NHS England

NHS Breast Screening Programme Equipment Report: Technical Evaluation of Siemens MAMMOMAT B.brilliant digital mammography system in tomosynthesis mode

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Contents

Please note: The image shown in Figure 1 is courtesy of Siemens.

Executive Summary

The technical performance of the Siemens MAMMOMAT B.brilliant digital breast tomosynthesis system was assessed in tomosynthesis mode. The Dance mean glandular dose (MGD) to the 53mm standard breast was found to be 1.71mGy, which is below the dose limiting value of 2.5mGy for tomosynthesis in the EUREF protocol.

Technical performance of this equipment operating in tomosynthesis mode was found to be satisfactory and the system could proceed to practical evaluation of tomosynthesis. The technical evaluation of the performance in 2D mode is published as a separate report. 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
- projection modulation transfer function (MTF)

Background

Mammographic equipment approved for use in the NHSBSP is subject to evaluation commissioned by NHS England and carried out by a number of breast screening services in England who undertake the practical evaluation of equipment using protocols provided by the NHSBSP. These evaluations comprise a staged process as follows:

1. A technical evaluation by the National Coordinating Centre for the Physics of Mammography ("NCCPM") (the "Technical Evaluation")

2. If the Technical Evaluation meets requirements, a subsequent practical evaluation is conducted by one of the breast screening services involved in the NHSBSP (the "Practical Evaluation")

Technical and Practical Evaluations are undertaken to assess the use of equipment in a practical, clinical setting and are not intended to be clinical trials. Further information about the limitations of the Technical Evaluation and Practical Evaluations are set out below.

The purpose of the Technical and Practical Evaluations together are intended to:

- determine the suitability of the equipment for use within the NHSBSP
- assist potential purchasers in making their choice of equipment
- provide potential users with performance data about equipment
- provide potential users with a record of the practical experience of using the equipment in the NHSBSP
- enable comparisons to be made with other pieces of tested equipment.

Disclaimer

Whilst NHS England commissions testing for the purposes outlined above, in order to provide further information and support to providers of screening services within the NHSBSP, it is for informational purposes only and such testing is subject to the limitations described below. No representation is made by NHS England in relation to the reports generated from the Technical Evaluation or the Practical Evaluation and, insofar as the law allows, NHS England accepts no liability arising from purchase or use of equipment by providers of screening services within the NHSBSP subjected to them.

Providers of screening services within the NHSBSP must ensure that all equipment purchased and used within the NHSBSP complies with all relevant requirements of the NHSBSP, the terms of their contracts in respect of the NHSBSP, and all other relevant obligations including but not limited to ensuring that such equipment:

- complies with national equipment standards
- has been approved for use in the programme and is tested by appropriately trained staff and medical physics services, in accordance with NHSBSP guidelines
- is accredited for use within the NHSBSP and that image quality and radiation dose meet acceptable standards
- is suitable for the usage intended in the breast screening unit.

Providers are reminded that they should carry out their own due diligence in respect of the above.

Testing undertaken during the Technical Evaluation is a balance between time, evaluation costs and depth. There are therefore limitations to the scope of the Evaluations undertaken on the behalf of the NHSBSP.

The Technical Evaluation is undertaken over a short time and so will not assess if image quality may change over time. The equipment tested is generally selected by the equipment supplier and has been set up by them. It should be noted that individual centres may be set up differently for example to meet the requirements of the screening service.

The technical image quality as measured on this system must be acceptable. The image quality of the final displayed image will be affected by the image processing and display and this is separately evaluated qualitatively in the Practical Evaluation.

This evaluation report does not absolve the provider of their responsibility during the procurement process to ensure the equipment is suitable for the usage intended by the provider.

1. Introduction

1.1 Testing procedures and performance standards for digital mammography

This report is one of a series evaluating commercially available digital breast tomosynthesis (DBT) systems on behalf of the NHS Breast Screening Programme (NHSBSP) [1] [2] [3] [4] [5]. The testing methods and standards applied are those of the relevant NHSBSP protocols, which are published as NHSBSP Equipment Reports. Report 1407 [6] describes the testing of digital breast tomosynthesis systems.

The NHSBSP protocol is similar to the EUREF protocol [7], 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 Siemens MAMMOMAT B.brilliant system in tomosynthesis mode.

2. Methods

2.1 System tested

The tests were conducted at the Siemens Healthineers factory in Forchheim, Germany on the MAMMOMAT B.brilliant system. Details of the system tested are given in Table 1.

Table 1. System description

Manufacturer	Siemens Healthineers
Model	MAMMOMAT B.brilliant
System serial number	241
Target material	Tungsten (W)
Added filtration	1.0mm Aluminium (Al) for 2D, 0.7mm Al for tomosynthesis
Detector type	Amorphous Selenium
Detector serial number	PROTO-0014
Detector pixel pitch	85µm
Detector size	304.64mm x 239.36mm
Pixel array	2816 x 3584
Source to table distance	636mm
Source to detector distance	650mm
Pre-exposure mAs	2D Low Energy / Tomosynthesis: Compression force <=30N: 4mAs 0-30mm: 3mAs 31-50mm: 4mAs 51-200mm: 5mAs 2D_High Energy: 3mAs for all thicknesses Magnification: Compression force <=30N: 3mAs 0-30mm: 2mAs 31-50mm: 3mAs 51-200mm: 4mAs
Automatic exposure control (AEC) mode	OPDOSE, segmentation on or off, five selectable dose levels: normal, -20%, -11%, +12%, +25%. In addition to the selectable dose levels service engineers can configure relative dose levels either for the system as a whole or for specific CBT ranges. The default values on the system tested are shown in Table 5.
Tomosynthesis projections	25 projections covering range ± 25˚
Centre of rotation	47mm above breast support
Anti-scatter grid	Grid not used
Reconstructed focal planes	Focal planes at 1mm intervals
Software version	VA10C

In both 2D and tomosynthesis modes OPDOSE is used for automatic exposure control (AEC) and is based on compressed breast thickness. The system acquires a preliminary stationary 2D image at a tube angle of -30 degrees, the tube then begins moving and is up to full speed in time for the first projection which commences at approximately -25 degrees. The tube load for tomosynthesis is calculated using the preliminary -30 degree exposure and is divided equally between the subsequent 25 projections.

The displayed compressed breast thickness (CBT) in tomosynthesis mode is 3mm larger than in 2D mode for the same compression thickness. Siemens state that this added thickness will influence the OPDOSE AEC. However, a 3mm difference typically does not cause any significant changes in the configurations. When the thickness is at a switching point of the OPDOSE table at most this will cause a one kV step difference. No differences were observed in our tests at standard breast thicknesses.

The maximum CBT that can be reconstructed in tomosynthesis mode is 100mm. For thicknesses above this, the system will allow the exposure but will display a warning that only the lower 100mm will be reconstructed.

There is a mode to automatically perform combination exposures, comprising a 2D exposure followed by a tomosynthesis exposure in the same compression.

Table 2. Image file sizes for 60mm CBT, 24cm x 30cm field size

Format	Pixels per frame	Frames per image	Total image file size (MB)
Projections	2816x3584	26	507
Planes	2816x3584	61	821

Examples of the image file sizes are shown in Table 2. The projection images comprise of 25 images for the reconstruction. The file size of the reconstructed volume depends on the CBT and field size.

The MAMMOMAT B.brilliant is shown in Figure 1.

Figure 1. The Siemens MAMMOMAT B.brilliant digital breast tomosynthesis system

2.2 Software modes and processing

The MAMMOMAT B.brilliant has several options for the image processing known as “flavors”. There are additional configurations of the post processing possible to adapt the image impression to customer wishes. The settings include for example changes of image sharpness and image contrast. The datasets are displayed in projection coordinate system “screening mode” unless the user prefers a Cartesian coordinate system representation in which case “bio mode” can be used. The use of the Cartesian coordinate system is mandatory for Biopsy with the MAMMOMAT B.brilliant - this is set automatically by the system. For the evaluation, Siemens recommended the Premia0 bio setting and, unless explicitly specified otherwise, this was the processing used. For some tests, where appropriate, additional processing settings were tested as well.

2.3 Output and half value layer

To calculate the MGD to the standard breast, measurements were made of the half value layer (HVL) and tube output, at the available kV and target/filter combinations. The output measurements were made on the midline at 50mm from the chest wall edge (CWE) of the

breast support platform. The compression paddle was in the beam, raised well above the dosimeter.

2.4 Dose estimation

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 the equivalent breast thickness for that thickness of PMMA. Spacers were positioned at the nipple edge of the field, so as not to affect the operation of the AEC.

The method of measuring tomosynthesis doses described in the NHSBSP protocol differs slightly from the method described by Dance et al [8]. The incident air kerma is measured with the compression paddle well above, instead of in contact with, the dosimeter. Measurements on other systems show that this variation reduces the air kerma and thus the mean glandular dose (MGD) measurement by 3% to 5%. Otherwise the MGDs 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:

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

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 [7] for the Siemens Inspiration for different CBTs, and the same values are appropriate for the MAMMOMAT B.brilliant, because it has the same geometry.. Although not yet adopted in UK breast screening programmes, a joint AAPM TG282 and EFOMP report on breast dosimetry was published earlier this year [9]. The model proposed in this collaboration is intended by the authors as a future international standard. Mean glandular doses were therefore also estimated and tabulated using the TG282 model for Cranio-caudal (CC) views applying TG282 median percentile glandularities.

It is worth noting that the Siemens displayed values are estimated using the Boone model with a fixed 50% glandularity across the whole compressed breast thickness range.

2.5 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 PMMA thickness and the variation in projection CNR with projection angle for a 45mm thick PMMA block were also assessed.

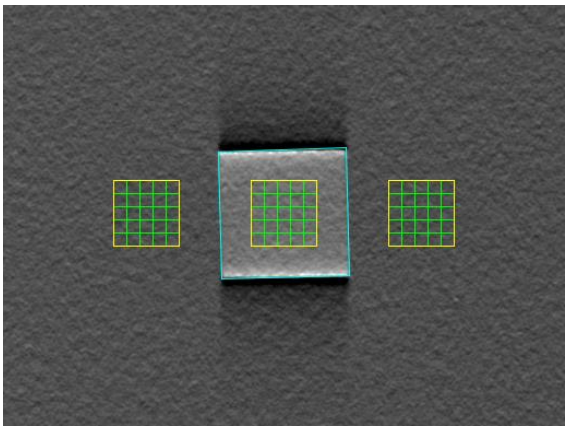

Figure 2. The position of 5mm x 5mm ROIs for assessment of CNR. (The CWE is to the right)

2.6 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 breast support is sloped and so a spacer of 5mm was used at the front of the blocks to ensure the plane of the CDMAM phantom was parallel to the detector. The exposure factors were chosen to be close to those selected by the AEC, when imaging a 50mm thick block 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 two software tools: CDCOM version 1.6 (www.euref.org) and CDMAM Analysis version 2.1 (NCCPM, Guildford, UK). This was repeated for two 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.

The process was repeated using a CDMAM 4.0 phantom (serial number 4306, version 4.0, UMC St. Radboud, Nijmegen University, Netherlands).

2.7 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 (7.5, 32.5, and 52.5mm) within a 60mm stack of plain sheets of PMMA. The block of PMMA was tilted using the same method as used in section 2.3. 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 assessed.

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/).

2.7.1 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.

2.7.2 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. It should be noted that this test was performed using the Cartesian coordinates of the “bio mode”. The accuracy of scale measurements will be degraded and vary by height within the volume in the “screening mode”.

2.7.3 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.

2.8 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 (staples) 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.

2.9 Image uniformity and repeatability

The reproducibility of the tomosynthesis exposures was tested by acquiring a series of 5 images of a 45mm thick block of PMMA using AEC. A 10mm x 10mm ROI was positioned 50mm from the chest wall edge in the plane corresponding to a height of 30.0mm above the breast support table at the chest wall edge. 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.

Thirteen more images were acquired and analysed as described above at intervals over the full four days of testing. Time points were chosen such that some repeats were in the morning before any other exposure whilst others were immediately after an intensive series of exposures or at the end of the day after a full day of use.

2.10 Detector response

The 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. The beam quality 28kVp W/Al0.7mm 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 or anti-scatter grid. 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.

2.11 Timings

Using a stopwatch, image timings were measured whilst imaging a 45mm thickness of PMMA using AEC with spacers to give 56mm displayed CBT in tomosynthesis mode and 53mm displayed CBT in 2D mode. Scan times were measured, from when the exposure button was pressed until the compression paddle was released, to when the reconstructed image appeared and to the moment when it was possible to start the next exposure.

2.12 Modulation transfer function

Modulation transfer function (MTF) measurements were made in tomosynthesis projection images as described in the EUREF protocol [7]. The radiation quality used for the measurements was adjusted by placing a uniform 2mm thick aluminium filter at the tube housing. The beam quality used was 28kVp W/$Al_{0.7mm}$. The test device to measure the MTF comprised a 100mm x 80mm rectangle of stainless steel with a polished straight edge, of thickness 2mm. This test device was placed directly on the breast support table and at 20mm, 40mm and 70mm above the breast support table. The test device was positioned to measure the MTF in two directions, first perpendicular to the CWE (direction of tube motion) and then parallel to it.

2.13 Local dense area

This test is described in the EUREF protocol [7]. Images of a 40mm thick block of PMMA, of size 180mm x 240mm, were acquired using AEC. Extra pieces of PMMA between 2 and 14mm thick and of size 20mm x 40mm were added to provide extra attenuation. The compression plate remained in position at a height of 50mm, as shown in Figure 3. The simulated dense area was positioned 50mm from the CWE of the table. The MAMMOMAT B.brilliant AEC pre-exposure is at an angle of -30 degrees and so the relative x-ray beam path length through the PMMA must be considered when setting up this test. Due to the geometry of the initial exposure the path length through the far side of the main PMMA without the extra pieces is longer than through the centre of the main PMMA including the additional pieces. To avoid this the main PMMA was rotated such that the short edge was parallel to the chest wall as shown in Figure 3.

In the simulated local dense area the mean pixel value and standard deviation for a 10mm x 10mm ROI were measured and the SNRs were calculated for the central projection images.

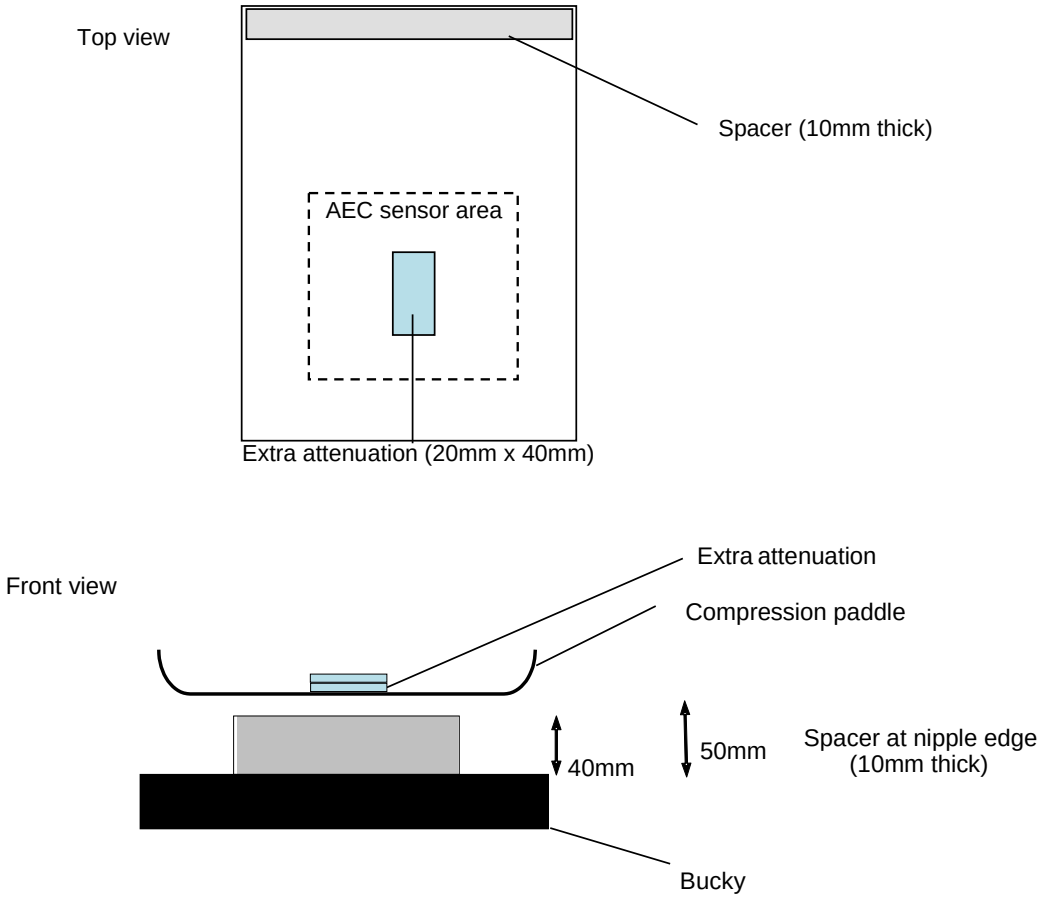

Figure 3. Setup to measure AEC performance for local dense areas

3. Results

3.1 Output and HVL

The measurements of HVL and tube output of the system in tomosynthesis mode are summarised in Table 3.

Table 3. HVL and tube output measurement in tomosynthesis mode

kVp	Target/filter	HVL (mm Al)	Output (μGy/mAs at 1m)
25	W/$Al_{0.7mm}$	0.46	15.9
28	W/$Al_{0.7mm}$	0.54	23.5
31	W/$Al_{0.7mm}$	0.62	31.3
34	W/$Al_{0.7mm}$	0.69	39.2
37	W/$Al_{0.7mm}$	0.75	47.2

3.2 Dose and contrast-to-noise ratio using AEC

The Dance MGDs to the standard breast model are shown in Figure 4. All MGDs include the preliminary exposure (variable depending on compression), which is not used in the reconstruction of the tomosynthesis planes. The dose limiting value from the EUREF protocol [7] is shown. The MGDs are shown in Table 4. For each thickness in table 4 we manually adjusted the CBTs by 3mm and saw no differences in OPDOSE factors. There were differences between the 2D and Tomosynthesis selected factors but since these modes use different filters this is unsurprising.

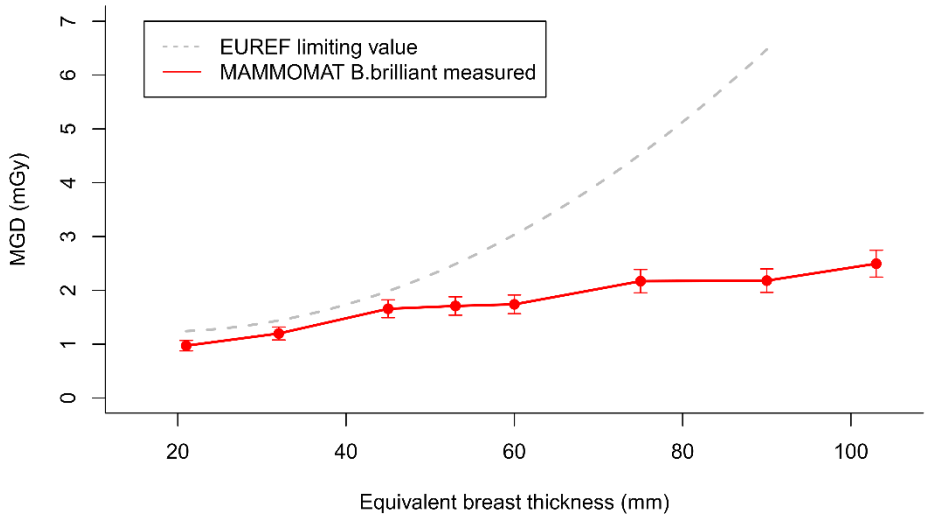

Figure 4. Dance MGD for tomosynthesis exposures acquired using AEC for different equivalent breast thickness. Error bars indicate 95% confidence limits.

Table 5. MGD for tomosynthesis images acquired using AEC

PMMA thickness (mm)	Equivalent breast thickness (mm)	AEC dose level	kV	Target/ filter	mAs	Dance MGD (mGy)	Dose limiting value (mGy)	Displa-yed dose (mGy)	TG282 MGD (mGy)
20	21	177%	25	W/Al$_{0.7mm}$	50	0.97	1.2	0.93	0.98
30	32	163%	26	W/Al$_{0.7mm}$	64	1.20	1.5	1.15	1.20
40	45	147%	26	W/Al$_{0.7mm}$	105	1.66	2.0	1.49	1.51
45	53	140%	27	W/Al$_{0.7mm}$	98	1.71	2.5	1.51	1.49
50	60	135%	28	W/Al$_{0.7mm}$	90	1.74	3.0	1.54	1.43
60	75	127%	29	W/Al$_{0.7mm}$	106	2.17	4.5	1.85	1.55
70	90	138%	32	W/Al$_{0.7mm}$	83	2.18	6.5	1.90	1.51
80	103	130%	33	W/Al$_{0.7mm}$	94	2.50	-	1.93	1.63

Figure 5 shows the CNRs measured in focal planes and unprocessed central projection images. Premia0 and Premia1 are the two main image processing “flavors” that Siemens provide by default on the system. The CNRs are also shown in Table 6 for the unprocessed projections and the default clinical processing for screening (premia0_screening). Figure 6 shows the CNR in the raw projection images at different projection angles.

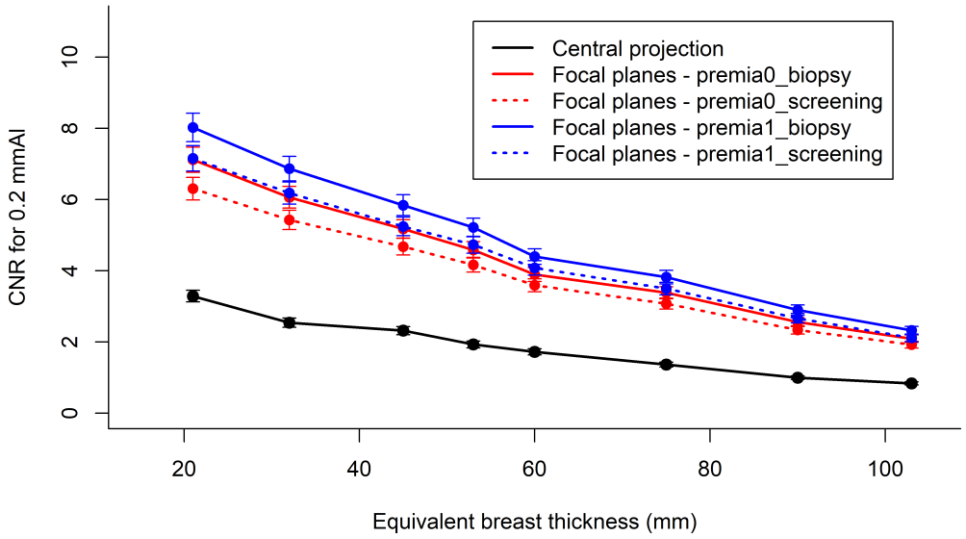

Figure 5. CNR for tomosynthesis images acquired using AEC for different equivalent breast thickness and image processing modes. Error bars indicate 95% confidence limits.

Table 6. CNR for tomosynthesis images acquired using AEC

PMMA thickness (mm)	Equivalent breast thickness (mm)	kV	Target/ filter	mAs	CNR	
					Focal planes (premia0_ screening)	Central projections
20	21	25	W/Al$_{0.7mm}$	1.89	6.30	3.29
30	32	26	W/Al$_{0.7mm}$	2.40	5.42	2.54
40	45	26	W/Al$_{0.7mm}$	4.03	4.68	2.32
45	53	27	W/Al$_{0.7mm}$	3.70	4.17	1.93
50	60	28	W/Al$_{0.7mm}$	3.41	3.59	1.72
60	75	29	W/Al$_{0.7mm}$	4.03	3.08	1.37
70	90	32	W/Al$_{0.7mm}$	3.14	2.34	0.99
80	103	33	W/Al$_{0.7mm}$	3.56	1.92	0.84

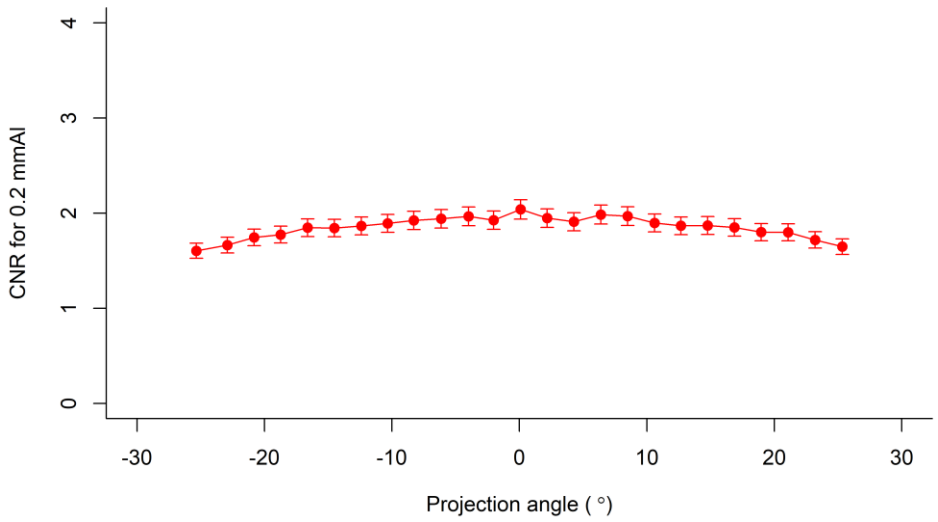

Figure 6. Variation of projection CNR with angle for images of 45mm PMMA. Error bars indicate 95% confidence limits.

3.3 Image quality measurements

In Figure 7 the threshold gold thicknesses are shown for the plane of best focus at approximately the AEC dose and twice and half the AEC dose using the Premia0 biopsy processing. The threshold gold thicknesses shown in Figure 7 are summarised in Table 7.

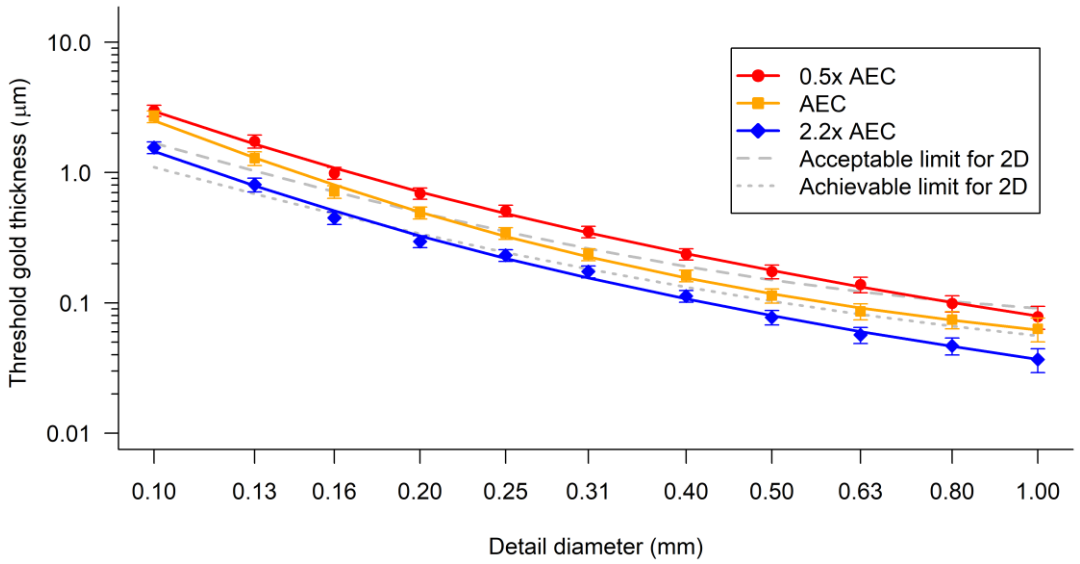

Figure 7. Threshold gold thickness for focal plane, at 3 dose levels for CDMAM 3.4. Error bars indicate 95% confidence limits.

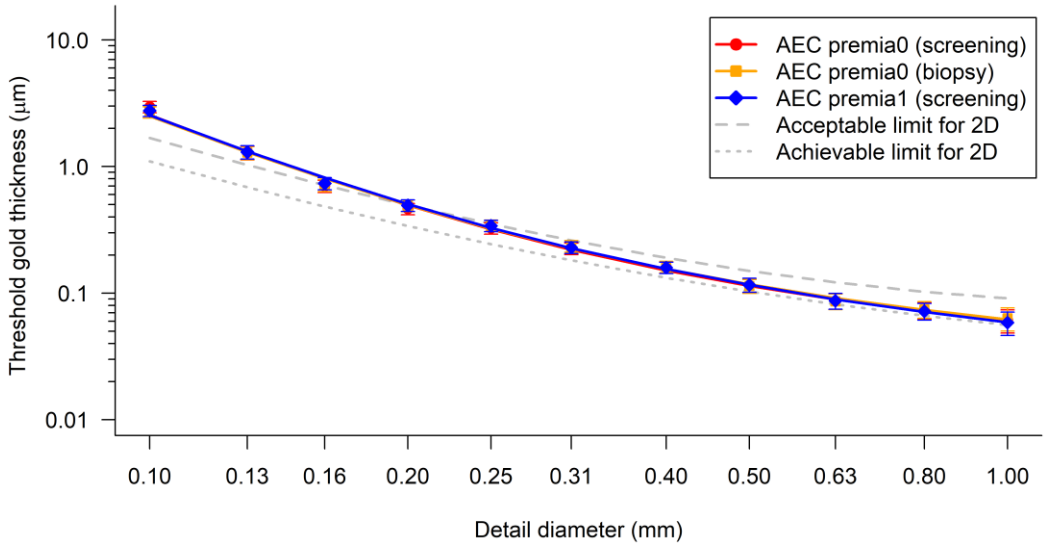

Figure 8. Variation with processing for CDMAM 3.4

Figure 8 shows how the CDMAM scores vary with the different processing options available. The differences between the curves are very small compared to the uncertainties in the fits.

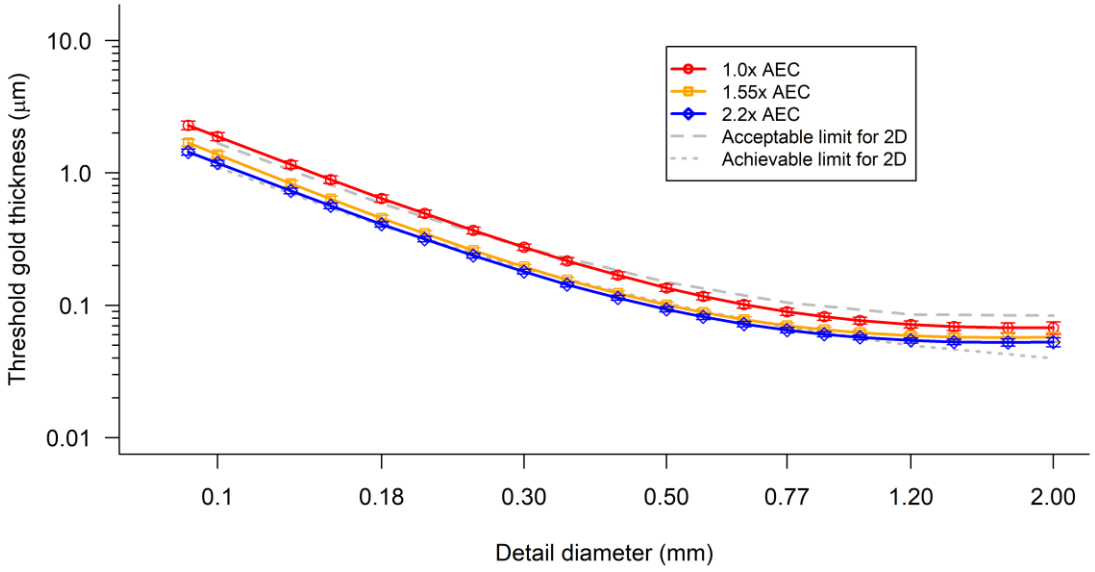

Figure 9 – CDMAM 4.0 Threshold gold thickness for focal plane, at 3 dose levels.

Figure 9 shows the result for the CDMAM 4.0 phantom. No results were available for the lowest dose setting. This is because the thickest details in the CDMAM 4.0 phantom are too thin to be resolved by the system in tomosynthesis mode at these very low dose levels. There was close agreement between the CDMAM 3.4 fits and the corresponding CDMAM 4.0 fits.

Table 7. Threshold gold thickness for reconstructed focal plane of the image of the CDMAM 3.4 phantom (automatically predicted data) for 3 dose levels (MGD)

Detail diameter (mm)	Threshold gold thickness (µm)		
	0.87mGy	1.74mGy	3.87mGy
0.1	2.96 ± 0.23	2.5 ± 0.2	1.45 ± 0.12
0.25	0.48 ± 0.04	0.32 ± 0.03	0.22 ± 0.02
0.5	0.18 ± 0.02	0.12 ± 0.01	0.08 ± 0.01
1.0	0.079 ± 0.011	0.062 ± 0.009	0.037 ± 0.005

3.4 Geometric distortion and resolution between focal planes

3.4.1 Height of best focus

All balls within each image were brought into focus at the same height (±1mm) above the table and within 2mm of the expected height. The phantom was tilted to be parallel to the

detector. This indicates that the focal planes are flat and parallel to the detector but not to the breast support table. There was no noticeable vertical distortion found in the image stack. The number of focal planes reconstructed is equal to the indicated breast thickness in millimetres plus one.

3.4.2 Positional accuracy within focal plane

In bio reconstruction mode the images are reconstructed to appear in Cartesian coordinates and so no significant distortion or scaling errors were seen within the focal planes. Scaling errors, in both the x and y directions, were found to be less than 0.4%. Maximum deviation from the average distance between the balls was 0.2mm in the x and y directions, compared to the manufacturing tolerance of 0.1mm in the positioning of the balls.

In screening mode, the pixel size varies with height in the image stack but the DICOM header only indicates a single value. This is set to the value for the central slice and so scaling errors are introduced as one moves through the focal planes away from the central slice. This is similar in other mammography systems.

The scaling errors in screening mode were found to be approximately 4% for the maximum height above the breast support tested (59.5mm). A maximum scaling error of roughly 11% was estimated for objects at the very upper or lower surface of a large breast (100mm compressed breast thickness).

3.4.3 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 faded and spread in the direction parallel to the CWE. The changing appearance of one of the balls through successive focal planes is shown in Figure 10.

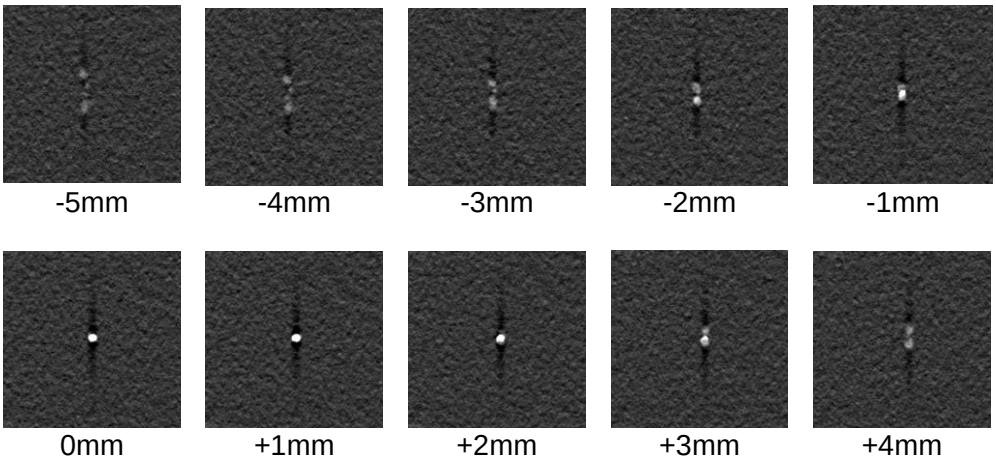

Figure 10. Appearance of 1mm aluminium balls in reconstructed focal planes at 1mm intervals, from 5mm below to 4mm above the plane of best focus

Image extracts for a ball positioned in the central area, 120mm from the chest wall, are shown in Figure 11 for both bio and screening reconstructions. In these images, pixels within the focal plane represent dimensions of approximately 85µm x 85µm. The spacing of reconstructed focal planes is 1mm.

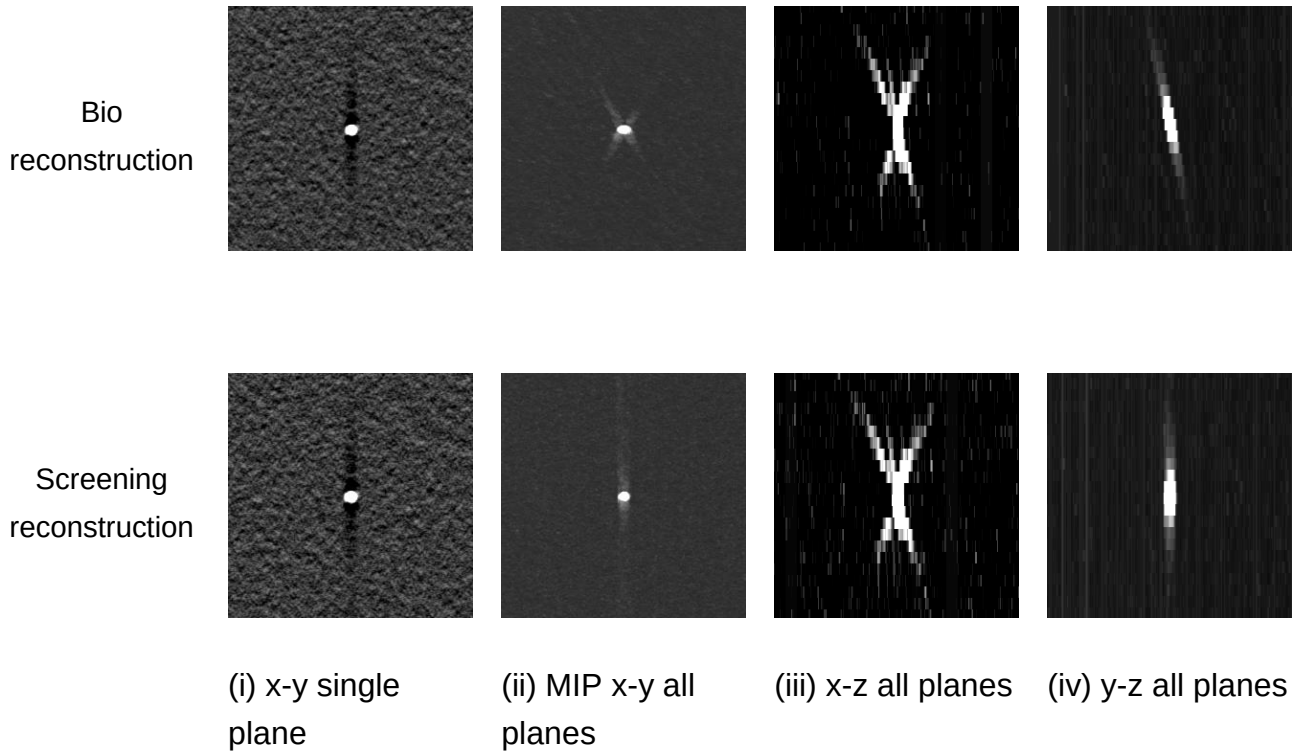

Figure 11. Extracts from planes showing 1mm aluminium ball in (i) single focal plane, (ii) Maximum Image Projection (MIP) through all focal planes, and through re-sliced vertical planes in the directions (iii) parallel and (iv) perpendicular to the chest wall.

Measurements of the z-FWHM of the reconstruction artefact associated with each ball are summarised in Table 8 for images of balls at several heights above the breast support table. These are slightly larger than the standard positions used in the NHSBSP protocol due to the presence of an angled wedge (7mm thick at the chest wall edge) which was used to tilt the phantom to keep it parallel to the detector plane.

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

Height above breast support (mm)	z-FWHM (range)
19.5	5.6 (4.3 to 8.3) mm
39.5	5.5 (4.2 to 7.6) mm
59.5	5.7 (3.8 to 7.6) mm

3.5 Alignment

The alignment of the X-ray field to the focal plane at the surface of the breast support table was assessed. At the chest wall edge the X-ray field overlapped the reconstructed tomosynthesis image by <5mm. The collimation at the lateral field edges was also assessed using a fluorescent screen which showed that the system implemented dynamic collimation.

The staples on the breast support and under the paddle were brought into focus within the reconstructed volume. There was no missed tissue at the bottom or top of the reconstructed volume.

3.6 Image uniformity and repeatability

In tomosynthesis mode the AEC selected the same tube voltage and target/filter combination for each of the five repeat exposures, and the tube load did not vary within the displayed precision of the mAs. For exposures repeated during the 4 days of the evaluation the tube load varied by a maximum of 0.8%, within the 5% limiting value in the EUREF protocol [7].

In the test of repeatability of the tomosynthesis reconstruction, over the full 4 days of testing, the maximum deviation from the mean SNR was found to be 4.0%, within the 10% limiting value in the EUREF protocol [7].

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

3.7 Detector response

The detector response for the central projection of tomosynthesis images acquired at 28kV W/Al0.7mm is shown in Figure 12.

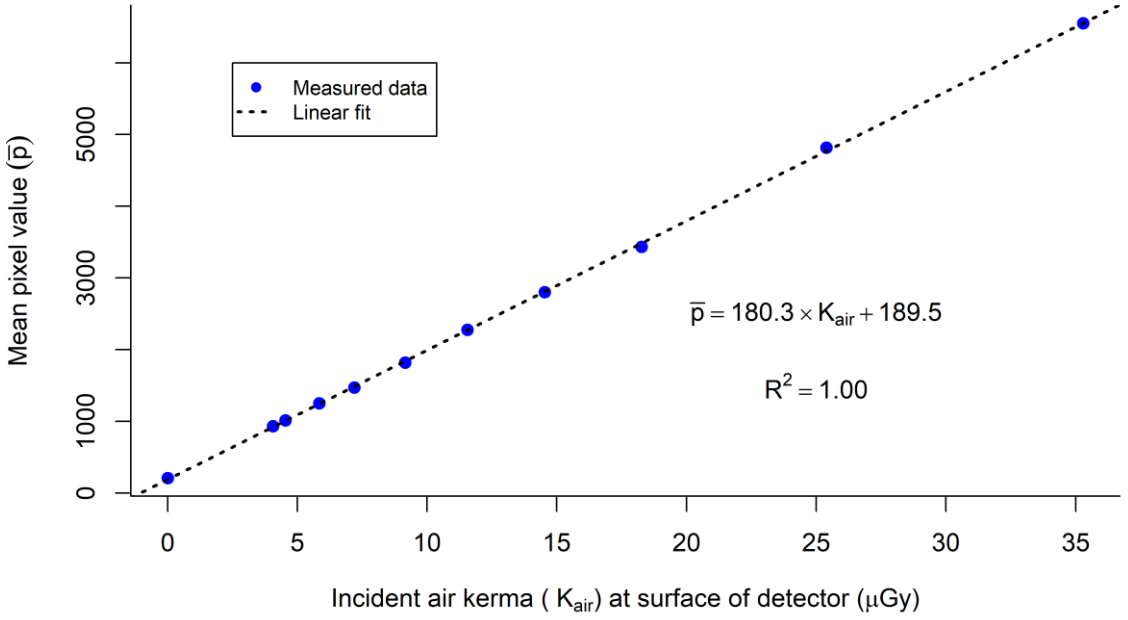

Figure 12. Detector response in tomosynthesis mode

3.8 Timings

Scan times for tomosynthesis only and tomosynthesis plus 2D combination modes are shown in Table 9. The times between consecutive exposures and between initiating the exposure to the release of the compression paddle were measured for acquiring images for a 53mm compressed breast thickness. These times include time for the reconstruction of the tomosynthesis planes and so those values will be related to the thickness of the volume being reconstructed.

Table 9. Scan and reconstruction timings

	Time
Tomosynthesis Only	
Time from start of exposure until decompression	10s
Time from start of exposure until next exposure is possible	10s
Time from decompression until reconstructed image displayed	56s
Combination mode (Tomosynthesis plus 2D)	
Time from start of exposure until decompression	34s
Time from start of exposure until next exposure is possible	34s

It is worth noting that, whilst the exposure can be undertaken without waiting for reconstruction of the previous exposure to complete, the reconstructions must all be completed before ending the examination. In addition, it would be good practice to inspect each reconstruction before proceeding to the next view in case any adjustments or repeats are required. If this approach is adopted then the effective time until the next exposure is possible should include the reconstruction time.

The timings presented here were measured after the acquisition of a very large number of tomosynthesis and 2D exposures over several days. Siemens state that the average time for reconstruction and display across their MAMMOMAT B.brilliant installations is <29s for a 48mm equivalent compressed breast thickness and <10s for 2D.

3.9 Modulation Transfer Function

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

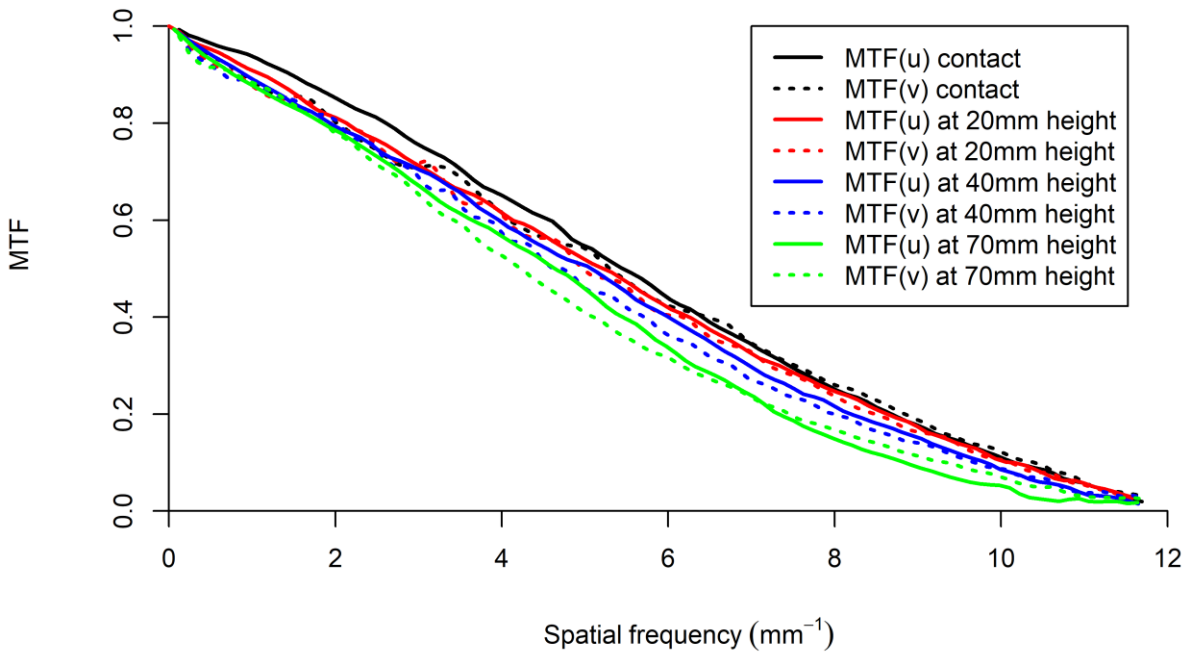

Figure 13. MTF for tomosynthesis central projections

Table 10. MTF for 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	0.94	0.89	0.90	0.89	0.88	0.88
2	0.86	0.81	0.79	0.81	0.78	0.79
3	0.75	0.71	0.71	0.69	0.68	0.65
4	0.65	0.62	0.59	0.58	0.57	0.53
5	0.55	0.54	0.51	0.46	0.46	0.41
6	0.44	0.43	0.40	0.37	0.33	0.32
7	0.34	0.34	0.30	0.27	0.24	0.23
8	0.25	0.26	0.21	0.20	0.15	0.17
9	0.17	0.19	0.15	0.14	0.09	0.11
10	0.11	0.12	0.08	0.09	0.05	0.07

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

Table 11. MTF50 for central projection

	u-direction (mm^{-1})	*v*-direction (mm^{-1})
0mm	5.4	5.3
20mm	5.2	5.0
40mm	5.0	4.7
70mm	4.7	4.2

3.10 Local dense area

The test in the EUREF protocol [7] 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 are presented in Table 12 and Figure 14. Unlike the Siemens Revelation and Inspiration the pre-pulse is acquired at an angle on the MAMMOMAT B.brilliant. This geometry means that, if the additional PMMA is positioned at the lateral midline, the path length through the main PMMA block can be longer than that through the additional PMMA and no change in mAs is observed. The results shown here were acquired with the additional PMMA positioned off centre from the midline. These show that the mAs was increased with the addition of the small pieces of PMMA, indicating that the AEC adjusts for local dense areas in tomosynthesis mode. The results show a small decrease in SNR but

are well within the 20% tolerance [7]. There was no change in the kV and anode/filter combination selected

Table 12. AEC performance for local dense areas, measured on the midline and 50mm from the CWE

Total attenuation (mm PMMA)	kV	Target/ filter	Tube load (mAs)	SNR	% SNR difference from mean SNR
40	27	W/Al$_{0.7mm}$	3.86	27.9	10.9
42	27	W/Al$_{0.7mm}$	3.80	26.6	5.6
44	27	W/Al$_{0.7mm}$	3.80	25.6	1.8
46	27	W/Al$_{0.7mm}$	3.66	24.0	-4.7
48	27	W/Al$_{0.7mm}$	4.0	24.3	-3.2
50	27	W/Al$_{0.7mm}$	4.33	24.1	-4.0
52	27	W/Al$_{0.7mm}$	4.68	24.3	-3.3
54	27	W/Al$_{0.7mm}$	4.96	24.4	-3.1

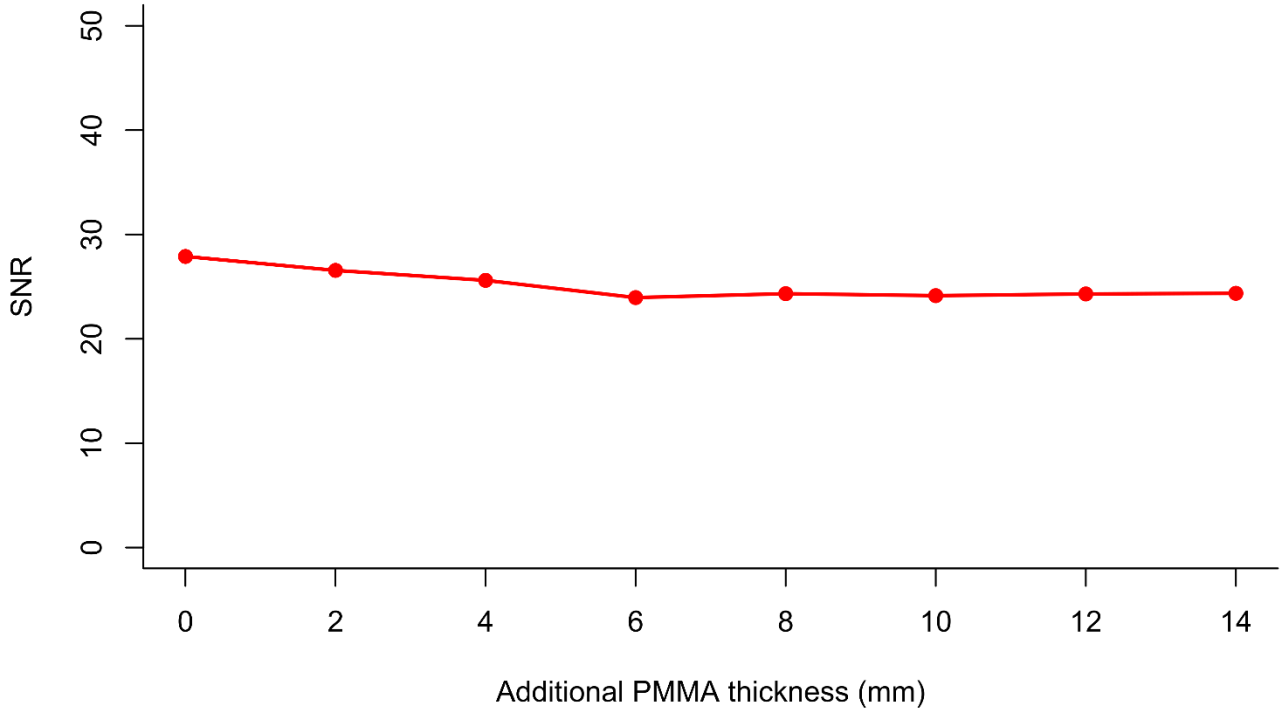

Figure 14. AEC performance in projection images for local dense areas

4. Discussion

4.1 Dose and contrast-to-noise ratio

The Dance MGDs in tomosynthesis mode were lower than the dose limiting values set for tomosynthesis systems in the EUREF protocol [7]. In the normal AEC dose mode the Dance MGD to the 53mm thick standard breast model was 1.71mGy (Table 5).

CNRs in projections and the resultant reconstructed planes showed a steady decrease with increasing breast thickness.

The “bio” reconstruction mode gave higher CNR in the tomosynthesis focal planes than the “screening” reconstruction and premia1 processing gave higher CNR than premia0.

4.2 Image quality

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. In the absence of any better test object for assessing tomosynthesis imaging performance, images of the CDMAM test object were acquired in tomosynthesis modes. This may help to quantify some aspects of the reconstructed image quality [10] and provide reference data for screening centres. At the dose close to that selected by the AEC, the threshold gold thickness for reconstructed focal planes was below the minimum acceptable level that is applied to 2D mammography for the two smallest details. However, it was close to or above the minimum acceptable level for mid-sized details and close to the achievable level for 2D for larger details. For increasing doses 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.

4.3 Geometric distortion and reconstruction artefacts

Assessment of geometric distortion demonstrated that the reconstructed tomosynthesis focal planes were flat and parallel to the detector rather than to the breast support, which is tilted. No vertical or in-plane distortion was seen and there were no significant scaling errors in bio mode.

In screening reconstruction mode, although only a single pixel size is given in the BTO format images, the true pixel size varies with height above the breast support. As a result scaling errors are larger in this mode. It is estimated that the scaling errors in screening mode will be no more than 11% for objects right at the upper or lower skin edge of a large (100mm CBT) breast. In practice there are many additional sources of uncertainty including radiologist choices of lesion edges; variations in mammographic positioning and compression; and differences in the imaging systems used between rounds. NHSBSP staff should be aware of the limitations on the accuracy of distance measurements in mammography.

Although the screening mode reconstruction introduces some scaling errors, as discussed above, Siemens state several advantages that the native cone beam geometry provides for radiologist viewing:

- When scrolling through the slices, out of plane artifacts that could not be compensated by the artifact reduction are at the same position as the structure that caused the artifacts
- When scrolling through the slices, micro-calcifications will stay at their location and will not jump between pixels.
- When scrolling through the slices the background noise does not tend to have a sideways moving direction.
- As there is no need to transfer from a perspective to a cartesian coordinate system, greater sharpness is seen in the final images
- When using a slabbing technology (at a viewing station), calcifications and breast structures will not be blurred.

The mean inter-plane resolution (z-FWHM) for the 1mm diameter balls was 5.7mm in bio mode and 5.8mm in screening mode.

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 with values of 0.8% and 4% respectively, below the limits of 5% and 10% respectively.

4.6 Modulation transfer function

Small differences are seen in the MTFs between the two orthogonal directions at all the heights above the breast support that were tested. The system acquires images while the x-ray tube is moving and this causes the *v*-direction (direction of tube motion) in the image to have a lower MTF. The system's flying focal spot is designed to oppose the motion of the tube and in effect keep the focal spot stationary during acquisition. Though this has not completely eliminated the degradation in the MTF in the direction of tube motion the fall in MTF is considerably less than was found in the evaluation of the Revelation system [5].

It is understood that the system applies processing to the projection images to correct for any additional signal present in images due to lag and/or ghosting. The effect of image acquisition during tube motion on the MTF of the projection tomosynthesis images is explored in a paper by Mackenzie et al [11].

4.7 Local dense area

The EUREF protocol [7] states that the system is expected to adjust the exposures in response to the thickness of added small pieces of PMMA. A provisional tolerance was that the SNR is kept within 20% of the average SNR.

The Siemens MAMMOMAT B.brilliant undertakes a low dose pre-exposure to set the radiographic factors. The factors are adjusted according to the densest area detected in the image. For increasing thicknesses of PMMA a small decrease in the SNR was seen but this was within the 20% tolerance.

With the additional small pieces of PMMA positioned at the lateral midline no change in mAs was observed. This was because the angled geometry of the pre-pulse was such that that the path length through the main PMMA block was actually greater than that through the additional PMMA. The consequence of this is that the exposure factors for the tomosynthesis acquisitions will be slightly higher than had the pre-pulses been acquired in the central position. However, arguably using the central projection for the pre-pulse could result in lower image quality in some regions of wider angle projections and, as shown in Figure 4, the Dance mean glandular doses for tomosynthesis were below the EUREF limiting values.

5. Conclusions

The technical performance of the Siemens MAMMOMAT B.brilliant digital breast tomosynthesis system was found to be satisfactory. At the moment, no image quality standards have been established for digital breast tomosynthesis systems.

The Dance MGD to the 53mm thick standard breast in tomosynthesis mode was found to be 1.71mGy. This is below the dose limiting value of 2.5mGy for tomosynthesis [7].

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