Public Health England

NHS

NHS Breast Screening Programme Equipment Report

Technical evaluation of Planmed Clarity 3D digital breast tomosynthesis system

March 2019

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Executive summary

The technical performance of the Planmed Clarity 3D digital breast tomosynthesis system was tested in tomosynthesis mode. The evaluation of the performance in the 2D imaging mode will be published as a separate report.

The mean glandular dose (MGD) to the standard breast in tomosynthesis mode was found to be 1.64mGy which is below the dose limiting value of 2.5mGy 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:

- radiation dose
- contrast detail detection
- contrast-to-noise ratio (CNR)
- reconstruction artefacts
- z-resolution
- detector response

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1. Introduction

1.1 Testing procedures and performance standards for digital mammography

This report is one of a series[1-5] 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 1407[6] describes tests for digital breast tomosynthesis.

NHSBSP protocols are like the EUREF protocol[7] but the latter also provide additional or more detailed tests and standards, some of which are included in this evaluation.

1.2 Objective

The aim of the evaluation was to measure the technical performance of the Planmed Clarity 3D digital breast tomosynthesis system in tomosynthesis mode.

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2. Methods

2.1 System tested

The tests were conducted at Planmed premises in Helsinki, on a Planmed Clarity 3D digital breast tomosynthesis system as described in Table 1. The system is shown in Figure 1.

Table 1. System description

Manufacturer	Planmed
Model	Clarity 3D
Target material	Tungsten (W)
Added filtration	75µm Silver (Ag)
Detector type	Caesium iodide / amorphous silicon
Detector serial number	CTY288392
Detector pixel size	83µm
Detector size	23.2mm x 29.7mm
Pixel array	2796 x 3584
Focal plane pixel size	95µm or 140µm (set by engineer)
Pixel value relationship to dose	Linear
Source to detector distance	650mm
Source to table distance	640mm
Software version	ESW: 1.1.1.10 CM: 1.1.1 (build 12)
Tomosynthesis projections	Number of projections: 15 Angular range: 30˚
Reconstruction algorithm	Iterative
Reconstructed focal planes	Vertical intervals: 1mm Number of planes: Compressed breast thickness in mm + 3 Pixel array: 2445 x 3138
Tomosynthesis image format	BTO Projections in TIFF format at time of testing
Exposure control Determination of exposure	Automatic exposure control (AEC) or manual Pre-exposure: 5mAs (not included in total mAs, excluded from image)

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The automatic exposure control has 2 options, which can be set by the engineer: ‘kV locked’ or ‘kV unlocked’. When using the ‘kV locked’ setting the kV is determined by the compressed breast thickness and remains set for the prepulse and main exposure. The ‘kV unlocked’ setting uses the AEC to alter the kV for the main exposure, after the prepulse. ‘kV unlocked’ is the default recommended setting and all testing was carried out in this mode.

The system uses separate buckys for 2D and tomosynthesis exposures. It is therefore not possible to carry out combination exposures comprising 2D and tomosynthesis exposures in a single compression.

The Clarity uses a ‘synch and shoot’ method of acquiring projections. The tube moves continuously and the detector (and breast support table) tilts during each exposure to eliminate blurring from movement of the X-ray tube focal spot relative to the breast and to the detector. The tilting of the breast support table is slight and barely noticeable to an observer. The manufacturer states that between 0.09 and 0.26 degrees of tilt is applied, depending on the compressed breast thickness.

At the time of testing no synthetic 2D image was available.

Post-reconstruction processing is applied to focal planes according to the user’s preferences. This means that QC results may vary between systems according to the processing applied. In future software versions it will be possible to remove the processing for QC purposes. For this evaluation Planmed made available to us images with and without the post-reconstruction processing.

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Figure 1. The Planmed Clarity 3D tomosynthesis system

2.2 Dose and contrast to noise ratio under AEC

2.2.1 Dose measurement

To calculate the MGD to the standard breast, measurements were made of half value layer (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 described in the UK protocol for measuring MGD 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.[8] This is an extension of the established 2D method, using the equation:

$$D = KgcsT \tag{1}$$

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[7] for the Planmed Clarity for different compressed breast thicknesses.

2.2.3 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.

Two sets of tomosynthesis images were acquired, using the 2 available focal plane pixel sizes, 95µm and 140µm. A further 2 sets of images were generated by Planmed engineers by removing the post reconstruction processing. Tomosynthesis CNR was measured in the focal plane corresponding to the height of the aluminium above the table. The locations of the regions of interest (ROIs) are shown in Figure 2.

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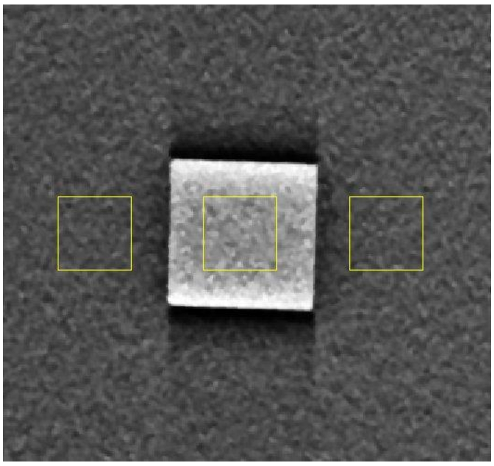
Figure 2. Location of 5mm x 5mm ROIs for assessment of CNR in tomosynthesis focal plane



2.3 Image quality measurements

Contrast detail detection measurements were made using a CDMAM phantom (serial number 1022, version 3.4, Artinis, Netherlands) sandwiched between two 20mm slabs of PMMA. Sets of 8 CDMAM images were acquired in tomosynthesis mode and reconstructed with 95µm and 140µm pixel spacing in the focal planes, both with and without post-reconstruction processing applied. The kV and mAs were chosen to match as closely as possible those selected by the AEC when imaging a simulated 60mm equivalent breast. 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 two adjacent focal planes. Results were quoted for focal plane 22, which gave the best (thinnest) threshold gold thicknesses.

The CDMAM images were read using CDCOM version 1.6, (www.euref.org) and CDMAM Analysis version 2.1 (www.nccpm.org)

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. This was done by imaging a geometric test tool, containing a rectangular array of 1mm diameter aluminium balls at 50mm intervals in the middle of a 5mm thick sheet of PMMA. The phantom was positioned at heights of 7.5mm, 32.5mm and 52.5mm within a 60mm stack of PMMA placed on the breast support table. Tomosynthesis images were acquired and reconstructed with 95µm and 140µm pixel spacing in the focal planes, both with and without post-reconstruction processing applied.

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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.

This analysis was carried out using a software tool NCCPM's Tomosynthesis QCTools (www.nccpm.org). This software is in the form of a plug-in for use in conjunction with ImageJ (http://rsb.info.nih.gov/ij/). Details of the analysis are given in the NHSBSP tomosynthesis protocol[1].

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 variation, indicating possible tilt of the test phantom relative to the reconstructed planes or any vertical distortion of the focal planes within the image.

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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. 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 balls between focal planes were assessed visually and are described in the results section of this report.

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 X-ray beam to one focal plane of the reconstructed tomosynthesis volume was assessed at the surface of the breast support table, using self-developing film and graduated markers positioned on each edge of the X-ray beam, as indicated by the light field.

The alignment of the imaged volume to the compressed volume was assessed at the top and bottom of the volume. 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 determine 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.

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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 in tomosynthesis mode. 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 signal-to-noise ratio (SNR) were measured in a uniform area in the corner in sets of 8 reconstructed images of the CDMAM test object.

2.7 Image uniformity

Tomosynthesis images of 45mm PMMA were assessed for uniformity, including evaluating for artefacts by visual inspection.

2.8 Detector response

The detector response in tomosynthesis mode was measured as described in the NHSBSP protocol, with a 2mm aluminium filter at the tube head. Measurements were made using a typical tube voltage of 31kV. Analysis was carried out using the central tomosynthesis projection images.

2.9 Other tests

Other tests carried out included cycle time, AEC backup timer and accuracy of indicated compressed breast thickness. The local dense area test from the EUREF protocol[7] was also carried out.

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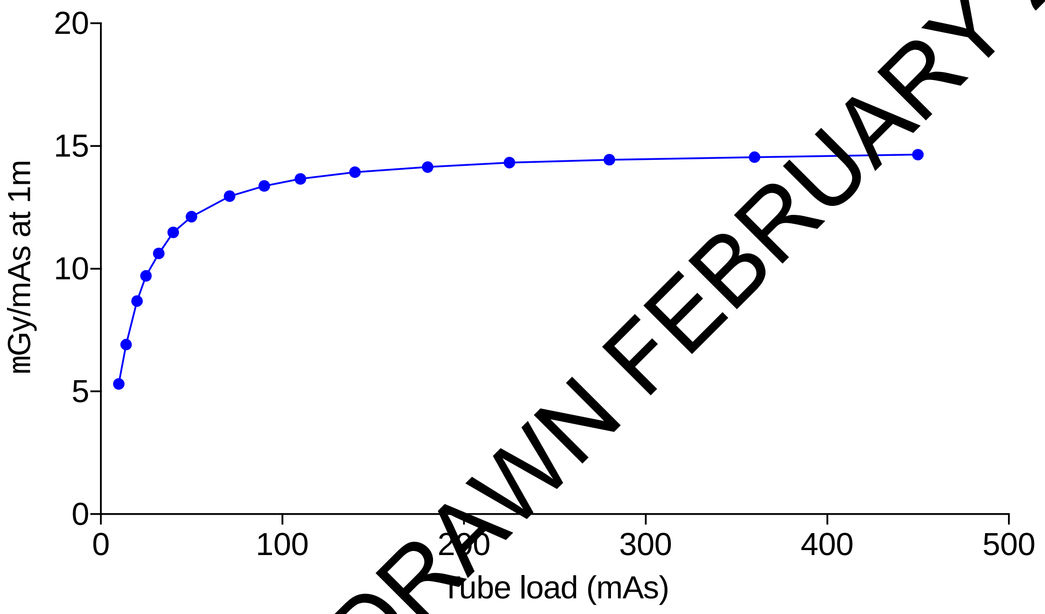
3. Results

3.1 Dose and contrast to noise ratio using AEC

3.1.1 Output and half value layer

The variation in tube output with tubeload in tomosynthesis mode is shown in Figure 3 at a tube voltage of 31kV.

Figure 3. Variation of tube output with tube load at 31kV



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The measurements of tube output and HVL of the system in tomosynthesis mode made at exposure factors close to those selected by the AEC for the range of simulated breast thicknesses are shown in Table 2.

Table 2. HVL and tube output measurement in tomosynthesis mode

kV	Target / Filter	mAs	Output (µGy/mAs at 1m)	HVL (mmAl)
29	W / Ag	45	9.34	0.62
29	W / Ag	71	10.41	0.64
30	W / Ag	100	12.33	0.66
31	W / Ag	110	13.76	0.67
32	W / Ag	125	15.23	0.68
33	W / Ag	160	16.77	0.70
34	W / Ag	180	18.19	0.70

3.1.2 Mean glandular dose

MGDs for AEC exposures under AEC in tomosynthesis mode are shown in Figure 4 and in Table 3. The MGDs include the preliminary exposure, which is not included in the image.

Table 3. MGD for tomosynthesis images acquired using AEC

PMMA (mm)	Equivalent breast (mm)	kV	Target / Filter	mAs	MGD (mGy)*	Dose limiting value (mGy)
20	21	29	W / Ag	47	0.71	1.2
30	32	29	W / Ag	71	0.98	1.5
40	45	30	W / Ag	100	1.39	2.0
45	53	31	W / Ag	112	1.64	2.5
50	60	32	W / Ag	130	1.99	3.0
60	75	33	W / Ag	155	2.36	4.5
70	90	34	W / Ag	185	2.70	6.5

*MGD includes the pre-pulse, which is not included in the mAs or the image

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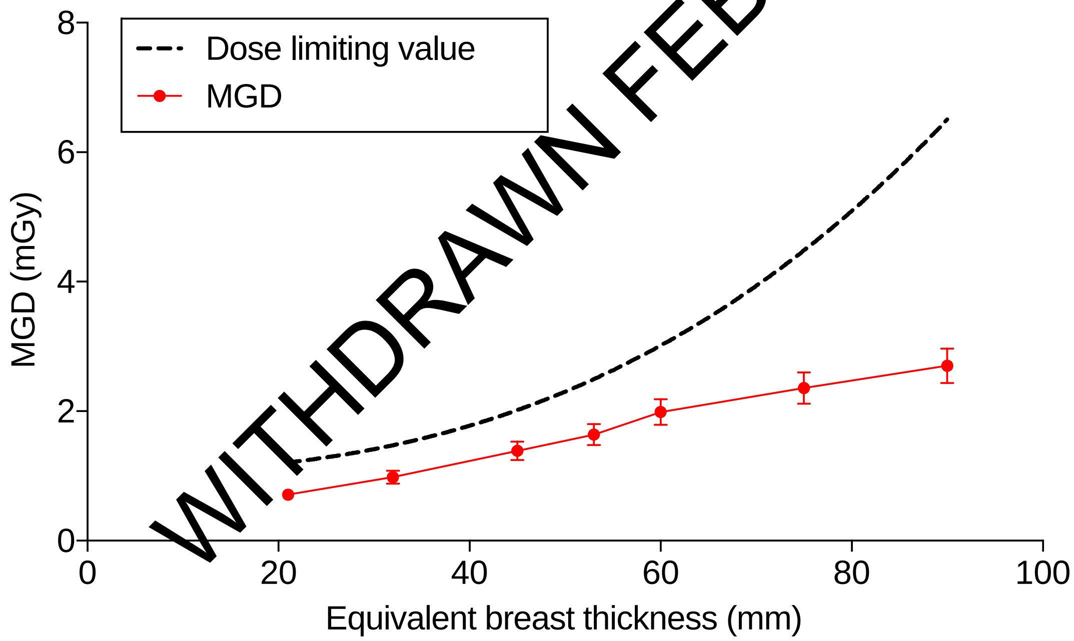
Figure 4. MGD for tomosynthesis exposures acquired using AEC for different equivalent breast thicknesses. Error bars indicate 95% confidence limits



Focal plane CNRs for reconstructed tomosynthesis images obtained under AEC are shown in Figure 5 and in Table 4. Results are shown for reconstructions with focal plane pixel spacing of 95µm and 140µm and with post-reconstruction processing and without processing.

Figure 5. CNR for tomosynthesis focal planes acquired using AEC for different equivalent breast thicknesses. Error bars indicate 95% confidence limits

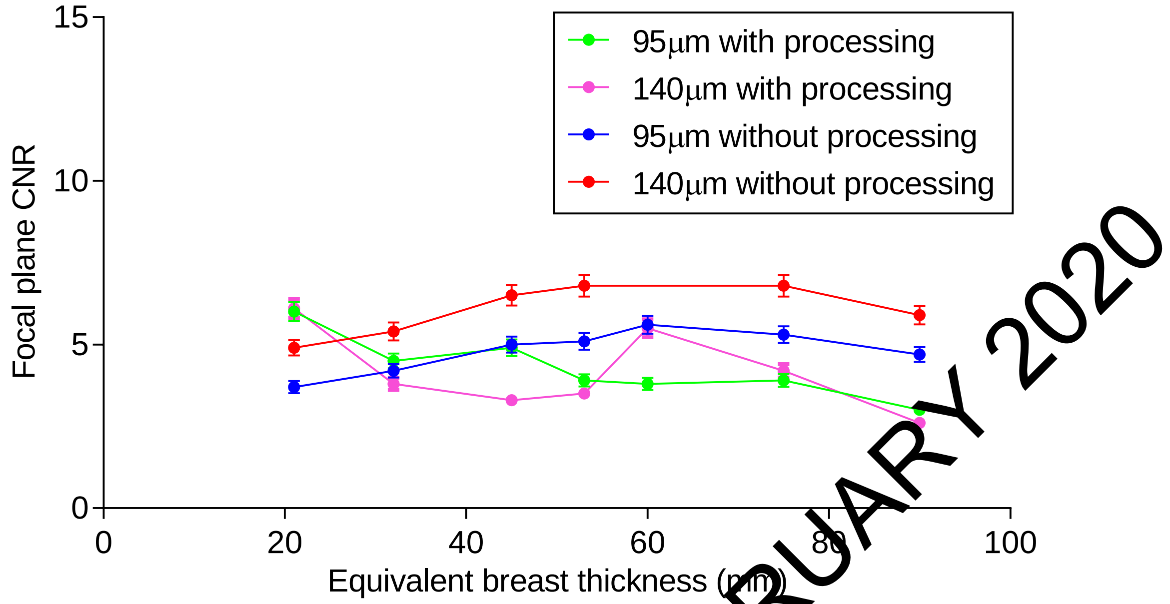


Table 4. CNR in tomosynthesis focal planes with and without post-reconstruction processing

PMMA thickness (mm)	Equivalent breast thickness (mm)	kV	Target/ filter	mAs	CNR With processing 95µm	CNR With processing 140µm	CNR Without processing 95µm	CNR Without processing 140µm
20	21	29	W/Ag	47	6.0	6.1	3.7	4.9
30	32	29	W/Ag	71	4.5	3.8	4.2	5.4
40	45	30	W/Ag	100	4.9	3.3	5.0	6.5
45	53	31	W/Ag	112	3.9	3.5	5.1	6.8
50	60	32	W/Ag	130	3.8	5.5	5.6	
60	75	33	W/Ag	155	3.9	4.2	5.3	6.8
70	90	34	W/Ag	185	3.0	2.6	4.7	5.9

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

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

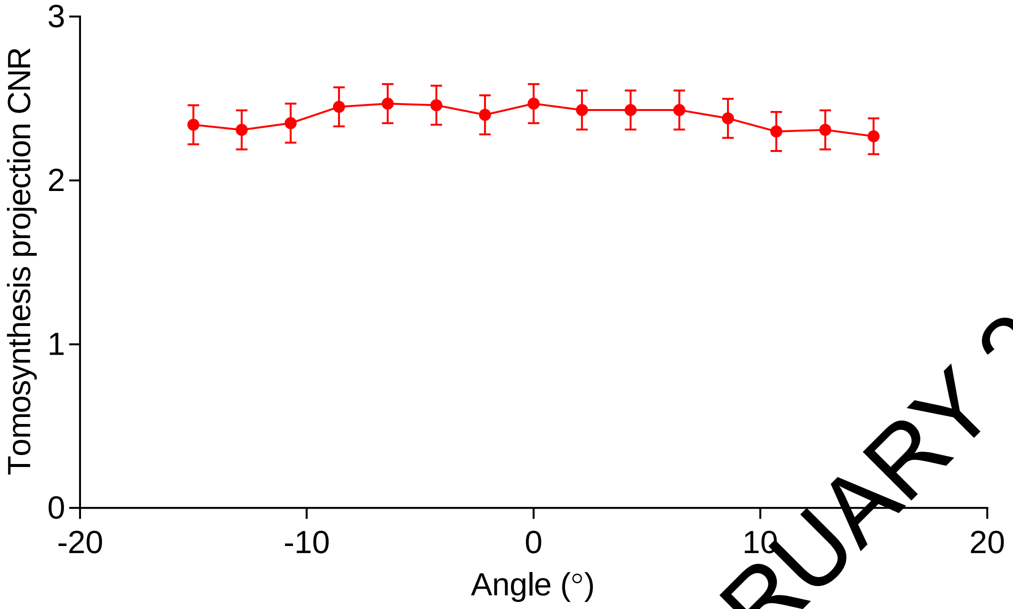
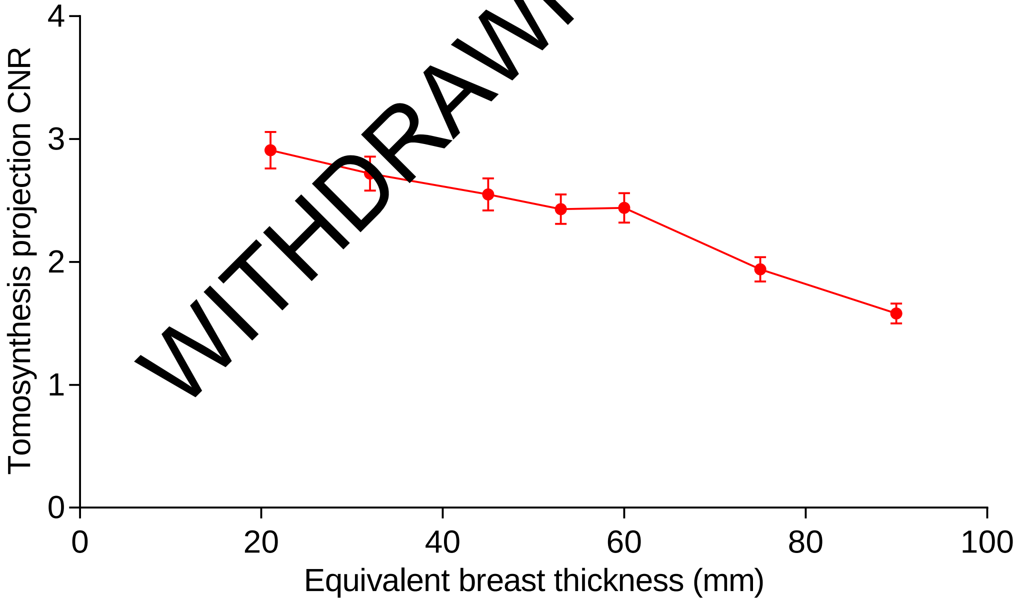


Figure 7. Variation of central projection CNR with equivalent breast thickness. Error bars indicate 95% confidence limits



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3.2 Image quality measurements

Details of the sets of CDMAM images acquired in tomosynthesis mode are summarised in Table 5.

Table 5. Details of images acquired of CDMAM test object

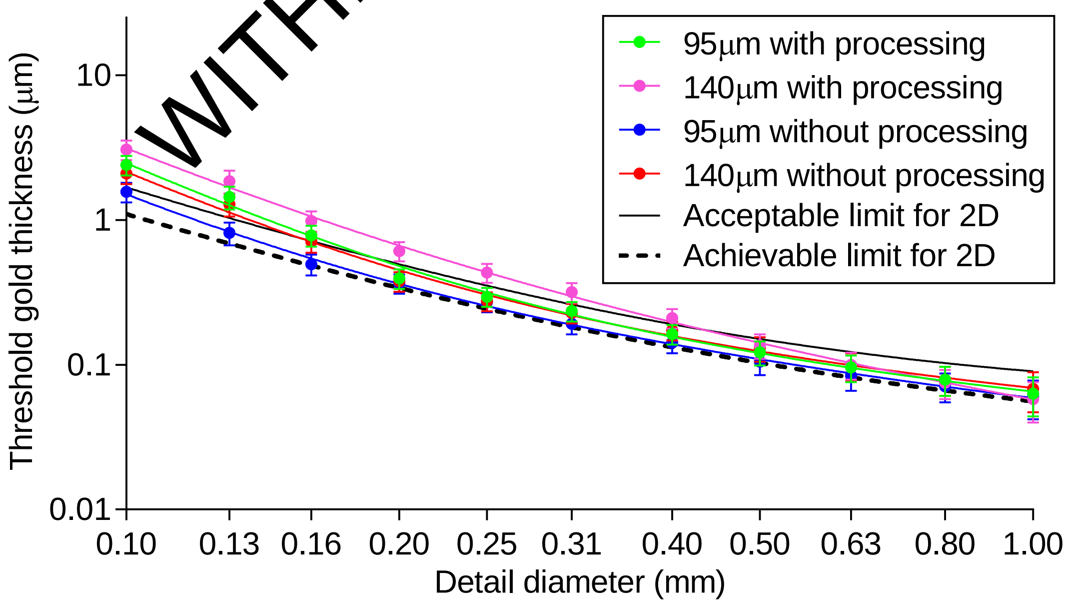
Pixel spacing in focal plane	kV	Target/filter	mAs	MGD (mGy)	Number of images
95µm	32	W/Ag	125	1.84	8
140µm	32	W/Ag	125	1.84	8

Tomosynthesis threshold gold thickness results for the focal plane with the lowest threshold gold thickness (focal plane 22) with 95µm and 140µm pixel spacing, both with and without post reconstruction processing applied, are shown in Table 6 and Figure 8.

Table 6. Threshold gold thickness (µm) for reconstructed focal plane 22 of the image of the CDMAM phantom (predicted human result)

Detail diameter (mm)	With processing		Without processing	
	95µm	140µm	95 µm	140µm
0.10	2.40±0.37	3.07±0.47	1.57±0.24	2.10±0.32
0.25	0.30±0.04	0.43±0.07	0.27±0.04	0.28±0.04
0.50	0.12±0.02	0.14±0.03	0.11±0.02	0.13±0.03
1.00	0.06±0.02	0.06±0.02	0.06±0.02	0.07±0.02

Figure 8. Threshold gold thickness detail detection curves for focal plane 22, with 95µm and 140µm pixel spacing, both with and without post reconstruction processing applied. Error bars indicate 95% confidence limits



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3.3 Geometric distortion and reconstruction artefacts

3.3.1 Height of best focus

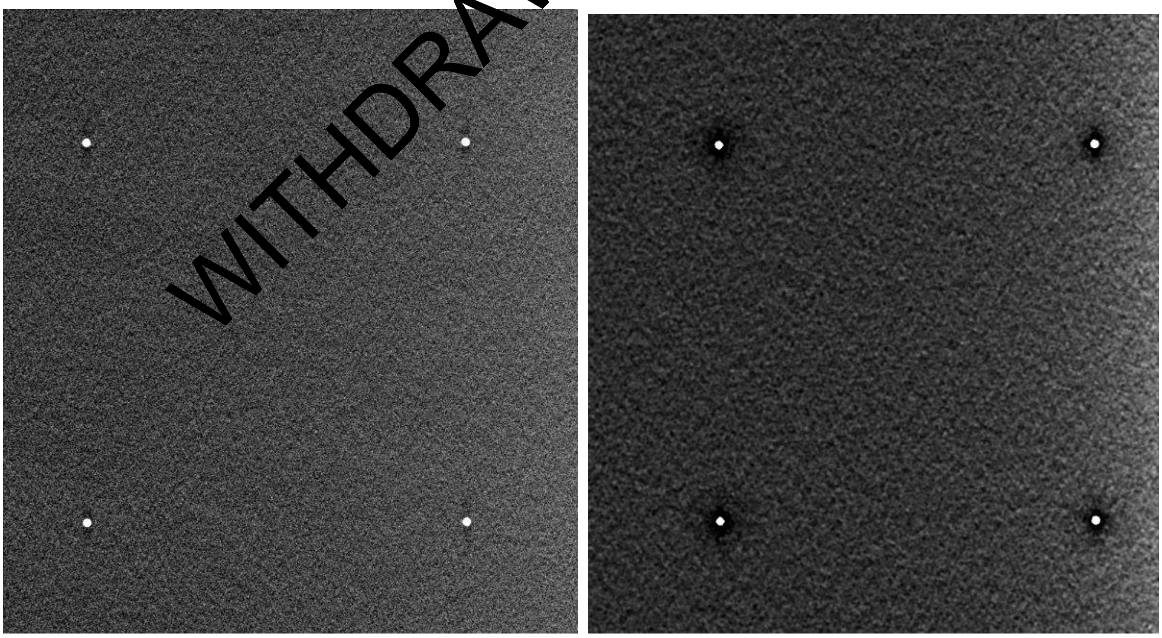
All balls within each image were brought into focus at the same height (±1mm) above the table, and within 1mm of the expected height, with the first focal plane representing a height approximately 1mm below the surface of the breast support table. These results indicate that focal planes are flat and parallel to the surface of the breast support table with no noticeable vertical distortion. The number of focal planes reconstructed is equal to the indicated breast thickness in mm plus 3, indicating that an additional 2 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 0.5%. Maximum deviation from the average distance between the balls in the x or y direction was 0.26mm, 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 9. Appearance in focal plane of best focus of 1mm aluminium ball in 60mm PMMA. Image without post-reconstruction processing is on the left and with post-reconstruction processing on the right. The chest wall edge is to the right of each view



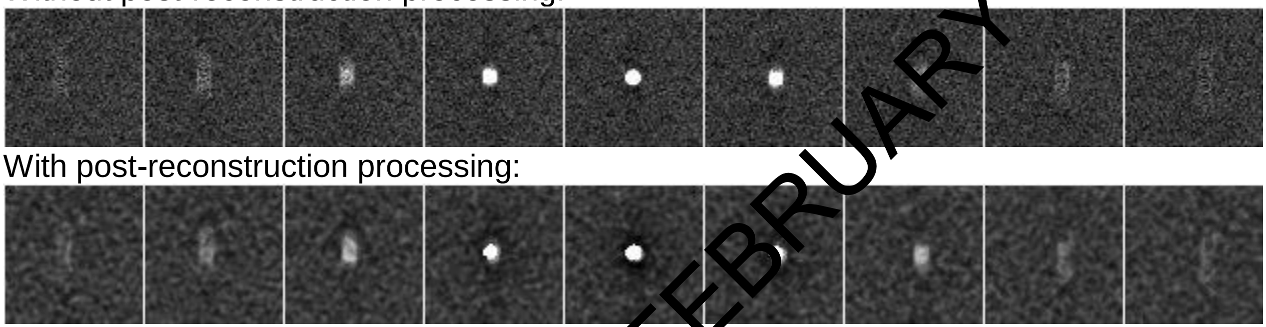
In the plane of best focus the aluminium balls appeared well defined and circular. Figure 9 shows the appearance of the balls in the 95µm focal planes without and with post-reconstruction processing. With post-reconstruction processing the appearance of a dark halo around the high contrast aluminium ball is enhanced, the background noise appears smoothed and the pixel values are higher (around 20000 compared to 3500 without processing).

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 in 140µm reconstructions of one of the aluminium balls, through successive focal planes, is shown in Figure 10, without and with post-reconstruction processing applied.

Figure 10. Appearance of a 1mm aluminium ball in focal planes at 2mm intervals from 8mm below to 8mm above the plane of best focus

Without post-reconstruction processing:

With post-reconstruction processing:



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 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 11. In these images, pixels within the focal plane represent dimensions of approximately 95µm x 95µm or 140µm x 140µm whereas the vertical 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 vertically by a distance exceeding their diameter.

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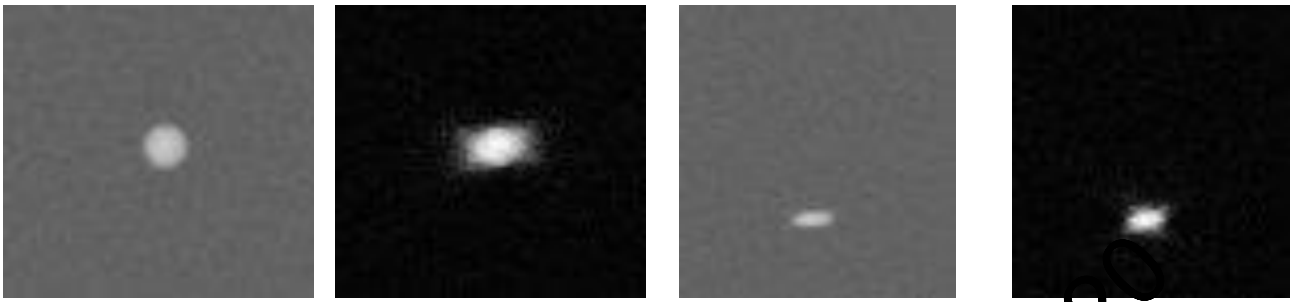
Figure 11. Extracts showing 1mm aluminium ball in (i) single focal plane, (ii) the maximum intensity projections through all focal planes, and through re-sliced vertical planes in the directions (iii) parallel and (iv) perpendicular to the chest wall



(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 7 for images of balls at heights of 7.5mm, 32.5mm, and 52.5mm above the breast support table. The range represents the minimum and maximum of the z-FWHM measured over all balls at all heights. In the images with post-reconstruction processing applied, the pixel values representing the aluminium balls reached their maximum value. This is because the processing is optimised for clinical images and does not have the dynamic range to include the artificial high contrasts within the test object used. The z-FWHM measured for these images is therefore a gross overestimate and not valid. Therefore, only measurements for without processing are presented here.

Table 7. z-FWHM measurements of 1mm diameter aluminium balls (mm)

	z-FWHM (range)
95µm without processing	5.5 (5.1 to 5.8)
140µm without processing	5.4 (5.1 to 5.6)

3.4 Alignment

The radiation field overlaps the base of the reconstructed image by no more than 4mm at the chest wall edge. At the left and right edges, the measured overlap was 7mm and 2mm respectively.

The missed tissue at the chest wall edge was 4mm, which is within the 5mm limit applied for 2D mammography. None of the compressed target volume was missed at the bottom or top of the reconstructed volume.

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3.5 Repeatability

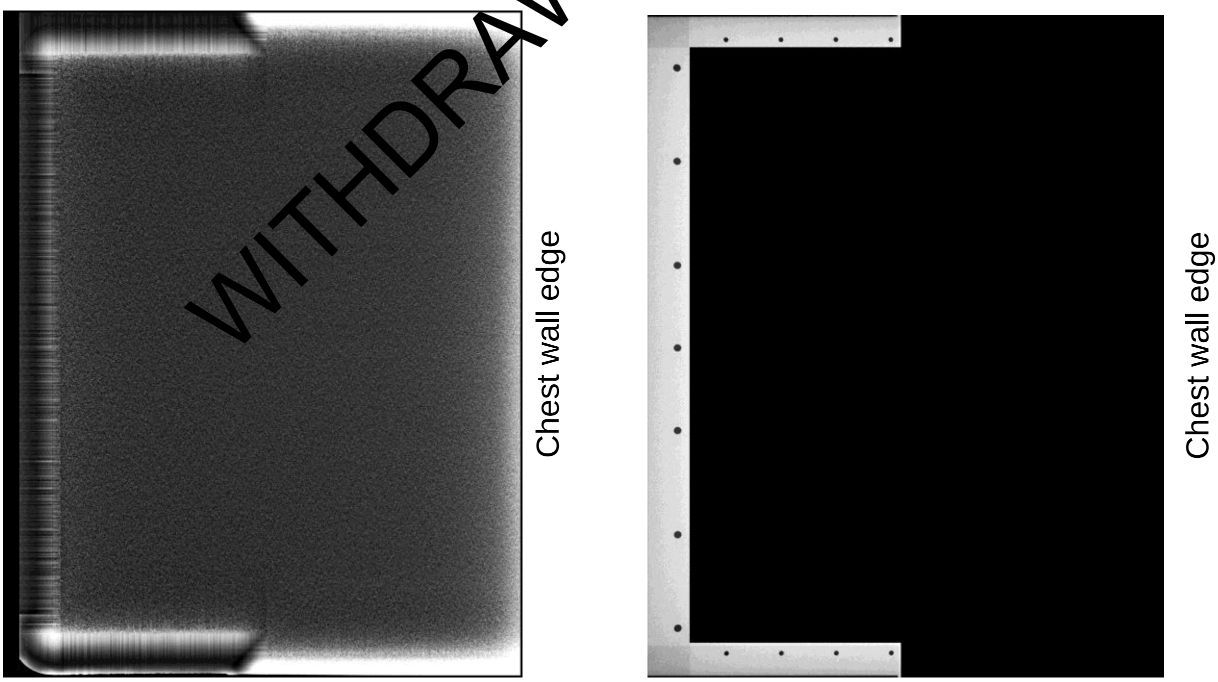
Repeated tomosynthesis exposures under AEC were at a constant kV and the mAs varied by no more than 0.1% for either a sequence of 5 exposures or between one day and the next.

The stability of the reconstruction was tested by sampling pixel values in a uniform region of sets of 8 reconstructed focal planes of the CDMAM test object. Reconstructions without post reconstruction processing were used. For 140µm pixel reconstructions the SNR varied by up to 2% from the mean for the 8 images. For the set of 8 images of the CDMAM phantom with a pixel spacing of 95µm, the maximum deviation in SNR was 4%.

3.6 Image uniformity

In reconstructed focal planes a border is obscured across the nipple edge and extending half way towards the chest wall along the lateral edges of the image, as shown in Figure 12. The border is approximately 20mm deep at the height of the surface of the breast support table. This is due to the presence of a physical mask with holes which is attached to the compression paddle to aid alignment in the image reconstruction process. A projection image showing this mask is also shown in Figure 12. Additionally, there is an increase in pixel value at the chest wall edge and lateral edges. Otherwise the reconstructed image appeared uniform with no disturbing artefacts.

Figure 12. Image of uniform PMMA (95µm with post-reconstruction processing). A reconstructed focal plane is shown on the left and a projection image on the right



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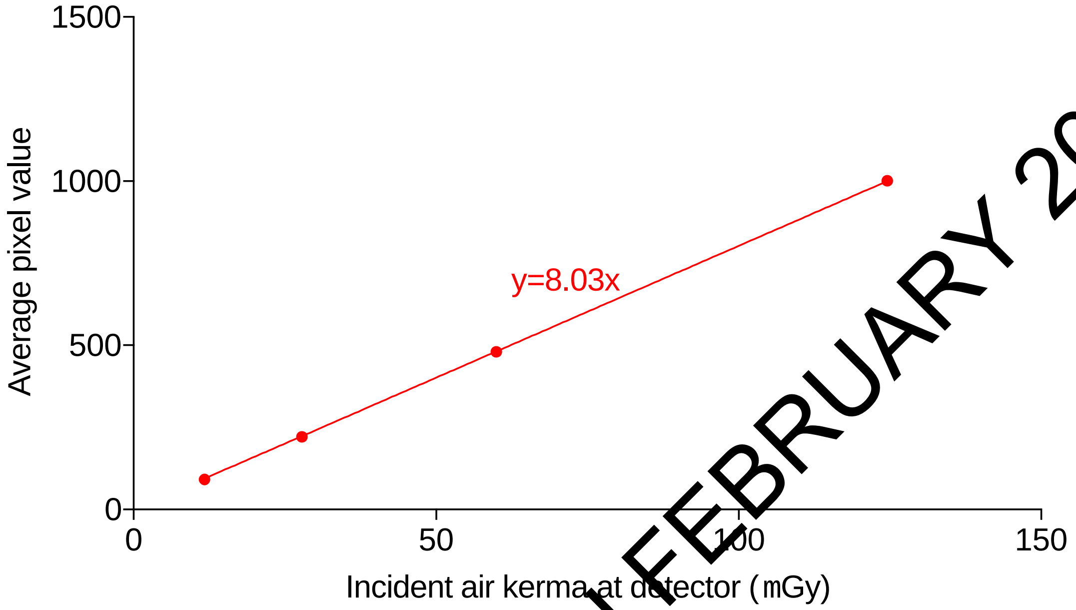
3.7 Detector response

Detector response tomosynthesis mode is shown in Figure 13 for 31kV, W/Ag. The incident air kerma at the detector is per projection and therefore one fifteenth of the total exposure for the tomosynthesis exposure.

Figure 13. Detector response in tomosynthesis mode



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3.8 Other tests

3.8.1 Timings

Scan times are shown in Table 8. The range in reconstruction times depended on breast thickness.

Table 8. Scan and reconstruction timings

	Tomosynthesis
Time from start of exposure until decompression	20s
Time from decompression until reconstructed image displayed	1-2mins (140µm reconstruction) 2-4mins (95µm reconstruction)

3.8.2 AEC backup timer

The AEC back-up timer was not functional in tomosynthesis mode at the time of testing.

3.8.3 Local dense area

The AEC was found to not respond to simulation of a local dense area using added PMMA.

3.8.4 Accuracy of compressed breast thickness indication

Indicated thicknesses were all within 3mm of actual thickness, which is within the 5mm NHSBSP limit.

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4. Discussion

4.1 Mean glandular dose

MGD to the standard breast simulated using PMMA, for tomosynthesis is within the limiting values for MGD for tomosynthesis in EUREF protocol[7]. For a 53mm equivalent breast the MGD is 1.64mGy.

4.2 Contrast-to-noise ratio

CNR measurements showed a steady decrease with increasing breast thickness for the projections, but the CNR in the reconstructed planes were relatively constant with breast thickness.

4.3 Image quality

In the absence of any better test object for assessing tomosynthesis imaging performance, threshold gold thickness was measured in tomosynthesis mode using the CDMAM test object.

At the dose selected by the AEC, the threshold gold thickness for reconstructed focal planes was better than the minimum acceptable level for 95µm pixel size, without processing, for diameters greater than 0.1mm. For 95µm pixel size with processing and 140µm without processing, the threshold gold thickness for the reconstructed focal planes was better than acceptable level for diameters greater than 0.2mm. For 140µm pixel size with processing, the threshold gold thickness for reconstructed planes is above the minimum acceptable level for diameters greater than 0.4mm.

These results are provided for comparison against future measurements on this system. These measurements take no account of the ability of tomosynthesis to remove the appearance of overlying structures.

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.

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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 number of focal planes reconstructed is equal to the indicated thickness in mm plus 3, indicating that an additional 2 planes are reconstructed above the base of the compression paddle, and 1 below the table surface.

The mean inter-plane resolution (z-FWHM) for the 1mm diameter balls was 5.5mm and 5.4mm for pixel sizes of 95µm and 140µm respectively, without post reconstruction processing.

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.

4.6 Repeatability

The repeatability of exposures under AEC and of mAs and SNR in tomosynthesis reconstructions were acceptable.

4.7 Uniformity

There is a 20mm obscured border along the chest wall and part of the lateral edges. There is an increase in pixel value at the chest wall and part of the lateral edges. The impact, if any, will be assessed during the practical evaluation.

4.8 Local dense area

The AEC was found to not respond to simulation of a local dense area using added PMMA.

4.9 Reconstruction time

Image reconstruction time ranged from 1-2mins for 140µm reconstructions to 2-4mins for 95µm reconstructions.

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5. Conclusions

The technical performance of the Planmed Clarity digital breast tomosynthesis system, tested in tomosynthesis mode, was found to be satisfactory. At the moment, no image quality standards have been established for digital breast tomosynthesis systems.

The MGD to the standard breast (53mm breast equivalent) in tomosynthesis mode was found to be 1.64mGy. This is within the dose limiting values for MGD for tomosynthesis in the EUREF protocol.

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