Public Health England

NHS

NHS Breast Screening Programme Equipment Report

Technical evaluation of Hologic Affirm prone biopsy system

March 2019

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Executive summary

The aim of the evaluation was to assess the performance of the Hologic Affirm prone biopsy system, and to provide baseline performance data, in 2D and tomosynthesis modes.

For a 53mm equivalent breast the mean glandular dose was 1.96mGy for 2D imaging and 1.76mGy for tomosynthesis, both within the dose limits for 2D mammography. Image quality was better than the achievable level, for small details up to 0.16mm in size. The contrast-to-noise ratio was better than achievable, for all breast thicknesses.

The Hologic Affirm prone biopsy system met the NHSBSP performance standards, except for visibility of the finest low-contrast lines on a 2 megapixel monitor.

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). The testing methods and standards applied are those of the relevant NHSBSP protocols, which are published as NHSBSP Equipment Reports. Report 0604[1] includes tests for full field digital mammography systems used for 2D imaging and Report 1407[2] includes tests for digital breast tomosynthesis.

NHSBSP protocols are similar to European protocols,[3,4,5] but the latter also provide additional or more detailed tests and standards, some of which are included in this evaluation.

Additional tests were also carried out according to the UK recommendations for testing mammography X-ray equipment as described in IPEM Report 89.[6]

1.2 Objectives

The aims of the evaluation were:

- to compare the 2D image quality of the Hologic Affirm prone biopsy system with the NHSBSP achievable standard and with the Hologic Selenia Dimensions full field digital mammography system
- to provide performance data for 2D and tomosynthesis modes, for comparison against other systems

2. Methods

2.1 System tested

The tests were conducted at Hologic premises in Brussels, on a Hologic Affirm prone biopsy system as described in Table 1. This system allows use of tomosynthesis or 2D imaging for lesion localisation. The system is shown in Figure 1.

Table 1. System description

Manufacturer	Hologic
Model	Affirm prone biopsy
Target material	Tungsten (W)
Added filtration	50µm silver (Ag) (2D), 720µm aluminium (Al) (tomosynthesis)
Detector type	Amorphous selenium
Detector serial number	YM300046
Detector pixel size	70µm
Image size	117mm × 143mm
2D image pixel size	59.3µm stated in image header implying a reference plane 22mm above breast support
Pixel array	1664 × 2048
Pixel value relationship to dose	Linear with a pixel value offset of +50
Source to detector distance	800mm
Source to table distance	700mm
Software version	1.0.1.61
Tomosynthesis projections	Number of projections: 30 Angular range: 15˚ Pixels unbinned
Reconstructed focal planes	Vertical intervals: 1mm Number of planes: Compressed breast thickness in mm + 6
Tomosynthesis image format	BTO (compressed), SC
Exposure control	Automatic exposure control (AEC) or manual
Determination of exposure	Pre-exposure (included in total mAs, excluded from image): 2D: 5mAs; 10mAs for thickness >50mm Tomosynthesis: 5mAs for all thicknesses
Image display	2MP (megapixel) monitor (3MP also available)

At the time of testing the system it was not possible to download tomosynthesis images in the uncompressed BTO format, nor in CT format. Images were therefore downloaded in the

Hologic proprietary SC format and a Hologic expansion tool was used to extract the tomosynthesis focal planes and projection images.

Figure 1. The Hologic Affirm prone biopsy system

2.2 Dose and contrast-to-noise ratio under AEC

2.2.1 Measurement of output and half value layer (HVL)

Measurements were made of output and HVL across the clinically relevant range of kV and filter combinations for the purpose of calculating mean glandular dose (MGD) to the standard breast. Tomosynthesis output and HVL measurements were made using the ‘zero degree tomo’ facility, which enables a pulsed tomosynthesis exposures without tube movement. Measurements were made with the paddle in place, raised well away from the ion chamber.

2.2.2 Mean glandular dose

Exposures were made under AEC of a range of thicknesses of polymethyl methacrylate (PMMA) blocks. The compressed breast thickness was set (with an airgap) so that the indicated thickness was the same as the equivalent breast for each thickness of PMMA.

An aluminium square, was included in the PMMA blocks, so that both MGD and contrast-to-noise ratio (CNR) could be calculated.

MGDs to the standard breast model were calculated using the recorded AEC exposure factors for a range of simulated breast thicknesses in 2D and tomosynthesis modes, as described in the NHSBSP protocols. Calculation of MGD in tomosynthesis mode is similar to that in 2D mode, but with the inclusion of a tomosynthesis factor, T. For this evaluation the value of T was taken to be the same as that for a Hologic Dimensions system, which employs the same angular range but fewer projections than the Affirm prone biopsy system.

2.2.3 Contrast-to-noise ratio

Images acquired during dose measurements were used to measure CNR. The aluminium square (10mm x 10mm and 0.2mm thick) was positioned at a distance of 10mm from the breast support table, on the midline of the detector, with its centre 60mm from the chest wall edge.

For CNR in 2D mode the unprocessed images were used. In tomosynthesis mode images were acquired in a clinical mode ('LCC tomo scout'), in addition to quality control (QC) mode, ('Flatfield tomo'). In tomosynthesis mode, CNR was measured in the focal plane corresponding to the height of the aluminium from the table.

The 2D images had a significant pixel gradient in the direction perpendicular to the chest wall edge. To minimise the effect of this on the CNR measurement the background regions of interest (ROI) were positioned laterally to the aluminium square. The reconstructed focal planes were more uniform so the ROI were positioned differently, to avoid potential reconstruction artefacts. The locations of the ROIs are shown in Figure 2.

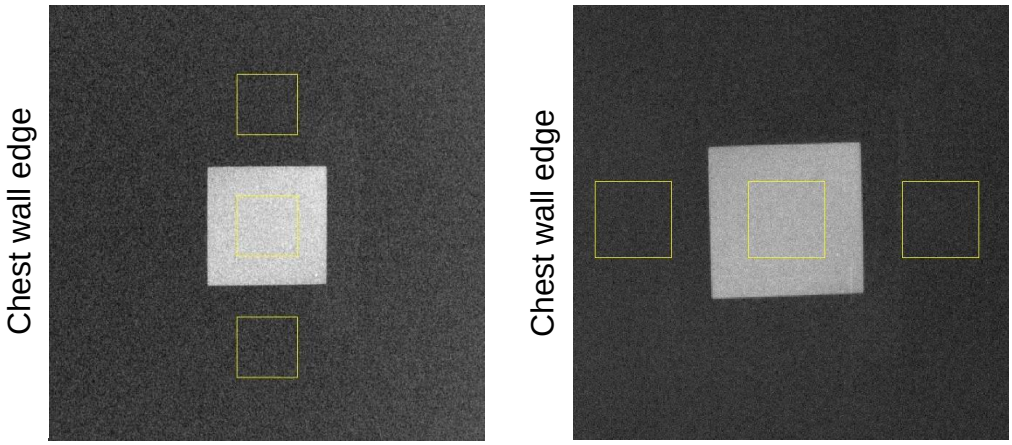


Figure 2. Location and size of ROI used to determine the CNR in 2D images (left) and tomosynthesis focal planes (right).

2.3 Image quality measurements

Contrast detail detection measurements were made using a CDMAM phantom (serial number 1897, version 3.4, Artinis, Netherlands) sandwiched between two 20mm thick slabs of PMMA.

As the CDMAM is larger than the detector, the CDMAM was positioned on the breast support table so that the smaller diameter details were included in the image.

Sets of partial CDMAM images were acquired in 2D mode and in tomosynthesis mode using both the QC 'Flatfield Tomo' and the clinical reconstructions. The kV and mAs were chosen to match as closely as possible those selected by the AEC when imaging a simulated 60mm equivalent breast. Tomosynthesis focal planes were extracted from the reconstructed images and assessed in the same way as 2D images. Assessment was made of the focal plane where the CDMAM appeared to be in focus and also the 2 adjacent focal planes. Results were quoted for focal plane 22 which gave the better threshold gold thickness results.

The usual automatic method of reading CDMAM images, CDCOM version 1.6 (www.euref.org), and CDMAM Analysis version 2.1 (www.nccpm.org) cannot be used to read partial CDMAM images. Instead, ReadCD, developed for the task of automatically reading of partial CDMAMs was used. Like CDCOM, this software searches for the position of the corner detail within each cell and then searches for a second time in the 3 remaining corners and central region to locate the centre detail. For each set of images mean detection probabilities were obtained for gold discs of diameter 0.1mm to 0.25mm.

For each diameter, a threshold gold thickness (62.5% detection probability) was deduced by linear interpolation. For comparison, a set of full CDMAM images acquired under AEC on a Hologic Selenia Dimensions were read using ReadCD across the same limited range of diameters. This set of images was also read in full using the usual automated software. The search radius and diameter of the search ROI used by ReadCD were adjusted to achieve results similar to CDCOM for the set of full 2D CDMAM images from the Dimensions system.

The correction factors used by CDMAM Analysis software were applied to the ReadCD results to predict approximate human results.

2.4 Geometric distortion and reconstruction artefacts

An assessment was made of the relationship between reconstructed tomosynthesis focal planes and the physical geometry of the volume that they represent. A geometric test tool, containing a rectangular array of 1mm diameter aluminium balls at 50mm intervals, was positioned at distances of 7.5mm, 27.5mm and 52.5mm within a 60mm stack of PMMA positioned at the breast support table. Tomosynthesis images were acquired for each configuration using both 'Flatfield tomo' and 'LCC tomo scout' views.

Reconstructed tomosynthesis planes were analysed to find the position 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.

This analysis was carried out using Tomosynthesis QCTools software (www.nccpm.org). This software is in the form of a plug-in for use in conjunction with ImageJ (rsb.info.nih.gov/ij). Details of the analysis are given in the UK tomosynthesis protocol.[2]

2.5 Alignment

The Affirm prone biopsy system has no light field to indicate the extent of the radiation field. Measurements were made to check the alignment of the radiation field to the image.

Missed tissue was assessed at the chest wall edge in 2D and tomosynthesis modes. In addition, missed tissue was assessed at the top and bottom of the reconstructed tomosynthesis volume.

2.6 Repeatability

To test the repeatability of exposures under AEC, 5 sequential images of a uniform block of 45mm thick PMMA, covering the entire detector, were acquired under AEC in 2D and tomosynthesis modes. An additional image was acquired in the same way on the next day. Exposure factors were recorded.

To test the repeatability of the reconstructed tomosynthesis image, the mean pixel value and SNR were measured in the central area of the focal plane representing a position 20mm away from the breast support of 4 ‘Flatfield tomo’ images. In addition a similar measurement was made in focal planes from 8 reconstructed images of the CDMAM test object.

2.7 Image uniformity

2D and tomosynthesis images of 45mm PMMA were assessed for uniformity, using the method described in the NHSBSP protocol.

2.8 Detector response

The detector response was measured as described in the NHSBSP protocol, but with a 2mm aluminium filter at the tube head. Measurements were made using a typical tube voltage of 28kV. The same method was followed to measure the detector response in tomosynthesis mode using a tube voltage of 29kV. Analysis was carried out using the central tomosynthesis projection images.

2.9 Modulation transfer function

The presampled modulation transfer function (MTF) was measured in both 2D mode and tomosynthesis projections, with the test tool placed in contact with the breast support table and with a 2mm aluminium filter in the beam, close to the tube head. The beam quality used for the 2D exposures was 28kV W/Ag, the same as that selected by the AEC for a 53mm thick simulated breast. In tomosynthesis mode the beam quality used for a 90mm simulated breast was used, 38kV W/Al. A 10th order polynomial fit was applied to the MTF results.

2.10 Image display

The 2MP monitor supplied with the Affirm prone biopsy system, for use during the lesion localisation process, was tested according to the UK protocol[1].

2.11 Other tests

Other tests, that would normally form part of a commissioning survey on new equipment, were carried out. These included tests prescribed in IPEM Report 89[4] for mammographic X-ray sets, as well as those in the NHSBSP protocol[1]. The accuracy of indicated compressed breast thickness, compression force, image retention and timings were measured.

Stereotactic accuracy was not tested (as no needles were available) but the Hologic engineers demonstrated their alignment test procedure. In normal working conditions, stereotactic testing is required to ensure clinical accuracy.

3. Results

3.1 Dose and contrast-to-noise ratio under AEC

3.1.1 Output and half value layer

The output and HVL measurements in 2D and tomosynthesis modes are shown in Tables 2 and 3.

Table 2. Output and HVL (2D)

kV	Target/filter	Output (µGy/mAs at 1m)	HVL (mm Al)
25	W/Ag	9.4	0.52
28	W/Ag	13.6	0.57
31	W/Ag	17.7	0.62
34	W/Ag	21.7	0.65
37	W/Ag	25.7	0.68

Table 3. Output and HVL (tomosynthesis)

kV	Target/filter	Output (µGy/mAs at 1m)	HVL (mm Al)
25	W/Al	17.1	0.44
28	W/Al	25.2	0.50
31	W/Al	33.8	0.56
34	W/Al	42.8	0.62
37	W/Al	52.4	0.67
40	W/Al	62.3	0.72

3.1.2 Mean glandular dose

MGDs for exposures under AEC in 2D and tomosynthesis modes are shown in Figure 3 and in Tables 4 and 5. The MGDs include the preliminary exposure which is not included in the image.

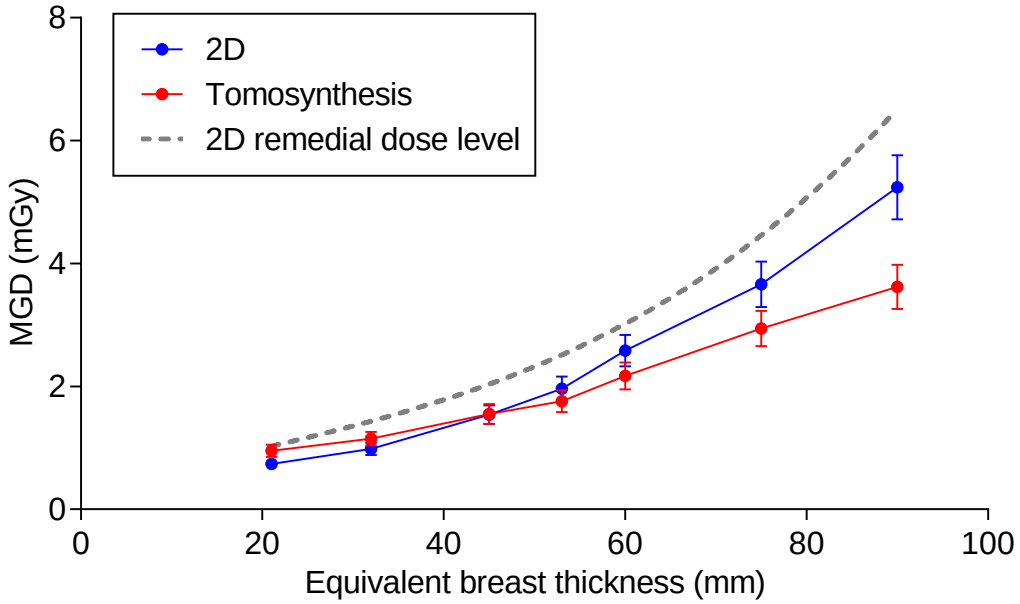


Figure 3. Mean glandular dose to equivalent breasts, simulated using PMMA. Error bars indicate 95% confidence limits.

Table 4. MGD for 2D images acquired under AEC

PMMA thickness (mm)	Equivalent breast thickness (mm)	kV	Target/ filter	mAs	MGD (mGy)	NHSBSP 2D remedial dose level (mGy)
20	21	25	W/Ag	72	0.74	1.0
30	32	26	W/Ag	100	0.98	1.5
40	45	28	W/Ag	142	1.54	2.0
45	53	28	W/Ag	197	1.96	2.5
50	60	30	W/Ag	218	2.58	3.0
60	75	33	W/Ag	265	3.66	4.5
70	90	36	W/Ag	343	5.24	6.5

Table 5. MGD for tomosynthesis images acquired under AEC

PMMA thickness (mm)	Equivalent breast thickness (mm)	kV	Target/ filter	mAs	MGD (mGy)	European reference dose level(mGy)
20	21	26	W/Al	47	0.95	1.0
30	32	26	W/Al	72	1.15	1.5
40	45	28	W/Al	84	1.55	2.0
45	53	29	W/Al	90	1.76	2.5
50	60	31	W/Al	90	2.17	3.0
60	75	34	W/Al	96	2.94	4.5
70	90	38	W/Al	94	3.62	6.5

3.1.3 Contrast-to-noise ratio

CNRs for 2D images acquired under AEC are shown in Figure 4 and in Table 6. Also shown are the target CNRs for the acceptable and achievable levels of image quality and the European limiting values, calculated according to the European protocol.

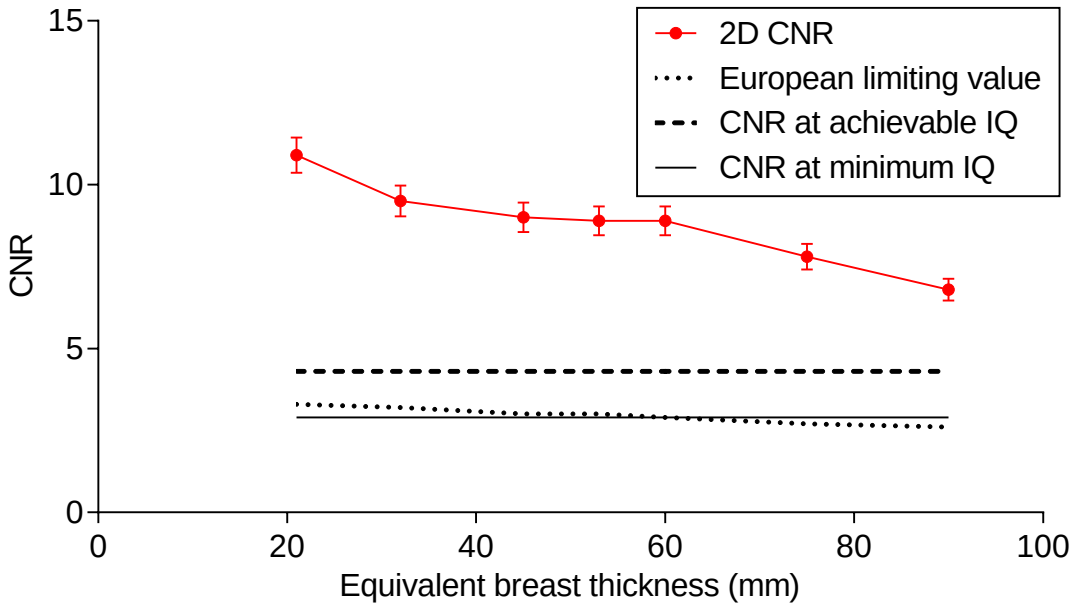


Figure 4. CNR for 2D images acquired under AEC. Error bars indicate 95% confidence limits.

Table 6. CNR for 2D images acquired under AEC

PMMA thickness (mm)	Equivalent breast thickness (mm)	kV	Target/ filter	mAs	CNR	Target for minimum standard	Target for achievable standard	European limiting value
20	21	25	W/Ag	72	10.9	2.9	4.3	3.3
30	32	26	W/Ag	100	9.5	2.9	4.3	3.2
40	45	28	W/Ag	142	9.0	2.9	4.3	3.0
45	53	28	W/Ag	197	8.9	2.9	4.3	3.0
50	60	30	W/Ag	218	8.9	2.9	4.3	2.9
60	75	33	W/Ag	265	7.8	2.9	4.3	2.7
70	90	36	W/Ag	343	6.8	2.9	4.3	2.6

CNRs in the focal planes of reconstructed tomosynthesis images acquired under AEC are shown in Figure 5 and in Table 7.

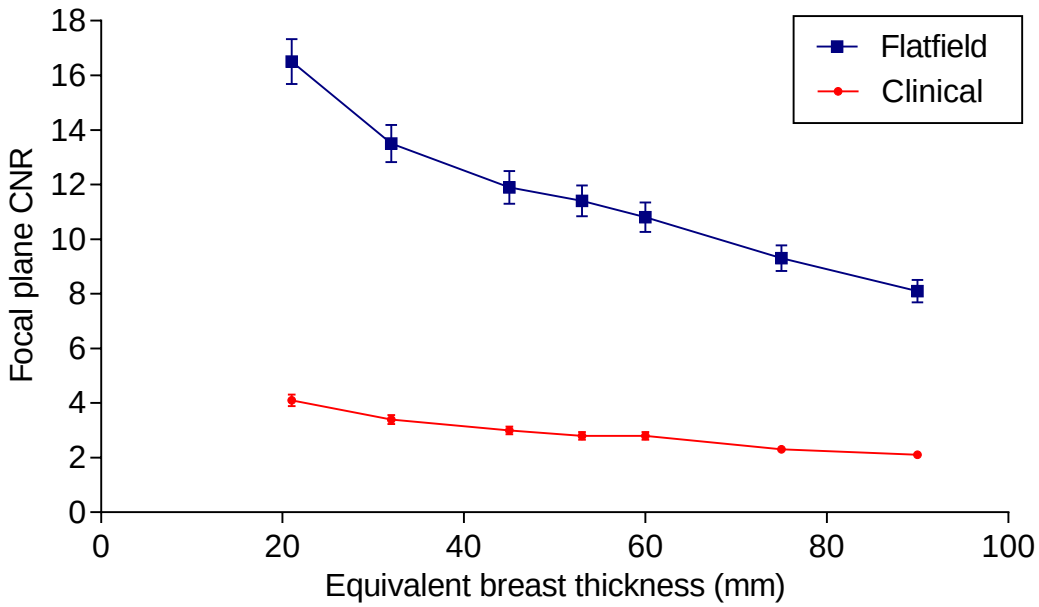


Figure 5. CNR in tomosynthesis focal planes, images acquired under AEC. Error bars indicate 95% confidence limits.

Table 7. CNR for tomosynthesis focal planes, images acquired under AEC

PMMA thickness (mm)	Equivalent breast thickness (mm)	kV	Target/ filter	mAs	CNR (flatfield)	CNR (clinical)
20	21	26	W/Al	47	16.5	4.1
30	32	26	W/Al	72	13.5	3.4
40	45	28	W/Al	84	11.9	3.0
45	53	29	W/Al	90	11.4	2.8
50	60	31	W/Al	90	10.8	2.8
60	75	34	W/Al	96	9.3	2.3
70	90	38	W/Al	94	8.1	2.1

CNR measurements were also made in the tomosynthesis projection images. Figure 6 shows the variation of CNR with projection angle for a 53mm thick equivalent breast. Figure 7 shows the variation of the central projection CNR with equivalent breast thickness.

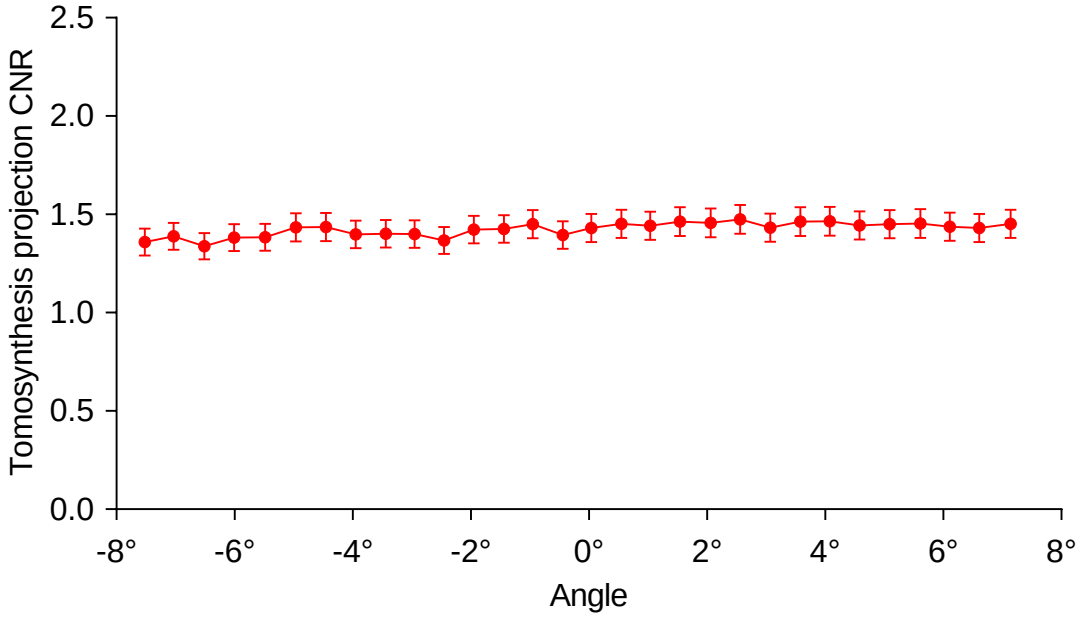


Figure 6. Variation of CNR with projection angle for a 53mm equivalent breast. Error bars indicate 95% confidence limits.

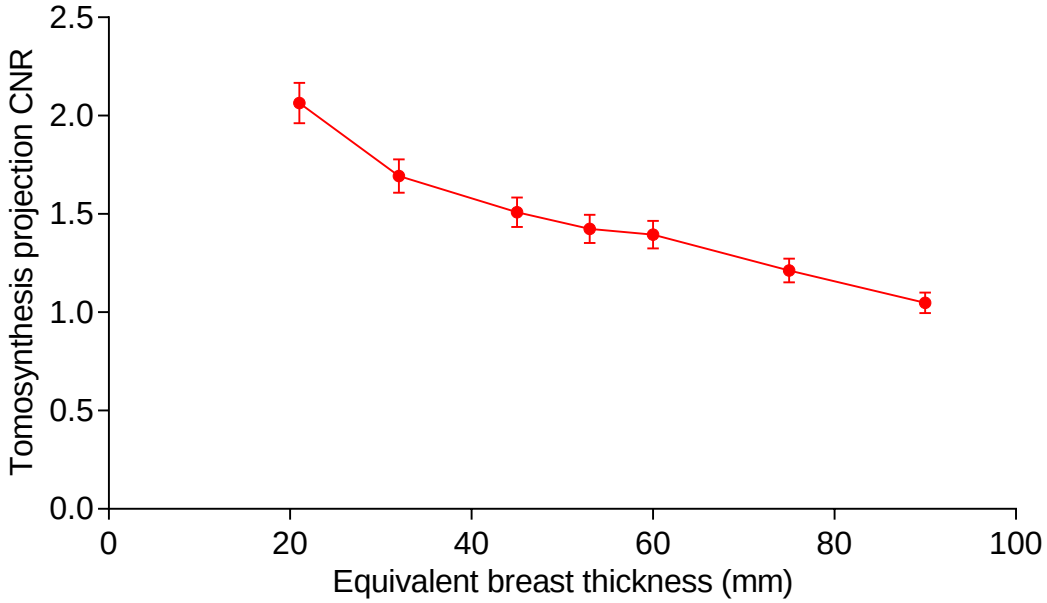


Figure 7. Variation of CNR in the central projection with equivalent breast thickness. Error bars indicate 95% confidence limits.

3.2 Image quality measurements

Details of the CDMAM images acquired in 2D and tomosynthesis modes are summarised in Table 8. The images acquired under AEC from a Hologic Dimensions system are presented for comparison.

Table 8. Details of CDMAM images

	kV	Target/ filter	mAs	MGD (mGy)	Number of images
Affirm 2D	30	W/Ag	220	2.60	16
Dimensions 2D	31	W/Rh	124	1.74	16
Affirm 'Flatfield tomo'	31	W/Al	90	2.17	8
Affirm 'LCC tomo scout'	31	W/Al	90	2.17	8

The predicted human threshold gold thicknesses for the Affirm 2D images, and for partial and full readings of the Dimensions images, are shown in Table 9. Figure 8 shows results from partial and full readings of the Dimensions images and Figure 9 shows the Affirm results compared to the results from partial readings of images from the Dimensions system. Errors shown represent the 95% confidence limits for CDMAM Analysis results. Confidence limits have not been determined for reading partial CDMAM images with ReadCD.

Table 9. Predicted human threshold gold thickness (µm), 2D images

Detail diameter (mm)	ReadCD		CDCOM	NHSBSP standards	
	Affirm	Dimensions	Dimensions	Acceptable	Achievable
0.1	0.58	0.66	0.63 ± 0.10	1.68	1.10
0.13	0.39	0.46	0.39 ± 0.07		
0.16	0.29	0.33	0.32 ± 0.05		
0.20	-*	0.28	0.26 ± 0.04		

*The partial CDMAM image did not include the complete row of gold discs of diameter 0.2mm.

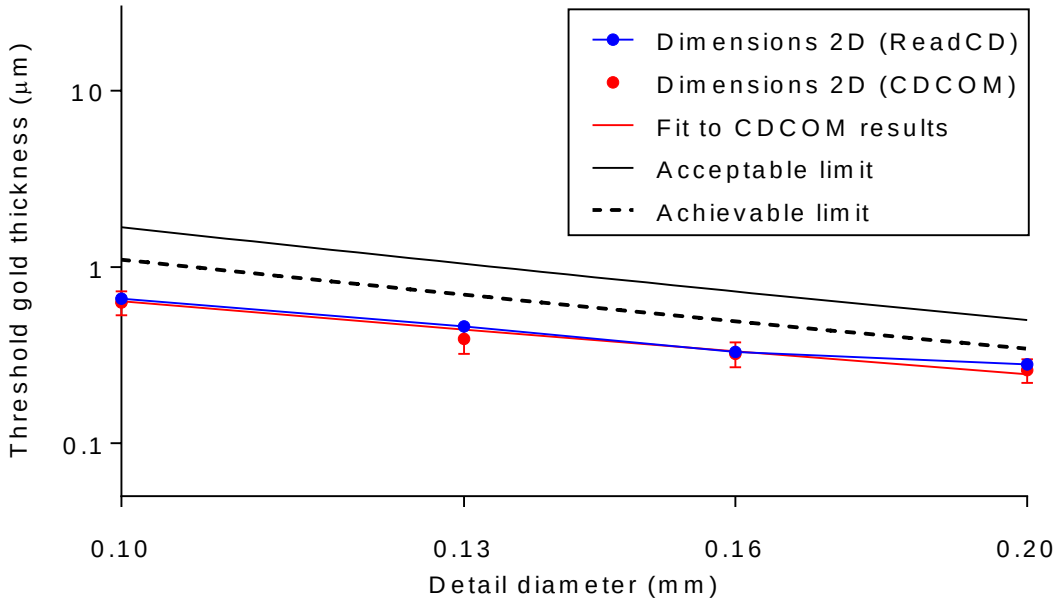


Figure 8. Predicted human threshold gold thickness results for small diameter details in 2D images from a Dimensions system, obtained using ReadCD and CDCOM

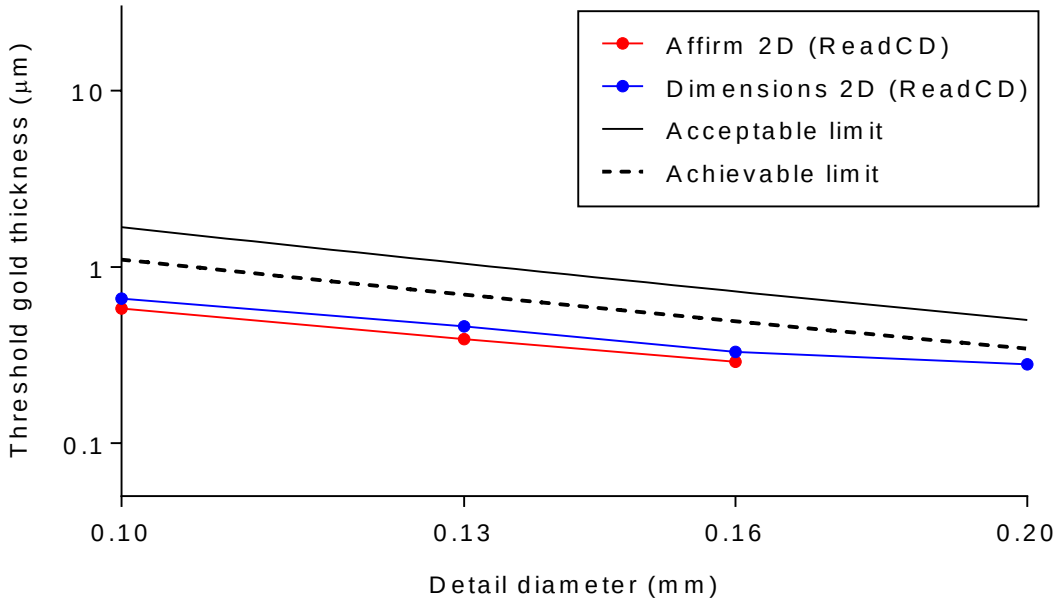


Figure 9. Predicted human threshold gold thickness results for 2D images from the Affirm and Dimensions systems, obtained using ReadCD

Threshold gold thicknesses for focal plane 22 from the QC 'flatfield tomo' and clinical 'LCC tomo scout' reconstructions are shown in Table 10 and Figure 10.

Table 10. Tomosynthesis predicted human threshold gold thickness (µm) for focal plane 22

Detail diameter (mm)	QC 'Flatfield tomo'	Clinical 'LCC tomo scout'
0.1	0.60	0.59
0.13	0.40	0.42
0.16	0.36	0.30
0.20	0.33	-

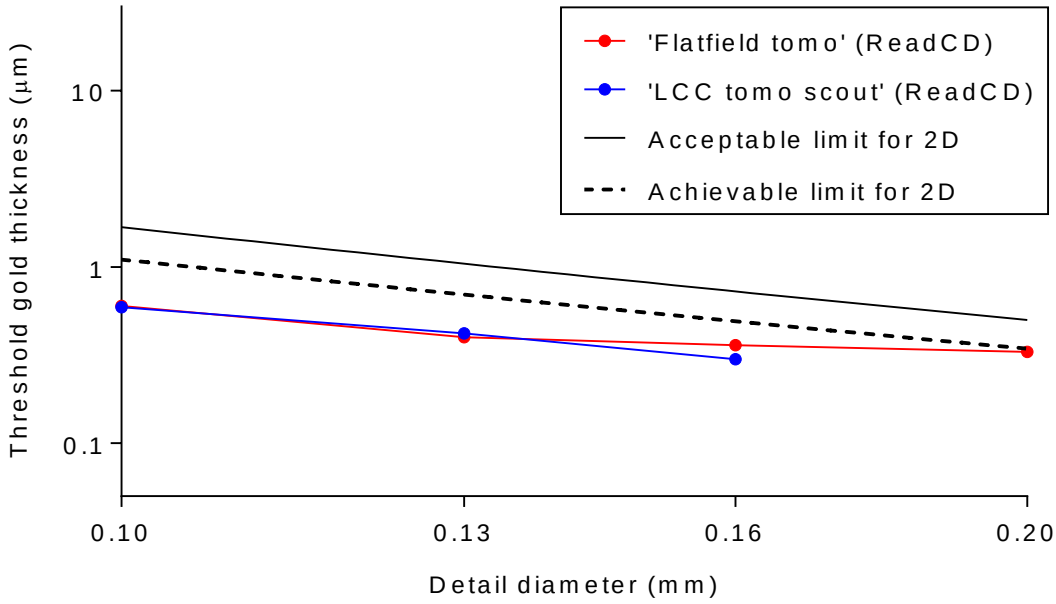


Figure 10. Predicted human threshold gold thicknesses for focal plane 22

3.3 Geometric distortion and reconstruction artefacts

3.3.1 Height of best focus

All balls within each image were brought into focus at the same distance (± 0.5mm) from the breast support, and within 1mm of the expected distance, with the first focal plane representing the surface of the breast table. These results indicate that focal planes are flat and parallel to the surface of the breast support, with no noticeable distortion in the z-direction. The number of focal planes reconstructed is equal to the indicated breast thickness in mm plus 6, indicating that an additional 5 planes are reconstructed above the base of the compression paddle.

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 1%. Maximum deviation from the average distance between the balls in the x or y direction was 0.16mm, compared to the manufacturing tolerance of 0.1mm in the positioning of each ball.

3.3.3 Appearance of 1mm aluminium balls in reconstructed focal planes

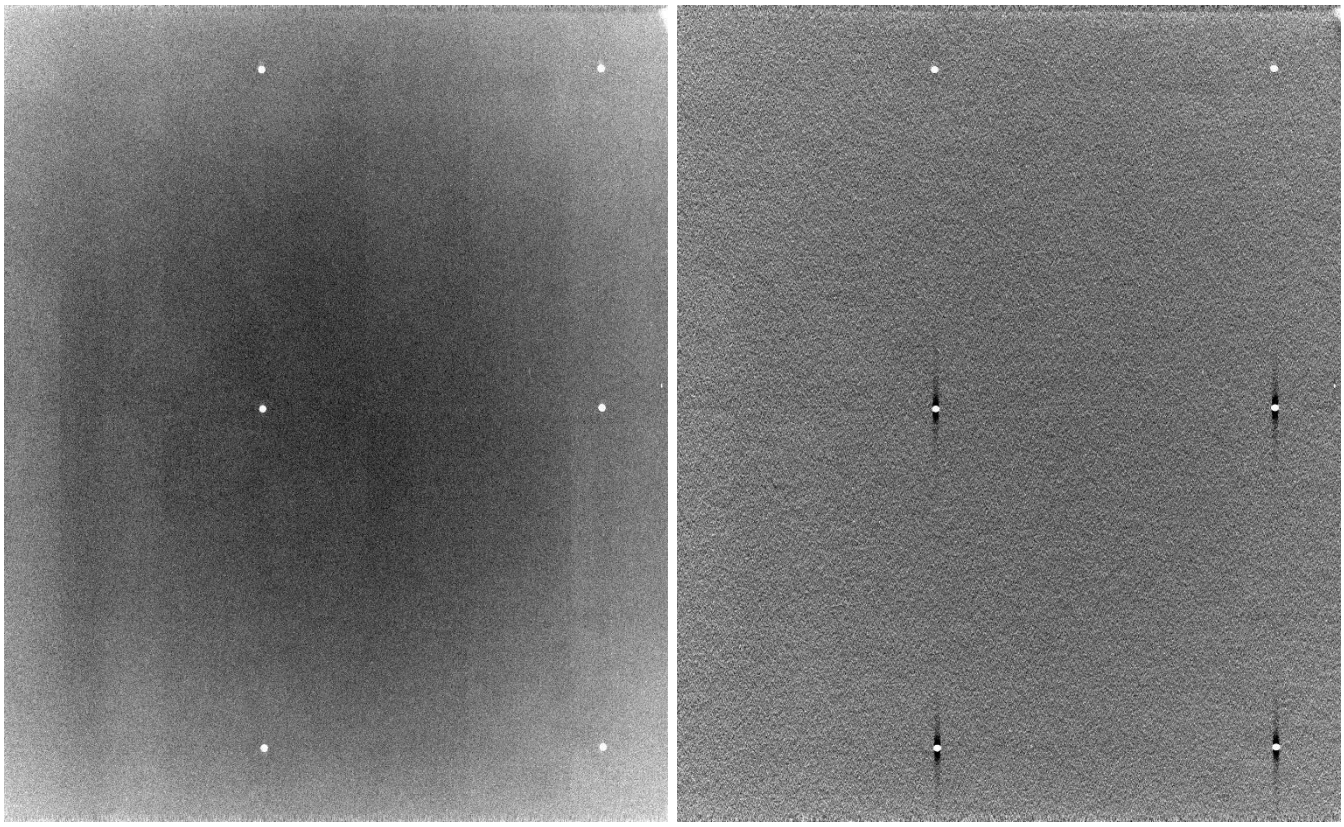


Figure 11. Appearance in focal plane of best focus of 1mm aluminium ball in 60mm PMMA. QC 'Flatfield tomo' view is on the left, and clinical 'LCC tomo scout' view on the right. The chest wall edge is to the left of each image

In the plane of best focus the aluminium balls appeared well defined and circular. Figure 11 shows the appearance of the balls in the QC and clinical views: In the QC 'Flatfield tomo' view the background is less uniform. In the clinical 'LCC tomo scout' view a shadow (reduced pixel value) extends laterally from the images of the balls in the direction of tube motion, except in the case of the 2 balls toward the left lateral edge (at the top in Figure 9). 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 one of the aluminium balls through successive focal planes is shown in Figure 12.

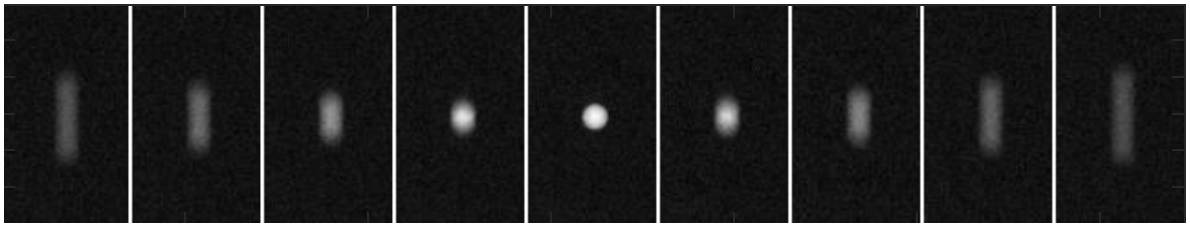
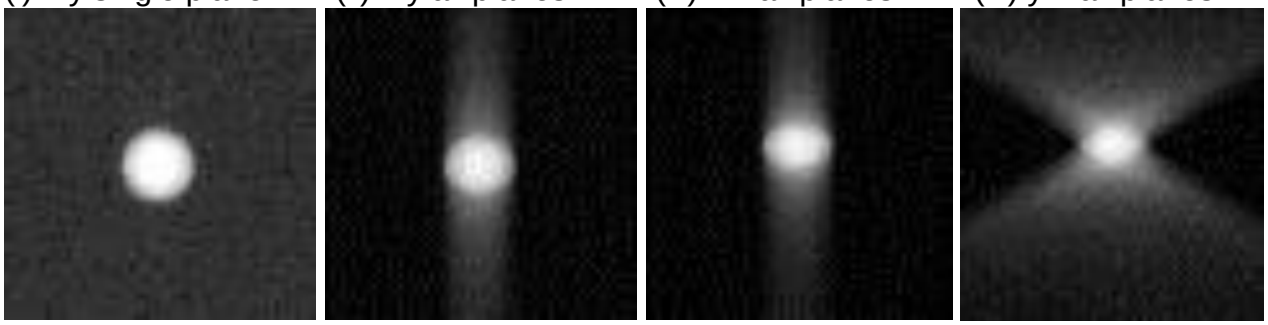


Figure 12. Appearance of a 1mm aluminium ball in reconstructed focal planes at 3mm intervals extending 12mm either side of the plane of best focus using QC 'Flatfield tomo' view

Using DICOM viewer software, it is possible to treat the stack of focal planes as though it were a true three-dimensional volume and re-slice it vertically to produce planes in the x-z and y-z orientations. The appearance of the ball and associated artefacts in all slices can be visualised in 2 dimensions by creating a maximum intensity projection through the re-sliced volumes. Image extracts for a ball positioned in the central area, approximately 40mm from the chest wall, are shown in Figure 13. In these images the z-dimension is not to scale relative to the x and y dimensions. Pixels within the focal plane represent dimensions of approximately 0.07mm x 0.07mm whereas the z-dimension of each pixel represents the 1mm spacing of the focal planes. Representation of the x-z and y-z planes using square pixels gives an apparent flattening of the balls, whereas in reality reconstruction artefacts associated with these balls extend in the z-direction by a distance exceeding their diameter by more than 10.

'Flatfield tomo':

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



'LCC tomo scout':

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

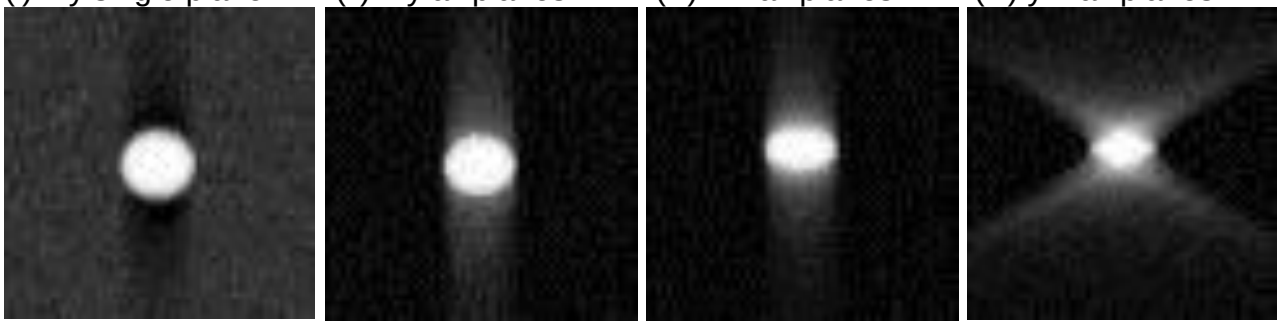


Figure 13. Extracts from 'Flatfield tomo' (top row) and 'LCC tomo scout' (bottom row) views showing 1mm aluminium ball in (i) single focal plane, (ii) the maximum intensity projections through all focal planes, and through re-sliced vertical planes in the directions (iii) parallel and (iv) perpendicular to the chest wall.

Table 11 shows the z-FWHM measurements for balls at distances of 27.5mm and 52.5mm from the breast support. It was not possible to make accurate z-FWHM measurements at a distance of 7.5mm as these were too close to the limit of the reconstructed volume.

Table 11. z-FWHM measurements of 1mm diameter aluminium balls (mm)

	z-FWHM (range)
'Flatfield tomo'	12.8 (12.3 to 13.5)
'LCC tomo scout'	12.1 (11.0 to 14.0)

3.4 Alignment

The x-ray field extended by no more than the NHSBSP limit of 5mm beyond the edges of 2D images or of the first focal plane in tomosynthesis images.

The missed tissue at the chest wall edge was 2mm in 2D images and in reconstructed focal planes.

No tissue was missed at the bottom or top of the reconstructed tomosynthesis volumes (ie in the z-direction).

3.5 Repeatability

Five exposures were made under AEC, in 2D and tomosynthesis modes, at the start of testing and a repeat exposure was made in each mode on the second day of testing.

The mAs deviated from the mean value by a maximum of 0.9% for 2D exposures and 0.0% for tomosynthesis exposures.

To test the stability of the reconstruction the mean pixel value and SNR were measured in 4 'Flatfield tomo' images. Measurements were made in the central area of focal planes 20mm from the breast support. A similar measurement was made in focal planes from 8 reconstructed images of the CDMAM test object. In both cases the mean pixel value deviated from the mean by no more than 0.3% and the SNR deviated from the mean by no more than 1.5%.

3.6 Image uniformity

The uniformity of a 2D image was found to be 0.2%, which is well within the 5% limit. When an image of PMMA was viewed using a very narrow window width the image appeared uniform, apart from a faint frame consisting of a 13mm border around the edges of the image. In this border region the pixel value was up to 0.3% lower than that within the central rectangle, as shown in Figure 14 (left).

Tomosynthesis projections appeared to be uniform. In the reconstructed focal planes bands 15mm wide are seen running across from left to right when the image was viewed with a very

narrow window, as shown in Figure 14 (right). The step in pixel value between adjacent bands was up to about 3%.

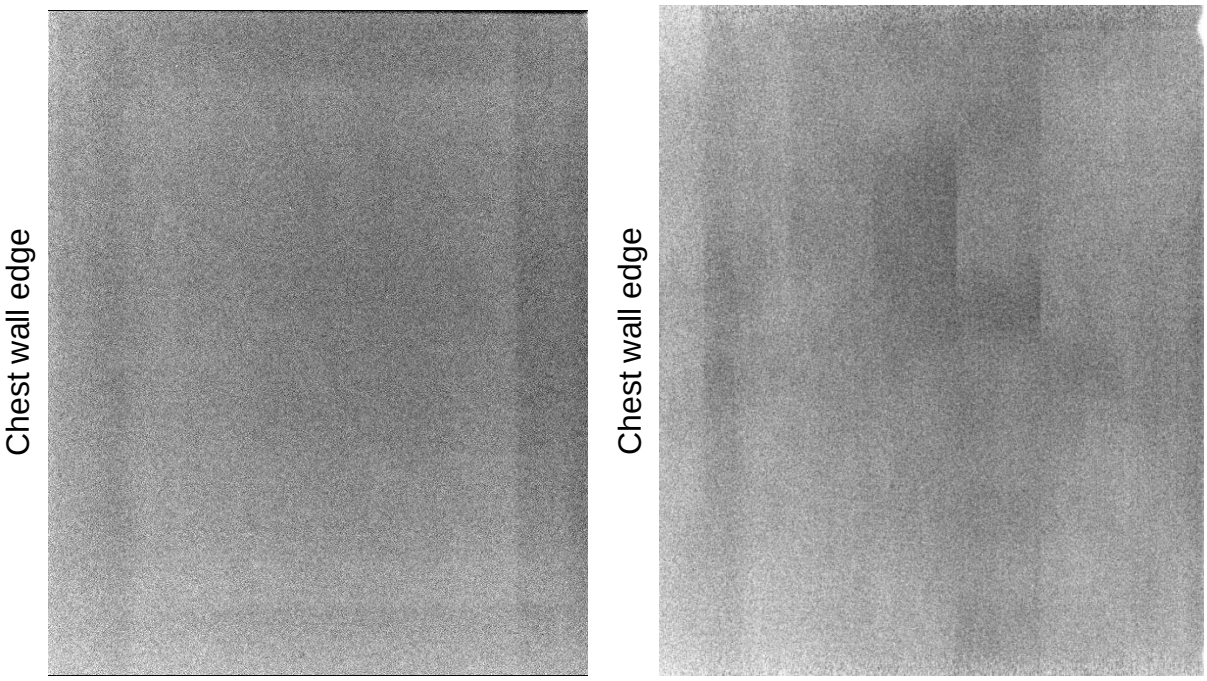


Figure 14. Images of uniform PMMA: 2D on the left and a tomosynthesis reconstructed focal plane on the right

3.7 Detector response

The detector response, in 2D and tomosynthesis modes, is shown in Figure 15. The entrance air kerma at the detector is per projection and therefore one thirtieth of the total exposure for the tomosynthesis scan.

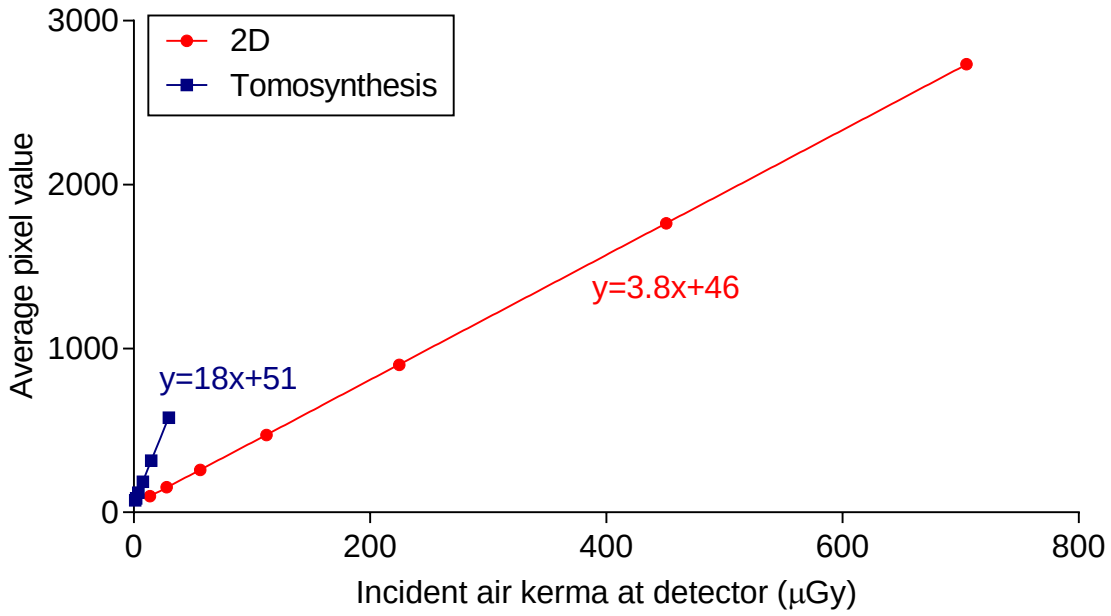


Figure 15. Detector response in 2D and tomosynthesis modes

3.8 Modulation transfer function

The presampled MTF for 2D imaging, for the direction perpendicular to the tube axis, is shown in Figure 16. Figure 17 shows the MTF in the 2 orthogonal directions in the central tomosynthesis projection.

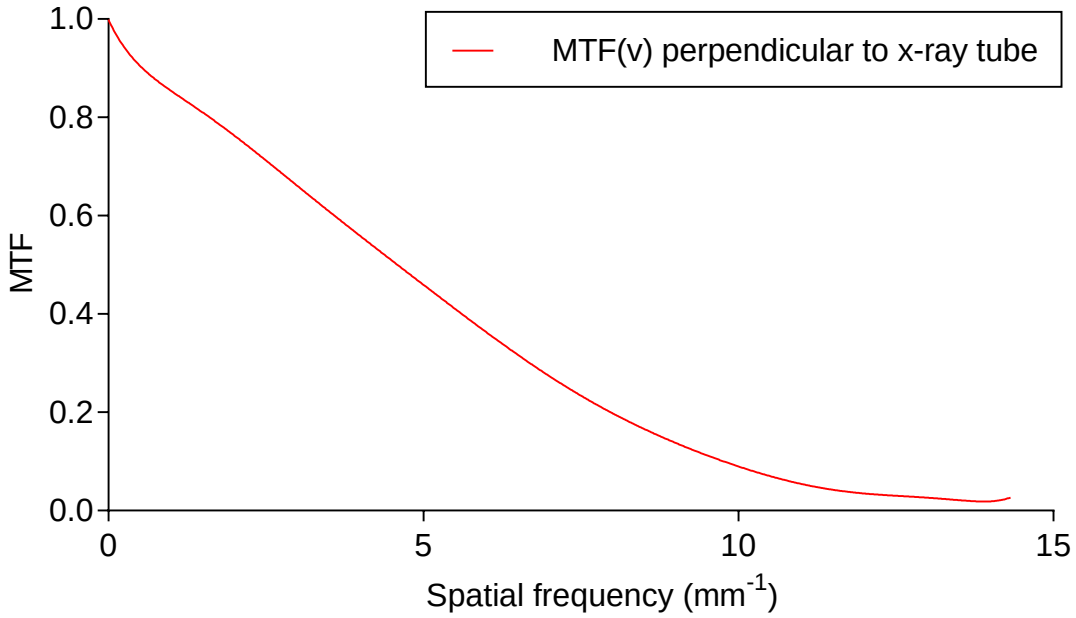


Figure 16. Presampled MTF in the v direction for 2D images

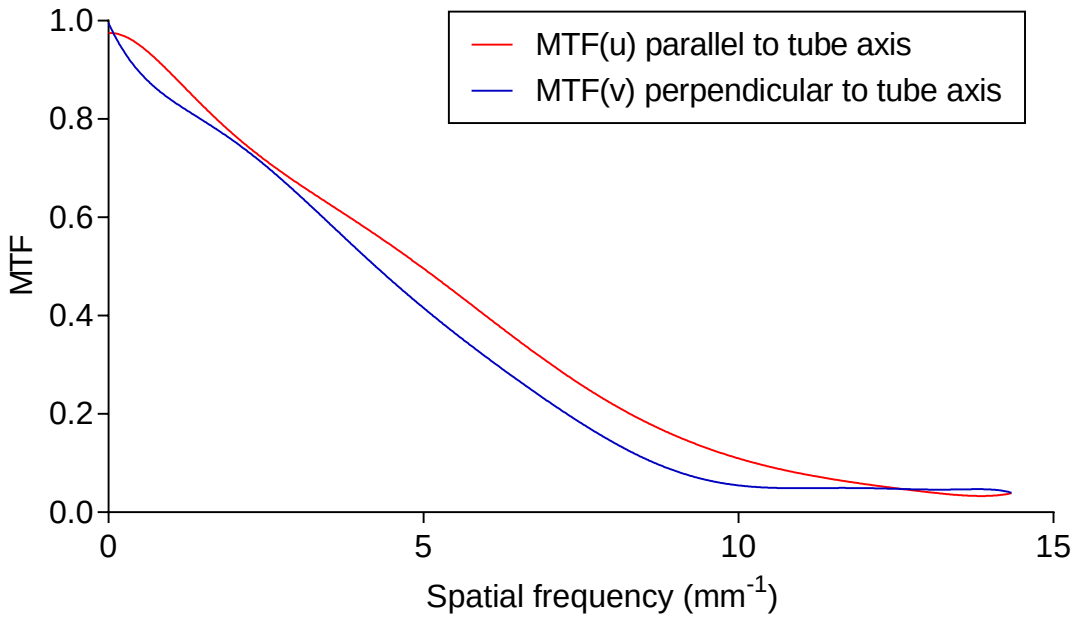


Figure 17. Presampled MTF in the u and v directions for the tomosynthesis central projection

The MTF measurements are interpolated to show values at standard spatial frequencies in Table 12.

Table 12. MTF measurements at standard frequencies

Frequency (mm^{-1})	2D	Tomosynthesis central projection	
	MTF (v)	MTF (u)	MTF (v)
0	1.00	1.00	1.00
1	0.86	0.88	0.85
2	0.76	0.77	0.75
3	0.66	0.68	0.64
4	0.56	0.58	0.53
5	0.46	0.49	0.42
6	0.36	0.40	0.31
7	0.27	0.31	0.22
8	0.20	0.23	0.14
9	0.14	0.16	0.09
10	0.09	0.11	0.06
11	0.06	0.07	0.05
12	0.04	0.06	0.05
13	0.02	0.05	0.05
14	0.02	0.03	0.04

3.9 Image display

All greyscale steps were visible. No distortion or artefacts were seen. All high contrast resolution gratings were visible. Some low contrast gratings were also visible but single-pixel lines were not seen. Measurements of light output, summarised in Table 13, indicate that the luminance and greyscale standards were met.

Table 13. Light meter measurements on 2MP monitor

		Result	NHSBSP standard
Luminance:	White	354cd/m^2	>240cd/m^2
	Black	0.2cd/m^2	<1cd/m^2
	Ratio white/black	1769	>250
Greyscale:	Maximum deviation from DICOM greyscale standard display function (GSDF)	8%	<10%

3.10 Other tests

3.10.1 Image size

The measured size of a 2D image using callipers was 121mm x 98mm at the reference plane of 22mm away from the breast support. Using the engineer's alignment test tool at the surface of the breast support table the image size was 125mm x 104mm. These measurements are consistent with the image size of 143mm x 117mm. This confirms calliper accuracy within 1%. The measured size of the first tomosynthesis focal plane was 125mm x 101mm.

3.10.2 Compression

The measured compressed breast thicknesses are compared with the displayed values in Table 14. They were within 2mm of displayed values. This is well within the remedial level of > 5mm.[4]

Table 14. Indicated compressed breast thickness

Object thickness (mm)	Indicated thickness (mm)	Difference (mm)
20	19	1
45	46	1
70	72	2

Compression force was not displayed. The maximum available motorised force was measured as 80N.This was unchanged at 2 minutes and 5 minutes after application.

3.10.3 Timings

The scan time (from pressing the exposure button until decompression) was approximately 11 seconds and the reconstruction time was approximately 5 seconds.

3.10.4 Couch movement

It was noted that movements of the breast support table and patient couch are not disabled during compression. Movements are disabled by pressing a lock button, and exposures cannot be made until this button is pressed. When power is turned off the compression can be released manually by turning the knob used to apply manual compression.

3.10.5 Image retention

The image retention factor was 0.045, compared to the NHSBSP upper limit of 0.3.

4. Discussion

4.1 Mean glandular dose

MGDs to standard breast model simulated using PMMA, in both 2D and tomosynthesis modes, are within the NHSBSP remedial dose levels for 2D mammography and European tomosynthesis reference dose levels for all thicknesses, 21mm to 90mm. For a 53mm equivalent breast the MGD is 1.96mGy and 1.76mGy for 2D and tomosynthesis respectively.

Our previously reported MGD to a 53mm equivalent breast for the Hologic Selenia Dimensions system were 1.49mGy and 1.81mGy for 2D and tomosynthesis respectively.[7] The MGDs for the Affirm prone biopsy system for a 53mm breast thickness are approximately 30% higher than for the Dimensions for 2D imaging and very similar for tomosynthesis.

No correction has been applied to the calculated MGDs, such as that suggested for small-field digital systems,[6] because the field size of the Affirm prone system is larger than the 100cm^2 field size used in the correction method. If larger breasts are imaged, and not totally covered by the radiation field, a correction could be applied to the MGD, based on the ratio of the field size to the total area of the compressed breast.

If only one breast is imaged during a biopsy procedure, the average MGD to the whole of the glandular tissue (both breasts) could be estimated as half of the MGDs quoted above.

4.2 Contrast-to-noise ratio

CNR in 2D mode exceeds the target level for achievable image quality for all breast thicknesses, 21mm to 90mm.

The measured CNRs in tomosynthesis mode, for QC ‘Flatfield tomo’ images and for clinical images, are presented for comparison with future measurements.

4.3 Image quality

Measurements of threshold gold thickness detection for 2D imaging showed that the Affirm prone system achieves a level of image quality for the smaller details (0.1mm to 0.16mm) that exceeds the achievable standard and is similar to that of the Dimensions system (within limits of measurement). The ReadCD program for reading partial CDMAM images was validated by comparing its results with CDCOM, for a set of Dimensions images; good agreement was found (Figure 8).

In the absence of a more suitable method for measuring tomosynthesis image quality, threshold gold thickness was also measured in tomosynthesis mode using the CDMAM test object. The results are provided for comparison against future measurements on this system.

The measurements take no account of the ability of tomosynthesis to remove the appearance of overlying structures.

4.4 Geometric distortion and reconstruction artefacts

Focal planes are flat and parallel to the surface of the breast support table with no distortion or scaling errors. The reconstructed image presents details at the expected distance from the breast support, with an additional 5 focal planes beyond the position of the compression paddle, which allows for any flexing of the paddle.

The z-FWHM measurement of 12.8mm is greater than the result of 11.0mm for the Dimensions system.[7] When making measurements of z-FWHM on the Affirm prone system it would be better to increase the thickness of PMMA between the geometric test tool and the breast support, as a minimum ball height of 7.5mm was not sufficient to obtain an accurate z-FWHM measurement.

4.5 Alignment

Alignment results met NHSBSP standards, including missed tissue at the chest wall. No tissue was missed at the top or bottom of the reconstructed tomosynthesis images (z-direction).

4.6 Repeatability

The repeatability of AEC exposures and of tomosynthesis reconstructions were acceptable.

4.7 Uniformity

Slight non-uniformity (up to 0.3% in pixel value) was detected in 2D images, well below the 5% limit. In tomosynthesis images, variation of up to 3% was seen.

4.8 Detector response

As is usually the case with tomosynthesis systems, a higher gain is used in acquiring the tomosynthesis projections, resulting in higher pixel values at a given detector dose.

4.9 Modulation transfer function

As expected, the MTF in tomosynthesis mode in the direction of tube motion was less than that in the orthogonal direction.

4.10 Image display

The performance of the 2MP monitor included with the system was mostly satisfactory in the DICOM greyscale performance tests, except that low-contrast lines 1 pixel wide were not seen.

It is recommended that the optional 3MP monitor be used in assessment, rather than the 2MP monitor that was evaluated.

4.11 Couch movement and compression

Movements of the breast support table and patient couch are not disabled during compression and there is no compression force display. These features would not be acceptable for a full field mammography system used in screening. However, exposures cannot be made without disabling movement using a manual switch, and appropriate procedures for safe use have been in place for previous prone biopsy systems, so in practice this may not prove to be a problem. This issue is considered further in the practical evaluation published separately.

5. Conclusions

The Hologic Affirm prone biopsy system met the NHSBSP performance standards, except for visibility of the finest low-contrast lines on a 2MP monitor. For a 53mm equivalent breast the mean glandular dose was 1.96mGy for 2D imaging and 1.76mGy for tomosynthesis, both within the remedial dose levels for 2D mammography and reference dose level for tomosynthesis.

When operating in 2D mode, the image quality of the Hologic Affirm prone biopsy system was similar to that of the Hologic Dimensions full field imaging system. There was no automatic prevention of movement of the breast support table and couch, when compression was applied. Suitable procedures will need to be followed in clinical use of this equipment.

This evaluation provides baseline performance data for this system, including radiation dose and 2D image quality data, for comparison against other systems.

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