO) or the Computerised Tomography (CT) format, enabling direct visualisation of the focal planes with DICOM viewer software. The BTO and CT formats have a fixed pixel size for all focal planes to enhance compatibility with third party Picture Archiving and Communication System (PACS) workstations

- The pixel spacing quoted in the DICOM header has been corrected in the later software version AWS 1.7. (see section 3.4.2)