Public Health England

NHS

NHS Breast Screening Programme Equipment Report

Technical evaluation of Hologic 3Dimensions digital breast tomosynthesis system

March 2019

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Public Health England, Wellington House, 133-155 Waterloo Road, London SE1 8UG
Tel: 020 7654 8000 www.gov.uk/phe
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Prepared by: A Mackenzie, JM Oduko, KC Young

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Executive summary

The technical performance of the Hologic 3Dimensions digital breast tomosynthesis system was tested in tomosynthesis modeThe mean glandular dose (MGD) to the standard breast was found to be 1.96mGy, which is below the dose limiting value of 2.5mGy for tomosynthesis in the EUREF protocol.

Technical performance of this equipment was found to be satisfactory, so that the system could proceed to practical evaluation in a screening centre. This report provides baseline measurements of the equipment performance including:

- dose
- contrast detail detection
- contrast-to-noise ratio (CNR)
- reconstruction artefacts, z-resolution
- detector response
- modulation transfer function of projection images

1. Introduction

1.1 Testing procedures and performance standards for digital mammography

This report is one of a series evaluating commercially available mammography systems on behalf of the NHS Breast Screening Programme (NHSBSP).[1-4] The testing methods and standards applied are those of the relevant NHSBSP protocols, which are published as NHSBSP Equipment Reports. Report 1407[5] describes the testing of digital breast tomosynthesis systems.

The NHSBSP protocol is similar to the EUREF protocol,[6] but the latter also provides additional or more detailed tests and standards, some of which are included in this evaluation.

1.2 Objectives

The aim of the evaluation was to measure the technical performance of the Hologic 3Dimensions system in tomosynthesis mode.

2. Methods

2.1 System tested

The tests were conducted at the Hologic factory, Danbury, CT, USA, on a Hologic 3Dimensions system as described in Table 1. Some additional measurements were made at the Jarvis Breast Screening Unit, Guildford, UK on the curved compression paddle.

Table 1. System description

Manufacturer	Hologic Inc
Model	3Dimensions
System serial number	PROTO 7
Target material	Tungsten (W)
Added filtration	700µm Aluminium (Al)
Detector type	Amorphous selenium
Detector serial number	YM868282
Image pixel size	70µm
Detector size	240mm x 300mm
Pixel array	3328 x 4096
Source to table distance	675mm
Source to detector distance	700mm
Acquisition modes	Low dose, Standard, Enhanced
Automatic exposure control (AEC) modes	Auto-Filter, Auto-kV, Auto-Time
Pre-pulse	5mAs
Tomosynthesis projections	15 equal dose projections, equally spaced, covering range ±7.5˚
Centre of rotation	0 mm above detector.
Anti-scatter grid	Not used in tomosynthesis
Reconstructed focal planes	Focal planes at 1mm intervals
Software version	1.9.0.632

In tomosynthesis mode, the system acquires a series of low dose images following a pre-pulse exposure of 5mAs. The kV for the pre-pulse is set using the displayed compressed breast thickness (CBT). The signal in a small region of interest of the pre-pulse image is examined to determine the appropriate radiographic factors for the main exposure.

The 3Dimensions has 3 acquisition dose modes: Low dose, Standard and Enhanced. The system is set up in either the Standard or Low dose modes by the engineer. The Enhanced mode is user-selectable, and is designed for use in assessment rather than screening. The

tomosynthesis images can be reconstructed with a pixel pitch of either 70µm or 100µm. This system was only tested for the pixel pitch of 70µm.

The system has a static mode for tomosynthesis, in which the 15 projection images are acquired with the x-ray tube at 0°. This mode was used for measuring half value layer (HVL) and tube output.

It is possible to perform combination exposures, comprising a 2D and a tomosynthesis exposure in the same compression.

Hologic have introduced an optional curved compression paddle (SmartCurve™) for this system, in addition to the standard flat paddle. The curved paddle is designed to more closely match the shape of the breast. There are 2 curved paddle sizes available: 18cm x 24 cm and 24cm x 29cm. The distance between the highest and lowest point of the paddles are 16mm and 23mm for the small and large paddles respectively. All tests were undertaken using the flat paddle apart from section 3.10, which tests the curved paddle.

Methods for evaluating synthetic 2D images created from the tomosynthesis planes are in development but no results are included in this report.

Typical image file sizes are shown in Table 2. The file size of reconstructed volumes depends on the compressed breast thickness, resolution mode and field size. The projections can be exported in the DICOM BPO format. The reconstructed planes can be exported in DICOM BTO format or Hologic's SC format. The images may also be exported in compressed format.

Table 2. Image file sizes for 60mm compressed breast thickness using a 18cm x 24cm flat paddle in BTO format

Format	Pixels per frame	Frames per volume	Total image file size (MB)
Projections	2560x4096	15	314.6
Planes	2560x3328	66	1120

The Hologic 3Dimensions is shown in Figure 1.

Figure 1. The Hologic 3Dimensions digital breast tomosynthesis system

2.2 Dose and contrast-to-noise ratio using AEC

2.2.1 Dose measurement

To calculate the MGD to the standard breast, measurements were made of HVL and tube output, across the clinically relevant range of kV and filter combinations. The output measurements were made on the midline at the standard position of 40mm from the chest wall edge (CWE) of the breast support platform. The compression paddle was in the beam, raised well above the ion chamber.

In tomosynthesis mode, exposures of a range of thicknesses of polymethyl methacrylate (PMMA) were made using AEC. For each measurement the height of the paddle was set to match the indicated thickness to the equivalent breast thickness for that thickness of PMMA.

The method of measuring tomosynthesis doses described in the UK protocol differs slightly from the method described by Dance et al.[7] The incident air kerma is measured with the compression paddle well above, instead of in contact with, the ion chamber. Measurements on other systems[1,2] show that this variation reduces the air kerma and thus the mean glandular dose (MGD) measurement by 3% to 5%. Otherwise the MGD in tomosynthesis mode were

calculated using the method described by Dance et al.[7] This is an extension of the established 2D method, using the equation:

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

Where *D* is the MGD (mGy), *K* is the incident air kerma (mGy) at the top surface of the PMMA blocks, 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[6] for the Hologic Selenia Dimensions for different compressed breast thicknesses, and the same values are appropriate for the 3Dimensions, because it has the same geometry.

2.2.2 Contrast-to-noise ratio

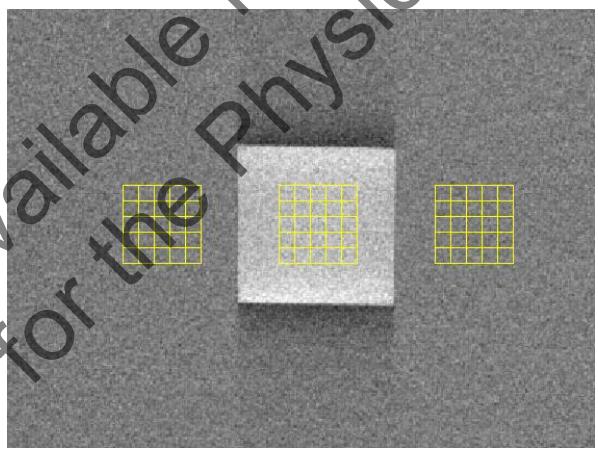
For contrast-to-noise ratio (CNR) measurements a 10mm x 10mm square of 0.2mm thick aluminium foil was included in the PMMA phantom, positioned 10mm above the table on the midline, 60mm from the CWE.

The CNR was measured in the focal plane in which the aluminium square was brought into focus. The 5mm x 5mm regions of interests (ROI) were subdivided into 1mm x 1mm elements and the background ROIs were positioned adjacent to the aluminium square, as shown in Figure 2. The mean pixel values and their standard deviations were averaged over all the 1mm x 1mm elements, and the CNR was calculated from these averages.

CNR was also assessed in the unprocessed tomosynthesis projections acquired for these images.

The variation in central projection CNR with breast thickness and the variation in projection CNR with projection angle for a 53mm breast were also assessed.

Figure 2. The position of 5mm x 5mm ROIs for assessment of CNR. (The CWE is to the left)



2.3 Image quality measurements

A CDMAM phantom (Version 3.4, serial number 1022, UMC St. Radboud, Nijmegen University, Netherlands) was positioned between 2 blocks of PMMA, each 20mm thick. The exposure factors were chosen to be close to those selected by the AEC, when imaging a 50mm thickness of PMMA. This procedure was repeated to obtain a representative sample of 16 images at this dose level. Two further sets of 16 images at double and half of this dose were then acquired.

The focal plane corresponding to the vertical position of the CDMAM phantom within the image was extracted from each reconstructed stack of images. The sets of CDMAM images were read and analysed using 2 software tools: CDCOM version 1.6 (www.euref.org) and CDMAM Analysis version 2.1 (NCCPM, Guildford, UK). This was repeated for 2 focal planes immediately above and below the expected plane of best focus to ensure that the threshold gold thickness quoted corresponded to the best image quality obtained.

2.4 Geometric distortion and reconstruction artefacts

The relationship between reconstructed tomosynthesis focal planes and the physical 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 at 50mm intervals in the middle of a 5mm thick sheet of PMMA. The phantom was placed at various heights (12.5, 22.5, and 32.5mm) above the breast support table within a 55mm stack of plain sheets of PMMA. 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, and the number of adjacent planes in which the ball was also seen. The variation in appearance of the ball between focal planes was quantified.

This analysis was automated using a software tool developed at the National Coordinating Centre for the Physics of Mammography (NCCPM) for this purpose. This software is in the form of a plug-in for use in conjunction with ImageJ (http://rsb.info.nih.gov/ij/).

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.

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 CWE, respectively). The mean distances between adjacent balls were calculated, using the pixel spacing quoted in the DICOM image header. For this system the

pixel spacing depends on the height of the plane. 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 focal planes adjacent to those containing the image of the balls, the reconstructed image was treated as though it were a true 3 dimensional volume. The software tool was used to find the z-dimension of a cuboid around each ball which would enclose all pixels with values exceeding 50% of the maximum pixel value. The method used was to re-slice the image vertically and create a composite x-z image using the maximum pixel values from all re-sliced x-z focal planes. A composite z line was then created using the maximum pixel from each column of the x-z composite plane, and a full width at half maximum (FWHM) measurement in the z-direction was made by fitting a polynomial spline. 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 (which depends on the size of the imaged ball) was used as a measure of the inter-plane resolution, or z-resolution.

2.5 Alignment

The alignment of the imaged volume to the compressed volume was assessed at the top and bottom of the volume. In order to assess vertical alignment, small high contrast markers were placed on the breast support table and on the underside of the compression paddle, and the image planes were inspected to check whether all markers were brought into focus within the reconstructed tomosynthesis volume. This was first done with no compression applied and then repeated with the chest wall edge of the paddle supported and 100N compression applied.

2.6 Image uniformity and repeatability

The reproducibility of the tomosynthesis exposures was tested by acquiring a series of 10 images of a 45mm thick block of PMMA acquired using AEC. A 10mm x 10mm ROI was positioned 60mm from the chest wall edge in the plane corresponding to a height of 22.5mm above the breast support table. The mean and standard deviation of the pixel values in the ROI were found and the SNR was calculated for each image. These images and others acquired during the course of the evaluation were evaluated for artefacts by visual inspection.

2.7 Detector response

Detector response was measured for the detector operating in tomosynthesis mode. A 2mm thick aluminium filter was placed in the beam and attached to the tube port. The compression paddle was removed. A typical beam quality was selected and images were acquired using a range of tube load settings in tomosynthesis mode. The air kerma was measured and corrected using the inverse square law to give the air kerma incident at the detector. No corrections were made for the attenuation of X-rays by the breast support. A 10mm x 10mm ROI was positioned on the midline, 50mm from the chest wall edge of the central projection image. The mean pixel value was measured and plotted against air kerma incident at the detector.

2.8 Timings

Using a stopwatch, image timings were measured whilst imaging a 45mm thickness of PMMA using AEC. Scan times were measured, from when the exposure button was pressed until the compression paddle was released, and to the moment when it was possible to start the next exposure.

2.9 Modulation transfer function

Modulation transfer function (MTF) measurements were made in tomosynthesis projection images as described in the EUREF protocol,[6] at heights of 0mm, 40mm and 70mm above the breast support table. Since the doses are low in the tomosynthesis projections and the MTF results are noisy, a 10th order polynomial fit was applied to the results.

2.10 Local dense area

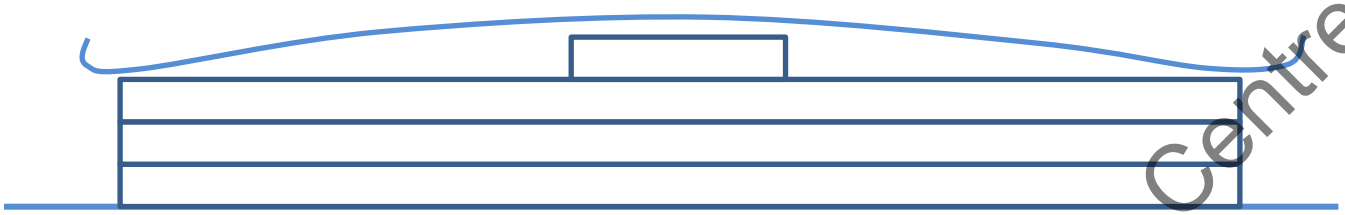
This test is described in the EUREF protocol.[6] Images of a 40mm thick block of PMMA, of size 180mm x 240mm, were acquired using AEC. Extra pieces of PMMA between 2 and 20mm thick and of size 20mm x 40mm were added to provide extra attenuation. The compression plate remained in position at a height of 40mm, as shown in Figure 3. The simulated dense area was positioned 50mm from the CWE of the table.

In the simulated local dense area the mean pixel value and standard deviation for a 10mm x 10mm ROI were measured and the signal-to-noise ratios (SNRs) were calculated for the projection images.

2.11 Testing AEC with curved paddles

It was not possible to test the AEC function using the standard size blocks of PMMA, as it was not possible to position the paddle at the required height due to its curvature. The required thickness of PMMA was therefore assembled using blocks of different sizes, an example is shown in Figure 3.

Figure 3. Curved paddle with PMMA



3. Results

3.1 Dose and contrast-to-noise ratio using AEC

The measurements of HVL and tube output are summarised in Table 3.

Table 3. HVL and tube output measurement in tomosynthesis mode

kV	Anode / Filter	HVL (mm Al)	Output (μGy/mAs at 1m)
25	W/Al	0.42	18.9
28	W/Al	0.49	27.7
31	W/Al	0.55	37.0
34	W/Al	0.61	46.9
37	W/Al	0.67	57.4
40	W/Al	0.69	68.4
43	W/Al	0.73	79.9

The MGDs to the standard breast model are shown in Figure 4. All MGDs include the preliminary exposure which is not included in the image. Figure 5 shows the CNRs measured in focal planes and Figure 6 shows the CNR of the central projection image, both for different thicknesses of PMMA. The values used in Figures 5 and 6 are shown in Tables 4 to 6. Figure 7 shows the CNR in the projection images at different projection angles.

Figure 4. MGD for tomosynthesis exposures using AEC. Error bars indicate 95% confidence limits.

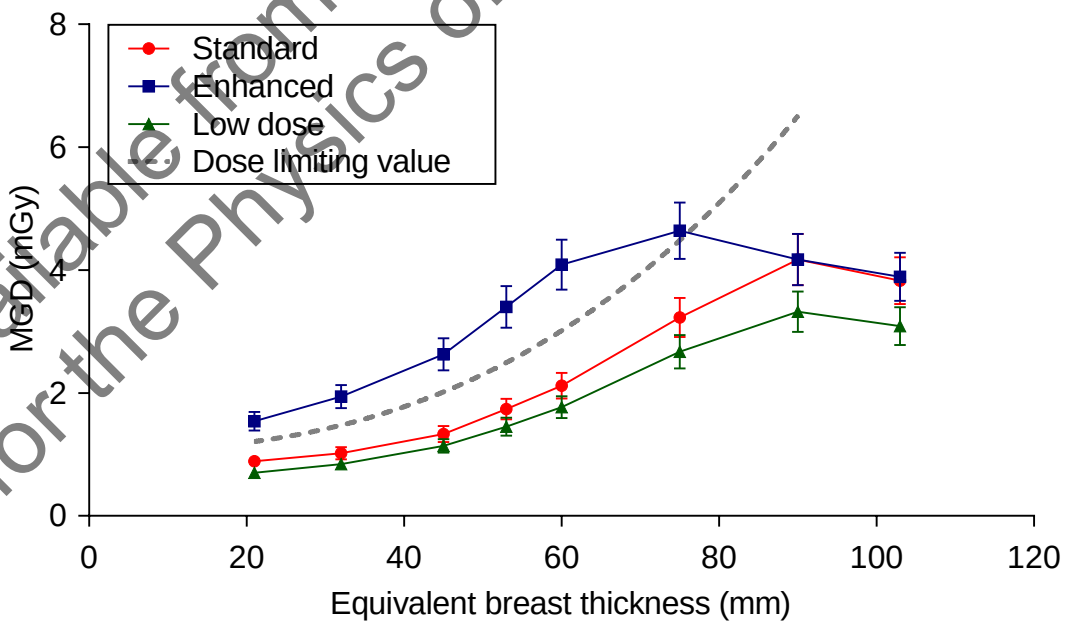


Figure 5. CNR for tomosynthesis planes obtained using AEC. Error bars indicate 95% confidence limits.

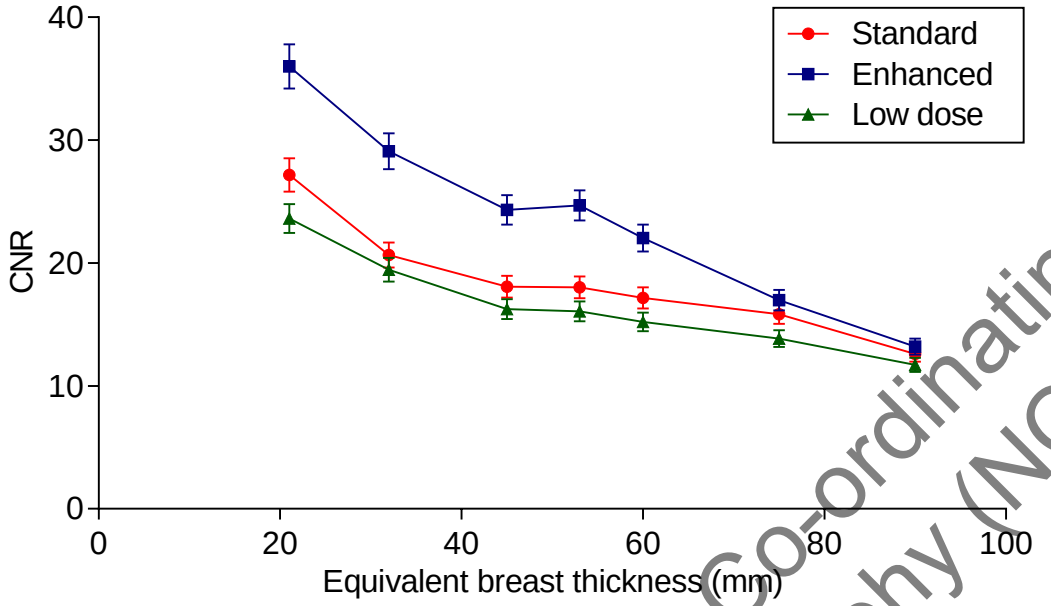


Figure 6. CNR for tomosynthesis central projection images obtained using AEC. Error bars indicate 95% confidence limits.

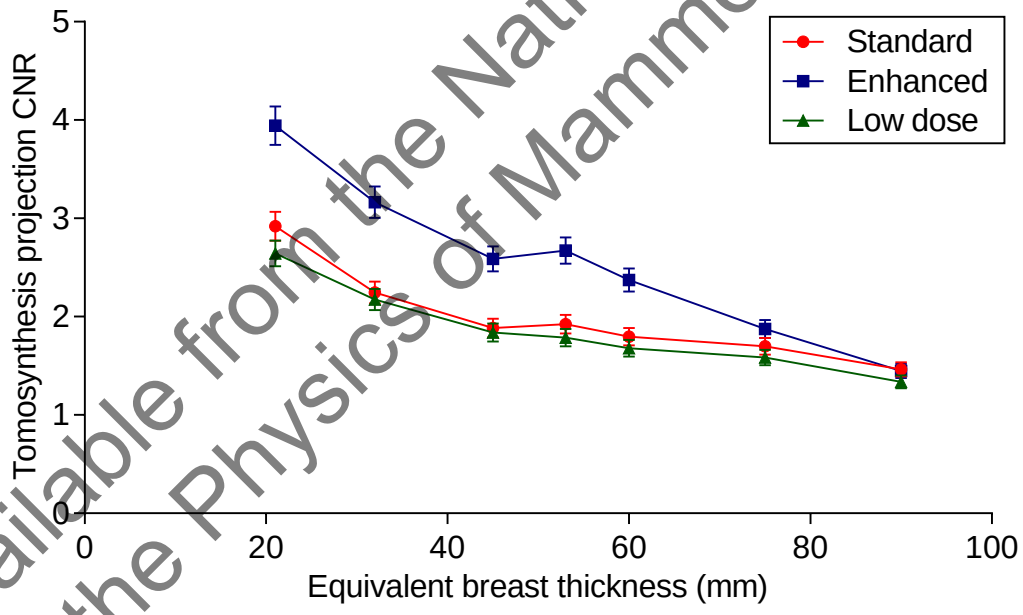


Table 4. Dose and CNR for tomosynthesis planes using AEC (Auto-Filter): Standard acquisition mode

PMMA thickness (mm)	Equivalent breast thickness (mm)	kV	Target/ filter	mAs	MGD (mGy)	Displayed MGD (mGy)	Dose limiting value (mGy)	CNR
20	21	26	W/Al	38	0.89	0.97	1.2	27.2
30	32	28	W/Al	41	1.02	1.11	1.5	20.7
40	45	30	W/Al	47	1.33	1.39	2.0	18.1
45	53	31	W/Al	59	1.74	1.78	2.5	18.0
50	60	33	W/Al	60	2.12	2.13	3.0	17.2
60	75	36	W/Al	76	3.23	3.20	4.5	15.8
70	90	42	W/Al	70	4.17	4.39	6.5	12.6
80	103	44	W/Al	63	3.83	4.77	-	-

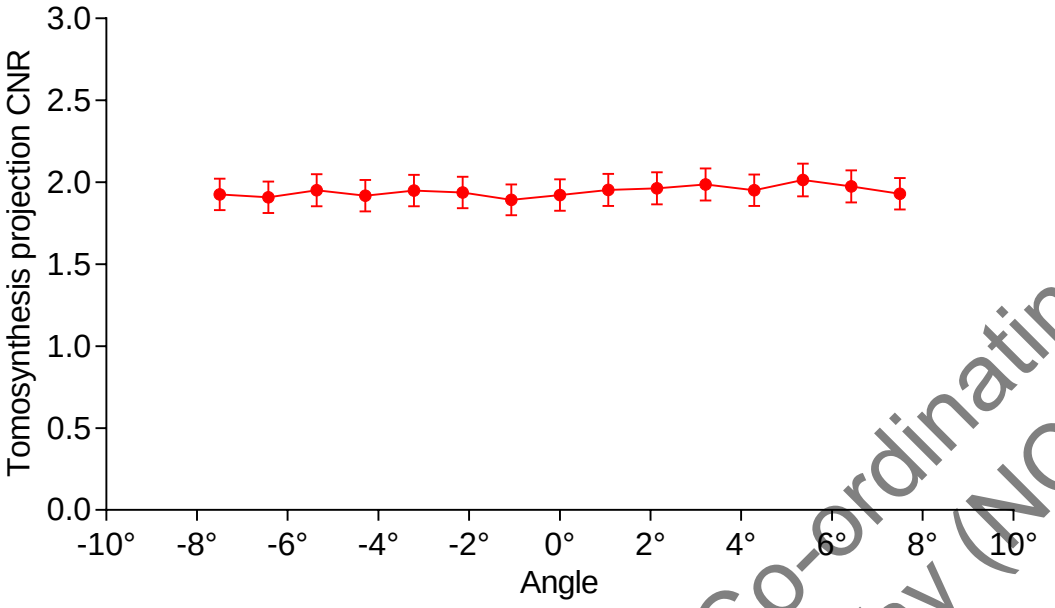
Table 5. Dose and CNR for tomosynthesis planes using AEC (Auto-Filter): Enhanced acquisition mode

PMMA thickness (mm)	Equivalent breast thickness (mm)	kV	Target/ filter	mAs	MGD (mGy)	Displayed MGD (mGy)	Dose limiting value (mGy)	CNR
20	21	26	W/Al	66	1.54	1.68	1.2	36.0
30	32	28	W/Al	76	1.94	2.02	1.5	29.1
40	45	32	W/Al	73	2.63	2.78	2.0	24.3
45	53	33	W/Al	92	3.40	3.53	2.5	24.7
50	60	36	W/Al	87	4.09	4.21	3.0	22.0
60	75	41	W/Al	74	4.64	4.81	4.5	17.0
70	90	42	W/Al	70	4.17	4.39	6.5	13.2
80	103	44	W/Al	64	3.89	4.86	-	-

Table 6. Dose and CNR for tomosynthesis planes using AEC (Auto-Filter): Low dose acquisition mode

PMMA thickness (mm)	Equivalent breast thickness (mm)	kV	Target/ filter	mAs	MGD (mGy)	Displayed MGD (mGy)	Dose limiting value (mGy)	CNR
20	21	26	W/Al	30	0.70	0.76	1.2	23.6
30	32	26	W/Al	46	0.84	0.90	1.5	19.5
40	45	28	W/Al	53	1.14	1.15	2.0	16.2
45	53	29	W/Al	64	1.45	1.47	2.5	16.1
50	60	31	W/Al	63	1.77	1.75	3.0	15.2
60	75	34	W/Al	75	2.67	2.56	4.5	13.8
70	90	38	W/Al	74	3.32	3.35	6.5	11.7
80	103	39	W/Al	70	3.09	3.58	-	8.9

Figure 7. Variation of projection CNR with angle for images of 45mm PMMA. Error bars indicate 95% confidence limits.



3.2 Image quality measurements

The lowest threshold gold thicknesses were obtained for focal plane 21. In Figure 8, the contrast detail curves are shown for focal plane 21 at 3 doses, where the mid-dose is similar to the AEC dose for Standard acquisition mode. The CDMAM results shown in Figures 8 are summarised in Table 7.

Figure 8. Threshold gold thickness for planes at 3 dose levels. Error bars indicate 95% confidence limits.

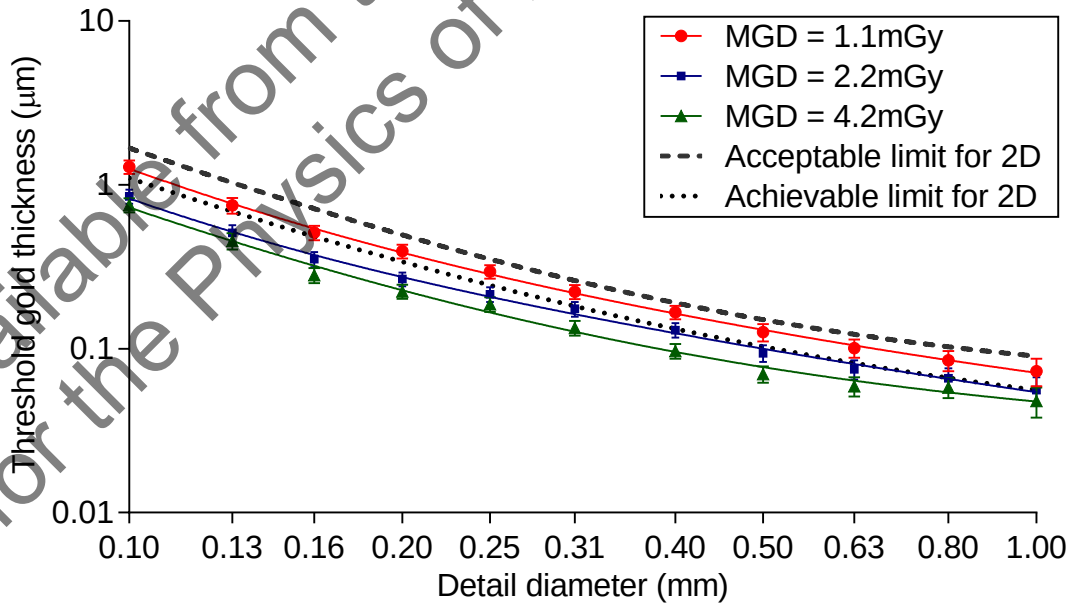
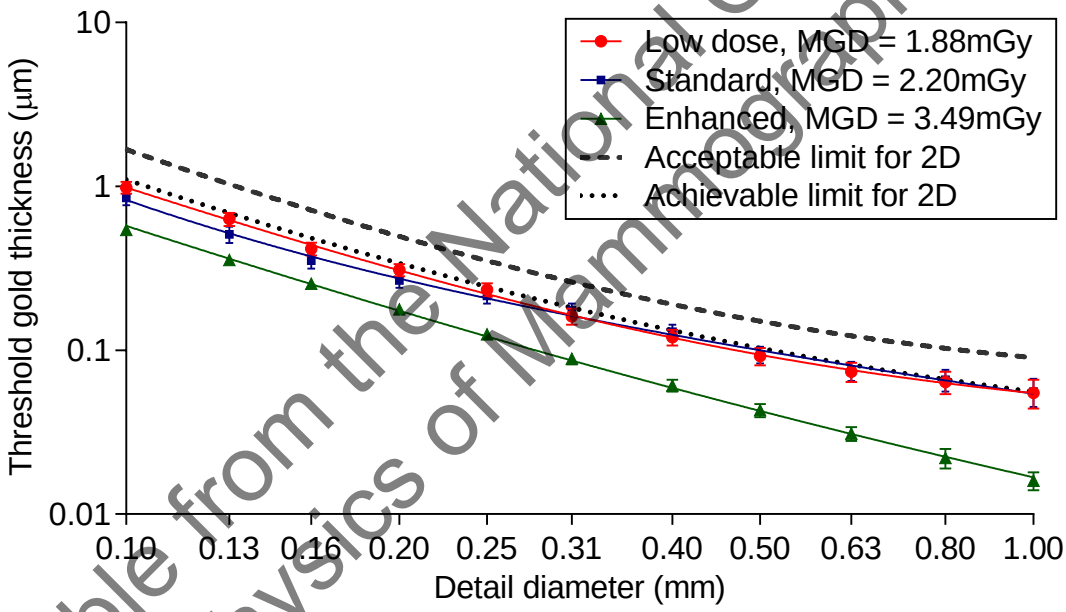


Table 7. Threshold gold thickness for reconstructed focal plane 21 of the CDMAM phantom (fit to predicted human data) for Standard acquisition mode.

Detail diameter (mm)	Threshold gold thickness (µm)				
	Acceptable value	Achievable value	MGD = 1.1mGy	MGD = 2.2mGy	MGD = 4.2mGy
0.1	1.680	1.100	1.29 ±0.12	0.85 ±0.08	0.75 ±0.07
0.25	0.352	0.244	0.30 ±0.03	0.22 ±0.02	0.19 ±0.02
0.5	0.150	0.103	0.13 ±0.02	0.094 ±0.011	0.070 ±0.008
1.0	0.091	0.056	0.073 ±0.014	0.056 ±0.011	0.048 ±0.010

In Figure 9, the contrast detail curves are shown for focal plane 21 at 3 acquistion modes. The images were acquired at 33kV, 36kV, and 31kV for the Standard, Enhanced and Low dose modes respectively.

Figure 9. Threshold gold thickness for planes at 3 acquisition modes. Error bars indicate 95% confidence limits.



3.3 Geometric distortion and resolution between focal planes

3.3.1 Height of best focus

All balls within each image were brought into focus at the same height (±1mm) above the table, and within 1mm of the expected height. This indicates that the focal planes are flat and parallel to the surface of the breast support table, with no noticeable vertical distortion.

The first focal plane corresponds to approximately 1mm below the breast support table. The last focal plane corresponds to approximately 5mm above the underside of the compression paddle. The number of focal planes reconstructed is equal the indicated breast thickness in mm plus 6.

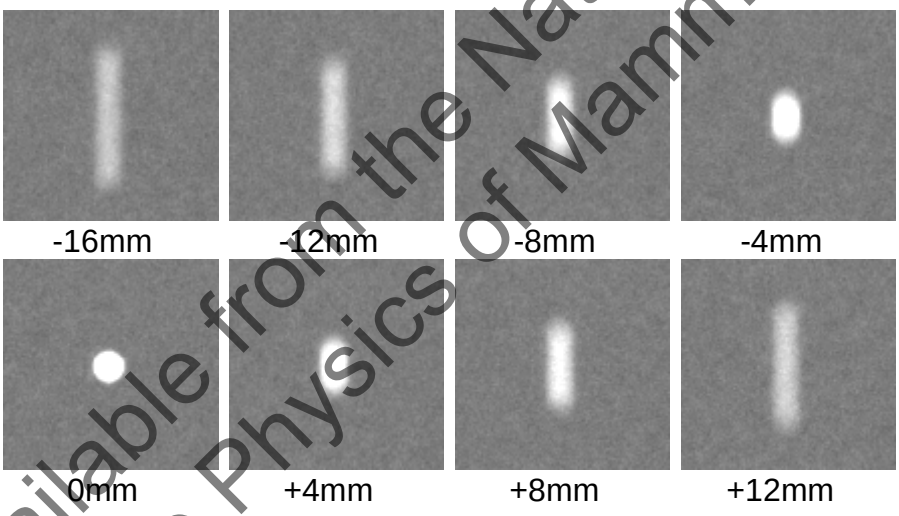
3.3.2 Positional accuracy within focal plane

No significant distortion or scaling error was seen within focal planes. Scaling errors, in both the x and y directions, were found to be less than 0.5%. Maximum deviation from the average distance between the balls was 0.1mm in the x and y directions, compared to the manufacturing tolerance of 0.1mm in the positioning of the balls.

3.3.3 Appearance of the ball in adjacent focal planes

In the plane of best focus the aluminium balls appeared well defined and circular. When viewing successive planes, moving away from the plane of best focus, the images of the balls fade and stretch in the direction parallel to the chest wall edge of the image. The changing appearance of 1 of the balls through successive focal planes is shown in Figure 10.

Figure 10. Appearance of 1mm aluminium balls in reconstructed focal planes at 1mm intervals from 16mm below to 12mm above the plane of best focus for planes



Using DICOM viewer software, it is possible to treat the stack of focal planes as though it were a true 3-dimensional volume and re-slice it vertically to produce planes in the x-z and y-z orientations. The appearance of a ball and associated artefacts in all slices can be visualised in 2-dimensions by creating a maximum intensity projections (MIP) through the re-sliced volumes. Image extracts for a ball positioned in the central area, 120mm from the chest wall, are shown in Figure 11. In these images, pixels within the focal plane represent dimensions of approximately 0.07mm x 0.07mm. The spacing of reconstructed focal planes is 1mm, therefore

the vertical dimension of each pixel in the re-sliced planes is 1mm. This gives rise to the apparent flattening of the balls, which actually extend vertically by a distance exceeding their diameter.

Figure 11. Extracts from planes showing 1mm aluminium ball in (i) single focal plane, (ii) the maximum intensity projections through all focal planes, and through re-sliced vertical planes in the directions (iii) parallel and (iv) perpendicular to the chest wall.

(i)x-y single plane (ii) x-y all planes (iii) x-z all planes (iv) y-z all planes

Measurements of the z-FWHM of the reconstruction artefact associated with each ball are summarised in Table 8 for images of balls at heights of 12.5mm, 22.5mm and 32.5mm above the breast support table.

Table 8. z-FWHM measurements of 1mm diameter aluminium balls (mm)

	z-FWHM (range)
Planes	11.0 mm (10.5 to 11.3mm)

3.4 Alignment

Small high contrast objects (staples) positioned on the breast support table and attached to the underside of the compression paddle (when no compression was applied). The staples on the breast support and under the paddle were brought into focus within the reconstructed volume. With 100N compression applied and only the chest wall edge of the paddle supported, the staples under the compression paddle along the CWE of the paddle were in focus within the reconstructed volume.

There was no missed tissue at the bottom or top of the reconstructed volume. The maximum compressed breast thickness that can be imaged is 150mm, if the paddle is higher than this then the acquisition cannot be made.

The chest wall edge of the breast support was measured to be 4.5mm from the edge of the detector.

3.5 Image uniformity and repeatability

In tomosynthesis modes the AEC selected the same tube voltage and target filter combination for each of the 5 repeat exposures and the tubeload varied by up to 1%. For exposures repeated during the 4 days of evaluation the tubeload varied by a maximum of 1%, within the 5% limiting value in the EUREF protocol.[6]

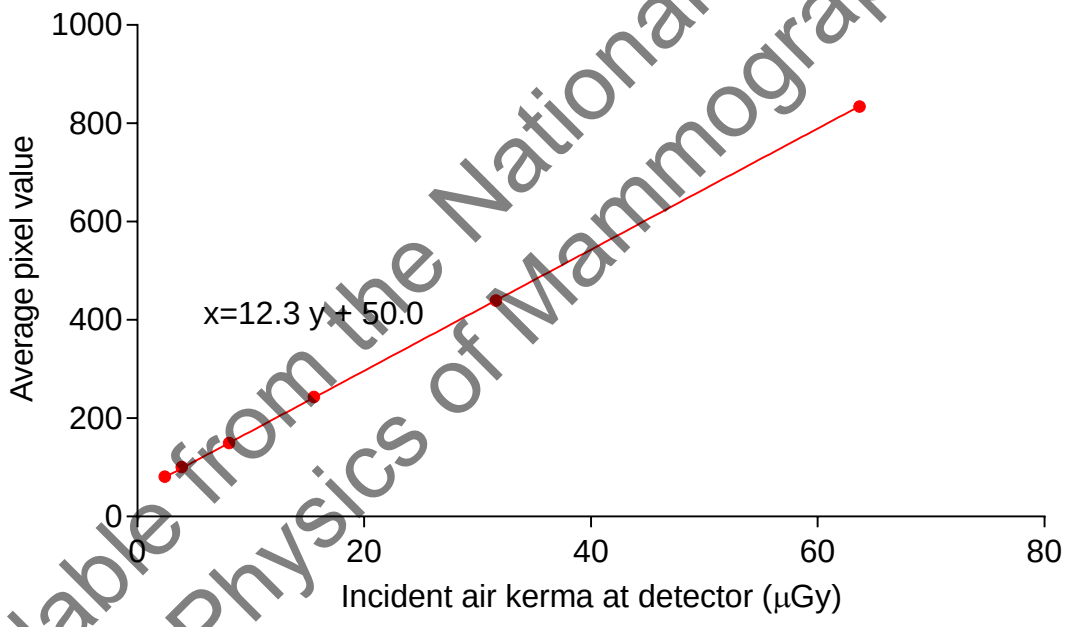
The repeatability of the tomosynthesis reconstruction was assessed by acquiring 5 images of 45mm thick PMMA images using AEC, the maximum deviation from the mean SNR was 1%.

The reconstructed images of plain PMMA were uniform with no visible artefacts.

3.6 Detector response

The detector response for the central projection of tomosynthesis images acquired at 31kV W/Al is shown in Figure 12.

Figure 12. Detector response in tomosynthesis mode for 31kV W/Al anode/filter combination with 2mm Al at the tube port



3.7 Timings

Scan times are shown in Table 9 for the Tomosynthesis combo imaging a 45mm thick stack of PMMA plates.

Table 9. Scan and reconstruction timings

	Tomosynthesis Combo (s)
Time from start of exposure until decompression	17s
Time from start of exposure until ready for next exposure	41s
Time from start of exposure until end of exposure	16s
Time from decompression until reconstructed image displayed (tomosynthesis only)	12s

3.8 Modulation Transfer Function

MTF results for the central projection images are shown in Figure 13. Results are shown in the 2 orthogonal directions parallel (u) and perpendicular (v) to the tube axis, at 0mm, 40mm and 70mm above the surface of the breast support table. These results are summarised in Table 10.

Figure 13. MTF for tomosynthesis central projections

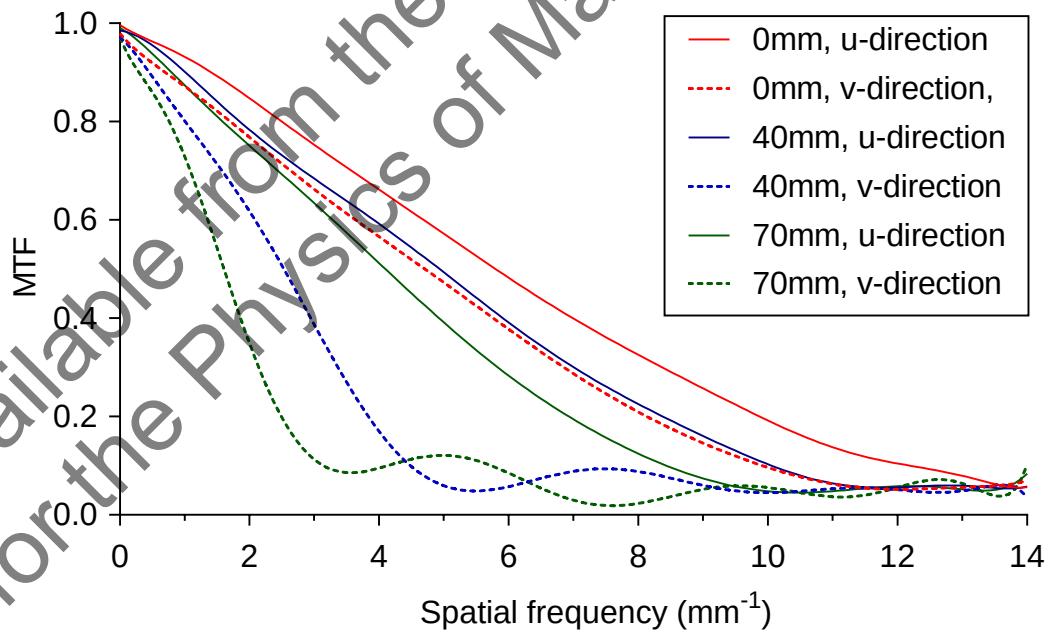


Table 10. MTF for tomosynthesis central projections in the directions parallel (u) and perpendicular (v) to the tube axis

Spatial frequency (mm^{-1})	0mm above table		40mm above table		70mm above table	
	u	v	u	v	u	v
0	1.00	1.00	1.00	1.00	1.00	1.00
1	0.93	0.87	0.90	0.80	0.87	0.73
2	0.85	0.77	0.78	0.62	0.75	0.35
3	0.75	0.66	0.68	0.39	0.63	0.11
4	0.66	0.57	0.59	0.17	0.51	0.10
5	0.57	0.47	0.49	0.06	0.39	0.12
6	0.48	0.38	0.39	0.06	0.28	0.08
7	0.40	0.29	0.30	0.09	0.19	0.03
8	0.33	0.21	0.23	0.09	0.12	0.02
9	0.26	0.15	0.16	0.06	0.07	0.05
10	0.19	0.10	0.10	0.05	0.05	0.06
11	0.14	0.06	0.06	0.05	0.05	0.04
12	0.10	0.05	0.06	0.05	0.06	0.06
13	0.08	0.06	0.06	0.05	0.05	0.06

The spatial frequencies of the 50% MTF (MTF50) are shown in Table 11.

Table 11. MTF50 for tomosynthesis central projection

	u-direction	v-direction
0mm	$5.8mm^{-1}$	$4.7mm^{-1}$
40mm	$4.9 mm^{-1}$	$2.5 mm^{-1}$
70mm	$4.1mm^{-1}$	$1.6mm^{-1}$

3.9 Local dense area

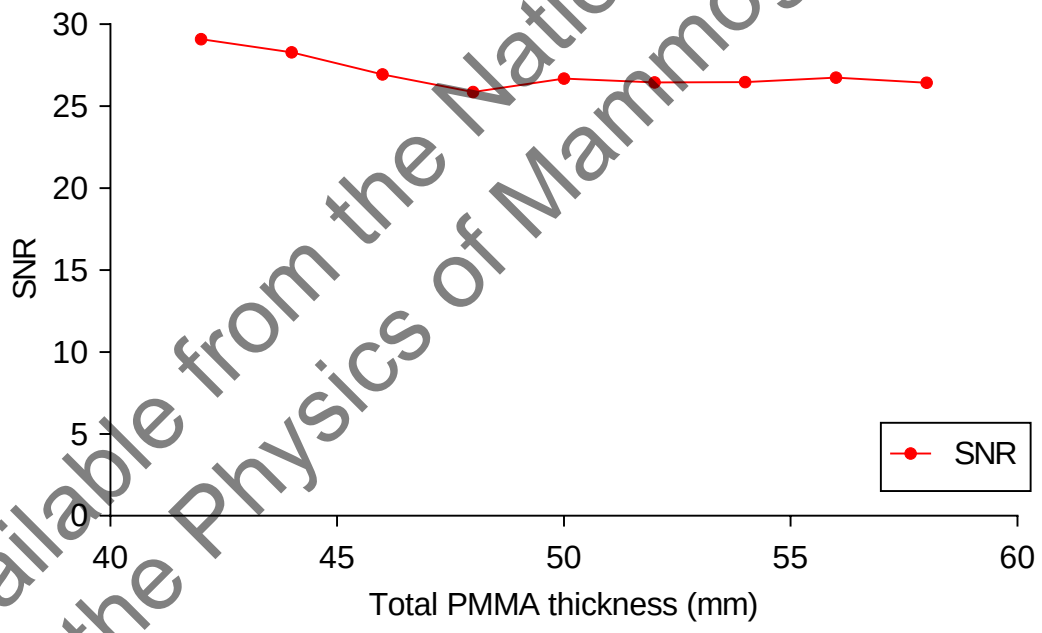
Exposures were found to vary with addition of the small pieces of PMMA, indicating that the AEC does adjust for local dense areas in tomosynthesis mode.

The test in the EUREF protocol[6] is based on an assumption that when the AEC adjusts for local dense areas, the SNR should remain constant with increasing thickness of extra PMMA. The results obtained are presented in Table 12 and Figure 14. The SNR differences from the mean SNR value are within the 20% tolerance.[6]

Table 12. AEC performance for local dense areas, 0mm from midline and 50mm from the chest wall edge

Total attenuation (mm PMMA)	kV	Target/ filter	Tube load (mAs)	SNR	% SNR difference from mean SNR result
32	31	W/Al	50	29.1	7.7%
34	31	W/Al	50	28.3	4.8%
36	31	W/Al	50	26.9	-0.2%
38	31	W/Al	50	25.9	-4.2%
40	31	W/Al	55	26.7	-1.2%
42	31	W/Al	56	26.5	-2.0%
44	31	W/Al	59	26.5	-1.9%
46	31	W/Al	62	26.8	-0.9%
48	31	W/Al	64	26.4	-2.1%

Figure 14. AEC performance in the projection images for local dense areas with extra PMMA at 50mm from the chest wall edge



3.10 Curved paddle

Table 13 shows the exposures factors for the curved and flat paddles for the same CBT and thicknesses of PMMA.

Table 13. Exposure factors and displayed MGD for simulated breasts using flat paddle (18cm x 24cm) and curved paddles (18cm x 24cm and 24cm x 29cm), exposures acquired using AEC

PMMA thickness (mm)	Displayed breast thickness (mm)	kV	Target/ filter	Flat 18cm x 24cm		Curved 18cm x 24cm		Curved 24cm x 29cm	
				mAs	MGD (mGy)	mAs	MGD (mGy)	mAs	MGD (mGy)
20	21	26	W/Al	41	1.03	42	1.02	41	1.01
30	32	28	W/Al	43	1.14	42	1.13	43	1.13
40	45	30	W/Al	50	1.44	50	1.44	50	1.44
45	53	31	W/Al	62	1.93	62	1.93	62	1.93
50	60	33	W/Al	63	2.35	63	2.34	63	2.35
60	75	36	W/Al	80	3.66	80	3.66	82	3.75
70	90	42	W/Al	74	4.89	74	4.89	74	4.89

4. Discussion

4.1 Dose and contrast-to-noise ratio

The tomosynthesis doses were within the dose limiting values set for tomosynthesis systems in the EUREF protocol[6] for the Standard and Low dose acquisition modes. The MGD for the Enhanced acquisition mode was above the dose limiting values for up to 75mm thick breasts. Enhanced mode must not be used for screening and only when justified for assessment.

CNR measurements showed an overall decrease with increasing breast thickness for the projections and reconstructed planes, as is usually expected.

4.2 Image quality

In the absence of any better test object for assessing tomosynthesis imaging performance, images of the CDMAM test object were acquired in tomosynthesis modes. At the dose close to that selected by the AEC, the threshold gold thicknesses for reconstructed focal planes is better than achievable level of image quality that is applied to 2D mammography for Standard, Low dose and Enhanced acquisition modes. These results are given for focal plane number 21, which gave the best results. For double and half the AEC selected dose, the threshold gold thickness changed as expected.

These results take no account of the ability of tomosynthesis to remove the obscuring effects of overlying tissue in a clinical image, and the degree of this effect is expected to vary between tomosynthesis systems. There is as yet no standard test object that would allow a realistic and quantitative comparison of tomosynthesis image quality between systems or between 2D and tomosynthesis modes. A suitable test object would need to incorporate simulated breast tissue to show the benefit of removing overlying breast structure in tomosynthesis imaging, as compared to 2D imaging.

4.3 Geometric distortion and reconstruction artefacts

Assessment of geometric distortion demonstrated that the reconstructed tomosynthesis focal planes were flat and parallel to the surface of the breast support table. No vertical or in-plane distortion was seen and there were no significant scaling errors.

The reconstructed tomosynthesis volume was found to start about 1mm below the surface of the breast support table and continue 5mm above the nominal height of the compression paddle. This is useful in that it allows for a small margin of error in the calibration of the indicated thickness or some slight tilt of the compression paddle, without missing tissue at the bottom or top of the reconstructed image.

The mean inter-plane resolution (z-FWHM) for the 1mm diameter balls was 11.0mm.

4.4 Alignment

The alignment of the X-ray beam to the reconstructed image was satisfactory.

There was no missed tissue at the bottom or top of reconstructed tomosynthesis images.

4.5 Image uniformity and repeatability

The repeatability of tomosynthesis AEC exposures and the repeatability of tomosynthesis reconstructions were satisfactory.

4.6 Modulation transfer function

There are large differences in the MTFs between the 2 orthogonal directions, especially at 40mm and 70mm above the breast support. The system acquires images while the x-ray tube is moving. This causes the y-direction (direction of tube motion) in the image to have a lower MTF.

4.7 Local dense area

The Hologic 3Dimensions undertakes a low dose pre-exposure to set the radiographic factors. The system detects the dense areas in the image and adjusts the radiographic factors accordingly. This system passes the tolerance for change in SNR as set in the EUREF protocol[6].

4.8 Curved paddle

The exposures factors selected by the system for the curved and flat paddles for the same CBT and thicknesses of PMMA were closely matched. The system also displayed the same MGD, although it should be noted that the breast model used for calculating MGD is based on the use of a flat paddle.

5. Conclusions

The technical performance of the Hologic 3Dimensions digital breast tomosynthesis system, was found to be satisfactory, although image quality standards have not yet been established for digital breast tomosynthesis systems.

The MGD to the 53mm thick standard breast in tomosynthesis mode was found to be 1.96mGy. This is within the dose limiting value of 2.5mGy for tomosynthesis.[6]

References

1. Strudley CJ, Looney P, Young KC. Technical evaluation of Hologic Selenia Dimensions digital breast tomosynthesis system (NHSBSP Equipment Report 1307 Version 2). Sheffield: NHS Cancer Screening Programmes, 2014

2. Strudley CJ, Warren LM, Young KC. Technical evaluation of Siemens Mammomat Inspiration digital breast tomosynthesis system (NHSBSP Equipment Report 1306 Version 2). Sheffield: NHS Cancer Screening Programmes, 2015

3. Strudley CJ, Oduko JM, Young KC. Technical evaluation of GE Healthcare SenoClaire digital breast tomosynthesis system (NHSBSP Equipment Report 1404). London: Public Health England, 2016

4. Strudley CJ, Hadjipanteli A, Oduko JM, Young KC. Technical evaluation of Fujifilm AMULET Innovality digital breast tomosynthesis system (NHSBSP Equipment Report). London: Public Health England, 2018

5. Burch A, Loader R, Rowberry B et al. Routine quality control tests for breast tomosynthesis (physicists) (NHSBSP Equipment Report 1407). London: Public Health England, 2015

6. van Engen RE, Bosmans H, Bouwman RW et al. Protocol for the Quality Control of the Physical and Technical Aspects of Digital Breast Tomosynthesis Systems. Version 1.03. www.euref.org 2018

7. Dance DR, Young KC, van Engen RE. Estimation of mean glandular dose for breast tomosynthesis: factors for use with the UK, European and IAEA breast dosimetry protocols. Physics in Medicine and Biology, 2011, 56, 453-471.