## NHS

Public Health
England

# NHS Breast Screening Programme Equipment Report 

Technical evaluation of GEOHealithcare Senographe Pristina digital breast tomosynthesis system

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## Executive summary

The technical performance of the GE Senographe Pristina digital breast tomosynthesis system was tested in tomosynthesis mode. The evaluation of the performance in 2D mode is published as a separate report. The mean glandular dose (MGD) to the standard breast was found to be 1.23 mGy , which is below the dose limiting value of 2.5 mGy for tomosynthesis in the EUREF protocol.

Technical performance of this equipment was found to be satisfactory, so that the system could proceed to practical evaluation in a screening centre. This reportprovides 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)


## 1. Introduction

1.1 Testing procedures and performance standards for digital mammography $Q$

This report is one of a series evaluating commercially available digital breast tomosynthesis systems on behalf of the NHS Breast Screening Programme (NHSBSP).1-4 The testing methods and standards applied are those of the relevant NHSBSP protocols, which are published as NHSBSP Equipment Reports. Report 14075 describes the testing of digitâ breast tomosynthesis systems.

The NHSBSP protocol is similar to the EUREF protocol,6 but the latter also providés additional or more detailed tests and standards, some of which are included tinthis evaluation.

### 1.2 Objectives

The aim of the evaluation was to measure the technical performance of the GE Senographe Pristina system in tomosynthesis mode.

## 2. Methods

### 2.1 System tested

The tests were conducted at the GE factory in Buc, France, on the Pristina system. Details of the system tested are given in Table 1.

Table 1. System description


The system can only select 1 of 3 different sets of radiographic factors using AEC. For 'radiological thicknesses' less than $35 \mathrm{~mm}, 26 \mathrm{kV}$ Mo/Mo is used. For radiological thickness equal to or greater than $35 \mathrm{~mm}, 34 \mathrm{kV} \mathrm{Rh} / \mathrm{Ag}$ is used. Radiological thickness is defined as the equivalent thickness of PMMA. The other set of radiographic factors $29 \mathrm{kV}, \mathrm{Mo} / \mathrm{Mo}$, is used for magnification views and is not used in tomosynthesis mode.

In both 2D and tomosynthesis modes, Automatic Optimization of Parameters (AOP) is used for automatic exposure control (AEC). The system acquires a low dose image with a pre-pulse exposure. The signal in a small region of interest is examined to determine the appropriate radiographic factors. If the radiological thickness is predicted to exceed 80 mm thickness of PMMA for tomosynthesis then an error message will be displayed, and it will not expose further. The radiographic factors selected for the pre-pulse are shown in Table 2.

Table 2. Radiographic factors for pre-pulse exposures, selected according to compressed breast thickness (CBT)

| CBT | Radiographic factors |
| :--- | :--- |
| $<38 \mathrm{~mm}$ | $26 \mathrm{kV} \mathrm{Mo} / \mathrm{Mo}, 2 \mathrm{mAs}$ |
| $\geq 38 \mathrm{~mm}$ and $\leq 65 \mathrm{~mm}$ | $34 \mathrm{kV} \mathrm{W} / \mathrm{Ag}, 2 \mathrm{mAs}$ |
| $>65 \mathrm{~mm}$ | 34 kV W $/ \mathrm{Ag}, 4 \mathrm{mAs}$ |

As the maximum compressed breast thickness (CBT) that canbe reconstructed in tomosynthesis mode is 130 mm , the system will prevent exposuresfor breasts exceeding that thickness.

The system has a static mode for tomosynthesis, in which the 9 projection images are acquired with the tube at $0^{\circ}$. This mode was used for measuring half value layer (HVL) and tube output.

The X-ray tube can travel from left to rightor right to left depending on which one is the closer when starting the tomosynthesis exposure.

This system uses a moving ant-scatter gridthat has been specifically designed for tomosynthesis. The grid lines are parallel to the tube motion.

There is no mode to automatically perform combination exposures, comprising a 2D and a tomosynthesis exposure in the same compression.

Table 3. Image file sizes for 60 mm CBT, $24 \mathrm{~cm} \times 29 \mathrm{~cm}$ field size

| Format | Pixelsper <br> frame | Frames per <br> image | Total image <br> file size (MB) |
| :--- | :---: | :---: | :---: |
| Projections | $2394 \times 2850$ <br> planes | 23 <br> $2394 \times 2850$ | 145 |
| Slabs | $2394 \times 2850$ | 17 | 120 |

Exampl volume depends on the CBT and field size.

The Senographe Pristina is shown in Figure 1.


Figure 1. The GE Senographe Pristina digital breast tomosynthesis system (image courtesy of GE Healthcare)

### 2.2 Dose and contrast-to-noise ratiousing AEC

### 2.2.1 Dose measurement

To calculate the MGD to the standard breast, measurements were made of HVL and tube output, at the 2 available kVand target/filter combinations. The output measurements were made on the midline at the standard position of 40 mm from the chest wall edge (CWE) of the breast supportyplatform. 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 PIMMA) weremade 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.
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The method of measuring tomosynthesis doses described in the UK protocol differs slightly from the method described by Dance et al. ${ }^{7}$ The incident air kerma is measured with the compression paddle well above, instead of in contact with, the ion chamber. Measurements on other systems ${ }^{1,2}$ show that this variation reduces the air kerma and thus the mean glandular
dose (MGD) measurement by $3 \%$ to $5 \%$. Otherwise the MGDs in tomosynthesis mode were calculated using the method described by Dance et al. ${ }^{7}$

This is an extension of the established 2D method, using the equation:
$D=K g c s T$
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 derivedlby summing weighted correction factors for each of the tomosynthesis projections. Values of $q$ are tabulated ${ }^{6}$ for the GE Senographe Essential for different CBTs, and the same values are appropriate for the Pristina, because it has the same geometry.

### 2.2.2 Contrast-to-noise ratio

For contrast-to-noise ratio (CNR) measurements, a $10 \mathrm{~mm} \times 10 \mathrm{~mm}$ square of 0.2 mm thick aluminium foil was included in the PMMA phantom, oosifioned tomm above the table on the midline, 60 mm from the CWE.

The CNR was measured in the focal plane in whien the aluminium square was brought into focus. The $5 \mathrm{~mm} \times 5 \mathrm{~mm}$ regions of interests (ROI) were subdivided into $1 \mathrm{~mm} \times 1 \mathrm{~mm}$ elements and the background ROIs were positioned adjacentrothe aluminium square, as shown in Figure 2. The mean pixel values and their standard deviations were averaged over all the 1 mm $\times 1 \mathrm{~mm}$ elements, and the CNR was calculated from these averages.

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

The variation in central projection ENR with breast thickness and the variation in projection CNR with projectionangle fer $a 53 \mathrm{~mm}$ breast were also assessed.

Figure 2. The position of $5 \mathrm{~mm} \times 5 \mathrm{~mm}$ ROls for assessment of CNR (The CWE is to the left)

### 2.3 Image quality measurements

A CDMAM phantom (Version 3.4, serial number 1022,UMC St. Radboud, Nijmegen University, Netherlands) was positioned between 2 blocks of PMMÂ, each 20 mm thick. The exposure factors were chosen to be close to those selected by the AEC, when imaging a 50 mm thickness of PMMA. This procedure was repeatedto obtain arepresentative sample of 16 images at this dose level. Two further sets of 8 images at double and half this dose were then acquired.

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

This analysis was repeated for the slab which included the height of the CDMAM phantom above the breast supporttable.
2.4 geometric distortion and reconstruction artefacts

The relationship between reconstructed tomosynthesis focal planes and the physical geometry of the volume that they represent was assessed. This was done by imaging a geometric test phantom consisting of a rectangular array of 1 mm diameter aluminium balls at 50 mm intervals in the middle of a 5 mm thick sheet of PMMA. The phantom was placed at various heights (7.5, 32.5 , and 52.5 mm ) above the breast support table, within a 60 mm stack of plain sheets of PMMA. Reconstructed tomosynthesis planes were analysed to find the height of the focal plane in which each ball was best in focus, the position of the centre of the ball within that plane, and the number of adjacent planes in which the ball was also seen. The variation in appearance of the ball between focal planes was quantified.

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

### 2.4.1 Height of best focus

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

### 2.4.2 Positional accuracy within focal plane

The $x$ and $y$ co-ordinates within the image were found for each ball)( $x$ and $y$ are perpendicular and parallel to the CWE, respectively). The mean distances petween 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 sealing 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 facal planes

Changes to the appearance of a ball between focalplanes 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 3dimensional volume. The software tool was used to find the z-dimension of a cuboid around each ball which would enclose allpixels with values exceeding $50 \%$ of the maximum pixel value. The methodused was to re-slice the image vertically and create a composite $x-z$ image using the maximumpixel 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 mâximúm (FWHM) measurement in the $z$-direction was made by fitting a polynomial spline. Allpixel 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.

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. This was first done with no compression
applied and then repeated with the chest wall edge of the paddle supported and 100 N compression applied.

### 2.6 Image uniformity and repeatability

The reproducibility of the tomosynthesis exposures was tested by acquiring a series of 5 images of a 45 mm thick block of PMMA using AEC. A $10 \mathrm{~mm} \times 10 \mathrm{~mm}$ ROI was positioned 60 mm from the chest wall edge in the plane corresponding to a height of 22.5 mm above the breast support table. The mean and standard deviation of the pixel values in the ROI were found and the SNR was calculated for each image. These images and others acquired during the course of the evaluation were evaluated for artefacts by visual inspection.

The set of 16 tomosynthesis CDMAM images was also used to test the repeatability of the reconstructed tomosynthesis images. The signal to noise ratio (SNR) was calculated just outside the CDMAM grid in the same position in the in-focus plane from each reconstructed image.

### 2.7 Detector response

The detector response was measured for the detector operating in tomosynthesis mode. A 2 mm thick aluminium filter was placed in the beam and attached to the tube port. The compression paddle was removed. The 2 available bean qualities ( $26 \mathrm{kV} \mathrm{Mo} / \mathrm{Mo}, 34 \mathrm{kV} \mathrm{Rh} / \mathrm{Ag}$ ) were selected and images were acquired using arange 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 $10 \mathrm{~mm} \approx 10 \mathrm{~mm}$ ROI was positioned on the midline, 50 mm from the chest wall edge of the centralprojection image. The mean pixel value was measured and plotted against air kermá incident at the detector.

### 2.8 Timings

Using a stopwatch, imagetimings were measured while imaging a 45 mm thickness of PMMA using AEG. Scan times were measured, from when the exposure button was pressed until the compression paddle was released, and to the moment when it was possible to start the next exposure. Reconstructed images were not displayed on the acquisition workstation, so the reconstructiontime was not noted.

### 2.9 Modulation transfer function

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

This test is described in the EUREF protocol. ${ }^{6}$ Images of a 30 mm thick block a PMMA, of size $180 \mathrm{~mm} \times 240 \mathrm{~mm}$, were acquired using AEC. Extra pieces of PMMA between 2 and 20 mm thick and of size $20 \mathrm{~mm} \times 40 \mathrm{~mm}$ were added to provide extra attenuation. The compression plate remained in position at a height of 40 mm , as shown in Figure 3. The simulated dense area was positioned 50 mm from the CWE of the table.

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


Figure 3. Set-up to measure AEC performance for local dense areas


## 3. Results

### 3.1 Dose and contrast-to-noise ratio using AEC

The measurements of HVL and tube output of the system in tomosynthesis mode are summarised in Table 4.

Table 4. HVL and tube output measurement in tomosynthesis mode

| kV | Target/filter | $\mathrm{HVL}(\mathrm{mm} \mathrm{Al})$ | Output $(\mu \mathrm{Gy} / \mathrm{mAs}$ at 1 m$)$ |
| :--- | :---: | :---: | :---: | :---: |
| 26 | $\mathrm{Mo} / \mathrm{Mo}$ | 0.34 | 26.7 |
| 34 | $\mathrm{Rh} / \mathrm{Ag}$ | 0.54 | 45.2 |

The MGDs to the standard breast model are shown in Figure 4. All MGDs include the preliminary exposure, which is not included in the image. The doselimiting value from the EUREF protocol ${ }^{6}$ is shown. The MGDs are shown in Table 5.


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

Table 5. Dose for tomosynthesis images acquired using AEC

| PMMA <br> thickness <br> $(m m)$ | Equivalent <br> breast <br> thickness <br> $(\mathrm{mm})$ | kV | Target/ <br> filter | mAs | MGD <br> $(\mathrm{mGy})$ | Dose <br> limiting <br> value <br> $(\mathrm{mGy})$ | Displa- <br> yed <br> dose <br> $(\mathrm{mGy})$ | Displayed <br> \% higher <br> than <br> MGD |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- |
| 20 | 21 | 26 | $\mathrm{Mo} / \mathrm{Mo}$ | 18.0 | 0.51 | 1.2 | 0.53 | $3.8 \%$ |

Figure 5 shows the CNRs measured in focal planes, central projection images and slabs. The CNRs are shown in Table 6. Figure 6 shows the CNR in the projection images at different projection angles.


Figure 5. CNB for tomosynthesis images acquired using AEC. Error bars indicate 95\% cońntidence limits.

Table 6. CNR for tomosynthesis images acquired using AEC


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

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The lowest threshold gold thicknesses were obtained for focal plane 54 and slab 5. In Figures 7 and 8, the threshold gold thicknesses are shown for focal plane 54 and slab 5 at approximately the AEC dose and twice and half the AEC dose. The threshold gold thicknesses shown in Figures 7 and 8 are summarised in Table 7.


Figure 7. Threshold gold thickness for plane 54, at 3 dose levels. Error bars indicate 95\% confidence limits.


Figure 8. Threshold gold thickness for slab 5, at 3 dose levels. Error bars indicate 95\% confidence limits.

Table 7. Threshold gold thickness for reconstructed focal plane 54 and slab 5 of the image of the CDMAM phantom (automatically predicted data)

| Detail <br> diameter <br> $(\mathrm{mm})$ | Threshold gold thickness $(\mu \mathrm{m})$ |  |  |  |  |  |
| :--- | :--- | :--- | :--- | :--- | :--- | :---: |
|  | Plane | Plane | Plane | Slab | Slab | Slab |
| 0.1 | $1.87 \pm 0.27$ | $1.41 \pm 0.14$ | $0.95 \pm 0.15$ | $3.69 \pm 0.62$ | $2.20 \pm 0.22$ | $1.77 \pm 0.27$ |
| 0.25 | $0.35 \pm 0.05$ | $0.25 \pm 0.03$ | $0.20 \pm 0.03$ | $0.62 \pm 0.10$ | $0.40 \pm 0.04$ | $0.33 \pm 0.05$ |
| 0.5 | $0.13 \pm 0.02$ | $0.11 \pm 0.01$ | $0.089 \pm 0.017$ | $0.22 \pm 0.05$ | $0.17 \pm 0.02$ | $0.17 \pm 0.03$ |
| 1.0 | $0.070 \pm 0.020$ | $0.063 \pm 0.013$ | $0.037 \pm 0.011$ | $0.12 \pm 0.04$ | $0.096 \pm 0.019$ | $0.088 \pm 0.027$ |

### 3.3 Geometric distortion and resolution between focal planes

### 3.3.1 Height of best focus

All balls within each image (planes and slabs) were brought into focus at the same height ( $\pm 1 \mathrm{~mm}$ ) above the table, and within 1 mm of the expected planes are flat and parallel to the surface of the breast support table, with no noticeable vertical distortion.

Additional planes are reconstructed below the breast sypport table and above the compression paddle. The first focal plane corresponds to approximately 5 mm below the breast support table. The last focal plane corresponds to approximately 7 mm above the underside of the compression paddle. With the 0.5 mm plane spacing used for testing, the number of focal planes reconstructed is equal to twice the indicated breast thickness in millimetre plus 25 for planes and $1 / 5$ of the indicatedBreast thickness plus 2 for slabs.

### 3.3.2 Positional accuracywithin focal plane

No significant distortion or scaling error was seen within focal planes. Scaling errors, in both the $x$ and $y$ directions, were found to be less than $0.5 \%$. Maximum deviation from the average distance between the balls was 0.18 mm in the $x$ and $y$ directions, compared to the manufacturing tolerance of 0.1 mm in the positioning of the balls.
3.3.3 Appearance of the ball in adjacent focal planes
in the ptane of best focus the aluminium balls appeared well defined and circular. When viewing süccessive planes, moving away from the plane of best focus, the images of the balls Shrank in the direction parallel to the CWE. The changing appearance of one of the balls through successive focal planes and slabs is shown in Figures 9 and 10.


Figure 9. Appearance of 1 mm aluminium balls in reconstructed focal planes at 1 mm intervals, from 4 mm below to 3 mm above the plane of best focus

$-5 \mathrm{~mm}$


0 mm

$+5 \mathrm{~mm}$

$+10 \mathrm{~mm}$

Figure 10. Appearance of 1 mm aluminium balls in reconstructed slabs at 5 mm intervals, from 5 mm below to 10 mm above the slab af best focus

Image extracts for a ballpositioned in the central area, 120 mm from the chest wall, are shown in Figure 11. In these images, pixels within the focal plane represent dimensions of approximately $0.1 \mathrm{~mm} \times 0.1 \mathrm{~mm}$, The spacing of reconstructed focal planes is 0.5 mm .


Figure 11. Extracts from planes showing 1 mm 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 pall are summarised in Table 8 for images of balls at heights of $7.5 \mathrm{~mm}, 32.5 \mathrm{~mm}$ and 52.5 mm above the breast support table.

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

|  | z-FWHM (range) |
| :--- | :---: |
| Planes | $7.9 \mathrm{~mm}(6.3$ to 14.0$)$ |
| Slabs | $13.1 \mathrm{~mm}(10.2$ to 17.0$)$ |

### 3.4 Alignment

The staples on the breast support and under the paddle were brought into focus within the reconstructed volume. With 100 N compression applied and only the chest wall edge of the paddle supported, the staples under the compression paddle near the CWE of the paddle were in focus within the reconstructed volume.

There was no missed tissue atthe bottom or top of the reconstructed volume.
The chest wall edge of the breast support was measured to be 5 mm from the edge of the detector This was on the limit of acceptability.

In tomosyntbesis mode the AEC selected the same tube voltage and target/filter combination for each of the 5 repeat exposures, and the tube load varied by a maximum of $1 \%$. For exposures repeated during the 3 days of the evaluation the tube load varied by a maximum of $2 \%$, within the $5 \%$ limiting value in the EUREF protocol. ${ }^{6}$

In the test of repeatability of the tomosynthesis reconstruction, using images of the CDMAM phantom, the maximum deviation from the mean SNR was found to be $2 \%$.

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

### 3.6 Detector response

The detector response for the central projection of tomosynthesis images acquired at 26 kV $\mathrm{Mo} / \mathrm{Mo}$ and $34 \mathrm{kV} \mathrm{Rh} / \mathrm{Ag}$, with anti-scatter grid, is shown in Figure 12.


Figure 12. Detector response in tomosynthesis mode

### 3.7 Timings

Scan times are shown in Table 9. The tomosynthesis images are reconstructed within the acquisition workstation and then sent to a review workstation for display. A review station was not available and so the time from decompression until the reconstructed image is displayed was not measured.

Table 9. Scan and reconstruction timings

|  | Time |
| :--- | :---: |
| Timefrom start of exposure until decompression | 9 s |
| Time from start of exposure until next exposure is possible | 17 s |
| Time from decompression until reconstructed image | not measured |
| displayed |  |

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


Figure 13. MTF for central projections
Table 10 MTF for central projections in the directions parallel (u) and perpendicular (v) to the tube axis

| Spatial frequency ( $\mathrm{mm}^{-1}$ ) | 0 mm above table |  | 40 mm $\therefore$ above table |  |
| :---: | :---: | :---: | :---: | :---: |
|  | u | v |  |  |
| 0 | 1.00 | 1.00 | 1.00 | 1.00 |
| 1 | 0.85 | 0.84 | 0.83 | 0.82 |
| 2 | 0.65 | 0.66 | 0.63 | 0.64 |
| 3 | 0.45 | 0.47 | 0.44 | 0.46 |
| 4 | 0.30 | 0.32 | 0.29 | 0.31 |
| 5 | 0.20 | 0.22 | 0.19 | 0.21 |
| 6 | 0.12 | 0.15 | 0.12 | 0.14 |
| 7 | 0.08 | 0.11 | 0.07 | 0.09 |
| 8 | 0.07 | 0.09 | 0.06 | 0.07 |
| 9 | 0.08 | 0.09 | 0.08 | 0.07 |
| 10 | 0.09 | 0.08 | 0.09 | 0.08 |

The spatiat frequencies of the 50\% MTF (MTF50) are shown in Table 11.
Fable 11 MTF50 for central projection

|  | u-direction | v-direction |
| :--- | :---: | :---: |
| 0 mm | $2.73 \mathrm{~mm}^{-1}$ | $2.83 \mathrm{~mm}^{-1}$ |
| 40 mm | $2.66 \mathrm{~mm}^{-1}$ | $2.75 \mathrm{~mm}^{-1}$ |

### 3.9 Local dense area

Exposures were found to vary with addition of the small pieces of PMMA, indicating that the AEC adjusts for local dense areas in tomosynthesis mode. The system changed from 26kV $\mathrm{Mo} / \mathrm{Mo}$ to 34 kV Rh/Ag between 34 mm and 36 mm of total thickness of PMMA. It was expectéd to switch at 35 mm .

The test in the EUREF protocol ${ }^{6}$ is based on an assumption that when the AEC adjusts for local dense areas, the SNR should remain constant with increasing thickness of extra PMMA. The results are presented in Table 12 and Figure 14. The results show a large change in SNR between 34 mm and 36 mm of PMMA, accompanied by a change in the kV and anode/fitter combination. This results in SNR differences from the mean SNR value of arger than the 20\% tolerance. ${ }^{6}$ If the SNR results for only the $34 \mathrm{kV}, \mathrm{Rh} / \mathrm{Ag}$ are used, then the SNR are within the $20 \%$ tolerance. It should be noted that this tolerance was set in the protoco for a base of 40 mm PMMA rather than 30mm PMMA used in this report.

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

| from the CW |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Total |  |  |  |  |  |  |
| attenuation <br> (mm PMMA) | kV | Target/ filter | Tube loa (mAs) |  |  | only 34 kV , <br> Rh/Ag |
| 32 | 26 | $\mathrm{Mo} / \mathrm{Mo}$ | 43.0 |  | -24\% | - |
| 34 | 26 | $\mathrm{Mo} / \mathrm{Mo}$ | - 55.1 | 3.3 | -23\% | - |
| 36 | 34 | $\mathrm{Rh} / \mathrm{Ag}$ | 20.2 | 20.0 | 14\% | 7\% |
| 38 | 34 | RhwAg | 21.4 | 19.6 | 12\% | 5\% |
| 40 | 34 | Rh/Ag | +23.0 | 18.9 | 10\% | 3\% |
| 42 |  | Rh/Ag | 24.6 | 18.8 | 8\% | 1\% |
| 44 |  | $\mathrm{Rh} / \mathrm{Ag}$ | 26.4 | 18.2 | 6\% | -1\% |
| 46 |  | $\mathrm{Rh} / \mathrm{Ag}$ | 27.8 | 18.2 | 2\% | -4\% |
| 48 | 34 | Bh/Ag | 29.4 | 17.4 | -5\% | -11\% |



Figure 14. AEC performance in projection images fo 1ocal dense areas

## 4. Discussion

### 4.1 Dose and contrast-to-noise ratio

The MGDs in tomosynthesis mode were lower than the dose limiting values set for tomosynthesis systems in the EUREF protocol. ${ }^{6}$


CNRs in projections showed a steady decrease with increasing breast thickness, but the ONR in the resultant reconstructed planes and slabs were relatively constant with breast thickhess.

### 4.2 Image quality

In the absence of any better test object for assessing tomosynthesis imaging performance, images of the CDMAM test object were acquired in tomosynthesis modes. At the dose close to that selected by the AEC, the threshold gold thickness for reconstrugted focal planes was better than the minimum acceptable level and, for detail diameters greater than 0.13 mm , close to the achievable level of image quality that is applied to 2D mammography. Results were determined for focal plane number 54 and slab 5 , which gayethe best results for planes and slabs respectively. For double and half the AEC selected dose the threshold gold thickness changed as expected.

These results take no account of the ability of tomosynthesis to remove the obscuring effects of overlying tissue in a clinical image and the degree of this effect is expected to vary between tomosynthesis systems. Thereis as yetno 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 tést object would need to incorporate simulated breast tissue to show the benefit ofremoving querlying breast structure in tomosynthesis imaging, as compared to 2D imaging.

### 4.3 Geometric distertion and reconstruction artefacts

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

The reconstructed tomosynthesis volume starts about 5 mm below the surface of the breast support table and continues 8 mm above the nominal height of the compression paddle. This is useful in that it allows for a small margin of error in the calibration of the indicated thickness or some slight tilt of the compression paddle, without missing tissue at the bottom or top of the reconstructed image.

The mean inter-plane resolution (z-FWHM) for the 1 mm diameter balls was 7.9 mm and 13.1 mm for the planes and slabs respectively.

### 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.
The distance between the chest wall edge and the detector was 5 mm . This is on the limit in the EUREF protocol. ${ }^{6}$

### 4.5 Image uniformity and repeatability

The repeatability of tomosynthesis AEC exposures and the repeatability oftomosynthesis reconstructions were satisfactory with values of between 1 and $2 \%$, well below the limit of $5 \%$.

### 4.6 Modulation transfer function

There are only small differences in the MTFs between the 2 orthogonal directions and there is little reduction in the MTF at 40 mm above the breast Support. The system uses step and shoot acquisition and so the x-ray tube is stationary during exposure. There is some geometric blurring due to the size of the focal spot. The effect on the MTF is small at this height, according to Marshall and Bosmans, 2012.8 The effect of step and shoot and tube motion during acquisition on the MTF of the projection tomosynthesis images is explored in a paper by Mackenzie et al. ${ }^{9}$

### 4.7 Local dense area



The EUREF protocol ${ }^{6}$ states that the system is expected to adjust the exposures in response to the thickness of added PMMA. A provisional tolerance was that the SNR is kept within $20 \%$ of the average SNR.

The GE Senogrâphe Pristina undertakes a low dose pre-exposure to set the radiographic factors. The factors are adjusted according to the densest area detected in the image. However there is a large change in SNR when the exposure factors change with added thickness of PMMA. If 40 mm thick block of PMMA had been used for this test (as described in the EUREF protocol ${ }^{6}$ ), then the change in kV and anode/filter combination would have been avoided. The appropriateness of the $20 \%$ tolerance is in doubt if a system changes the radiographic factors as the PMMA is added, as occurred here. For this system, using only the SNR results for radiographic factors of $34 \mathrm{kV}, \mathrm{Rh} / \mathrm{Ag}$, then the results were within the $20 \%$ tolerance.

## 5. Conclusions

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

The MGD to the 53 mm thick standard breast in tomosynthesis mode was found to be 1.23 mGy . This is below the dose limiting value of 2.5 mGy for tomosynthesis. ${ }^{6}$

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