Technical evaluation of Hologic Selenia Dimensions digital breast tomosynthesis system
NHSBSP Equipment Report 1307

October 2013
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Published July 2013
PHE gateway number:
## Document Information

<table>
<thead>
<tr>
<th>Title</th>
<th>Technical evaluation of Hologic Selenia Dimensions digital breast tomosynthesis system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy/document type</td>
<td>Equipment Report 1307</td>
</tr>
<tr>
<td>Electronic publication date</td>
<td>October 2013</td>
</tr>
<tr>
<td>Version</td>
<td>1</td>
</tr>
<tr>
<td>Superseded publications</td>
<td>None</td>
</tr>
<tr>
<td>Review date</td>
<td>None</td>
</tr>
</tbody>
</table>
| Author/s | CJ Strudley  
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| Owner | Comments may be sent to Ken Young ken.young@nhs.net in readiness for review. |
| Document objective (clinical/healthcare/social questions covered) | To provide an evaluation of this equipment’s suitability for use within the NHSBSP |
| Population affected | Women eligible for routine and higher-risk breast screening |
| Target audience | Physicists, radiographers, radiologists |
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Acknowledgements

The authors are grateful to the staff at Aberdeen Breast Screening Centre for their assistance in evaluating the unit at their site.
Executive summary

The purpose of this evaluation was to measure the technical performance of the Hologic Dimensions digital breast tomosynthesis system. Tests were carried out of both 2D and tomosynthesis technical performance. 2D performance met current NHSBSP standards for digital mammography, with 2D image quality better than the achievable target level. No performance standards have yet been set for digital breast tomosynthesis systems.

Measurements of the tomosynthesis mean glandular dose to the standard breast model were made, and found to be well within the NHSBSP dose limits for 2D mammography. This report also provides baseline performance measurements on other aspects of the equipment, including image quality, noise, spatial distortion, and alignment.
1. Introduction

1.1 Testing procedures and performance standards for digital mammography

Testing procedures and performance standards for conventional 2D mammography are well established and documented\(^1\)\(^2\) but there are not as yet any nationally agreed procedures and standards for digital breast tomosynthesis (DBT) systems. The tests of tomosynthesis performance employed for this evaluation were based on those used for the TOMMY trial.\(^3\)

1.2 Objectives

The purpose of this evaluation was to measure the technical performance of the Hologic Dimensions DBT system. The technical performance of 2D Hologic Selenia Dimensions systems with the original and with the more recently updated automatic exposure control (AEC) software has previously been assessed and reported\(^4\)\(^5\).

For this evaluation, some of the tests in 2D mode were repeated and further tests of performance in DBT mode were also carried out. Research is ongoing to assess the clinical effectiveness of DBT and further work will be required to establish measures of technical performance which indicate acceptable clinical performance. The results of this evaluation will establish whether the conventional 2D performance of the DBT system is compliant with current performance standards. The tomosynthesis performance results in this report may be suggestive of clinical performance and may allow comparisons between systems to be made, but should be interpreted with caution until further experience in tomosynthesis performance evaluation has been gained.

Any decision to approve the use of tomosynthesis in screening or assessment in the NHS Breast Screening Programme (NHSBSP) will depend on a review of the available evidence and a practical evaluation by the NHSBSP.
2. Methods

2.1 System tested

The Dimensions system employs a tungsten target with a rhodium or silver filter for conventional 2D imaging, and an aluminium filter for tomosynthesis imaging. To assist in the measurement of tube output and beam quality using the aluminium filter, a Zero Degree Tomo mode is provided, where a pulsed X-ray exposure is performed with the tube remaining stationary.

The same 18 x 24 cm and 24 x 29 cm compression paddles are used for tomosynthesis scans and for 2D imaging. As well as acquiring individual 2D and tomosynthesis images, the system is also able to acquire a ‘Combo view’ which consists of a tomosynthesis view automatically followed by a 2D view during the same compression.

There are three AEC modes available for tomosynthesis: Autofilter and AutokV, in which a pre-pulse (tube load 5 mAs) is used to determine the tube voltage and tube load; Autotime, which enables the user to select the tube voltage with the pre-pulse determining the tube load; and a manual mode, which allows the user to select both the tube voltage and tube load.

During a tomosynthesis acquisition the X-ray tube rotates about a centre of rotation which is at the height of the detector surface, 25 mm below the surface of the breast support table. The tube moves to the starting position at an angle of approximately -7.5 degrees, the pre-pulse is performed while the tube is stationary, and then the projections are acquired at approximately one degree intervals while the tube is in motion. Collimation is fixed during the tomosynthesis scan, the breast support is stationary, the detector rotates slightly as the tube moves, and no grid is used.

Hologic recommend that quality control (QC) images are acquired using the Flatfield Tomo views, which were used for all of the tomosynthesis tests included in this report. It should be noted that these views are reconstructed using raw projections to which no scatter corrections have been applied. Therefore, the reconstructed tomosynthesis planes have a noticeable low frequency variation which is not evident in the clinical tomosynthesis views.

Details of the system tested are given in Table 1.
Table 1  System description

<table>
<thead>
<tr>
<th>Software version</th>
<th>AWS:1.4.2.</th>
</tr>
</thead>
</table>
| Target/ filter combination | 2D: Tungsten target with 50 µm rhodium or 50 µm silver filter  
Tomosynthesis: Tungsten target with 700 µm aluminium filter |
| Tomosynthesis projections | 15 equal dose projections at approximately one degree intervals from -7.5 to +7.5 degrees. |
| Reconstructed focal planes | At 1 mm vertical intervals. Total number of planes equals the compressed breast thickness in mm plus 5. Maximum compressed thickness for tomosynthesis scan is 244 mm. |

Table 2  Conventional and tomosynthesis image file sizes for large (24 x 29 cm) format

<table>
<thead>
<tr>
<th>Pixel size</th>
<th>File downloaded from acquisition workstation</th>
<th>File containing extracted projections/focal planes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2D</td>
<td>70 µm</td>
<td>27 MB</td>
</tr>
<tr>
<td>Tomosynthesis projections</td>
<td>140 µm</td>
<td>30 – 40 MB*</td>
</tr>
<tr>
<td>Tomosynthesis reconstructed focal planes</td>
<td>Approx 100 µm**</td>
<td>33 – 80 MB*</td>
</tr>
</tbody>
</table>

*For a range of compressed breast thicknesses from 20 to 90 mm. **The pixel size varies with height of the reconstructed focal plane above the breast support table. In later software versions BTO and CT format tomosynthesis images have a fixed pixel size for all focal planes to enhance compatibility with third party Picture Archiving and Communication System (PACS) workstations.

Images for QC purposes can be downloaded from the acquisition workstation via a USB port or written to a DVD. The tomosynthesis images from this system are in the DICOM® secondary capture (SC) format. For each Flatfield Tomo image there are two SC files, the first containing the projections and the second containing the reconstructed focal planes. It is necessary to use a Hologic proprietary tool (which Hologic have not yet made generally available) to extract the focal planes and projections from the SC files. (More recent Dimensions AWS software versions make images available in the DICOM Breast Tomosynthesis Object (BTO) or the Computerised Tomography (CT) format, enabling direct visualisation of the focal planes with
DICOM viewer software.) Typical image file sizes for large (24 x 29 cm) format images from the system tested are shown in Table 2.

2.2 Dose and contrast to noise ratio under AEC control

Measurements were made of mean glandular dose (MGD) to the standard breast model simulated using Perspex (polymethylmethacrylate or PMMA) and measurements of contrast to noise ratio (CNR) were made using the same phantom with a contrast object included.

2.2.1 Dose measurement

Measurements were made of half value layer (HVL) and tube output across the clinically relevant range of kV and filter combinations for the purpose of calculating MGD to the standard breast. Output measurements were made both with the compression paddle in contact with the ion chamber and with the paddle raised well above the ion chamber.

In both conventional and tomosynthesis modes, exposures of a range of thicknesses of PMMA were made under AEC control (Autofilter). The paddle was positioned so that the correct equivalent breast thickness was displayed by the compressed breast thickness indicator for each thickness of PMMA, leaving an air gap between the top of the PMMA and the paddle. (It is not necessary to use spacers to create an air gap for the Dimensions system as compression is not required for QC images.)

2D doses were calculated using the established method as described in the UK protocol. Tomosynthesis doses were calculated using the method described by Dance et al. This method of calculating tomosynthesis MGD is an extension of the established 2D method and the equation used is shown below (Equation 1). An additional factor, T, is used, which is derived by summing weighted correction factors for each of the tomosynthesis projections. Values of T are tabulated for the Hologic Selenia Dimensions system in Dance’s paper, and vary with compressed breast thickness. The Dance method of MGD calculation uses a measured dose at the surface of the breast with the paddle in place, but the method described in the UK protocol differs in that dose is measured with the paddle raised well above the ion chamber. In order to allow comparisons to be made between systems, MGD results in this report are calculated with the paddle raised. A correction factor is provided, which may be used to obtain a more accurate calculation of MGD.

\[ D = KgcsT \]  \hspace{1cm} (1)
2.2.2 Contrast to noise ratio

For CNR measurements a 10 mm x 10 mm square of 0.2 mm thick aluminium foil was included in the phantom described above, positioned 10 mm above the table on the midline, 60 mm from the chest wall edge.

2D CNR was assessed using 5 mm x 5 mm regions of interest (ROIs) positioned in the centre of the aluminium square and at two background positions on the chest wall and nipple sides of the square.

Tomosynthesis focal plane CNR was assessed using 5 mm x 5 mm ROIs at the same positions as for the 2D image but subdivided into 1 mm x 1 mm elements, as shown in Figure 1. Subdivided ROIs were used to reduce the effect of image non-uniformity on the CNR result. (The non-uniformity is due to the use of Flatfield Tomo images for QC, which have been reconstructed without processing.) The CNR was measured in the focal plane containing the aluminium square and in two planes above and a further two planes below. The result quoted is the average of the results from the five planes.

CNR was also assessed in the unprocessed tomosynthesis projections acquired for the above images, using a 5 mm x 5 mm ROI (not subdivided).

Variation of tomosynthesis CNR with dose was assessed both in the projections and in the reconstructed images, for a simulated breast thickness of 53 mm (i.e. using a 45 mm thickness of PMMA).

![Figure 1](image.png)
2.3 Image quality measurements

Image quality was assessed in 2D mode using a CDMAM phantom. In the absence of a suitable test object for assessing tomosynthesis imaging performance, images were also acquired of the CDMAM in tomosynthesis mode. The CDMAM phantom (Version 3.4, serial number 1022)* was sandwiched between two blocks of PMMA, each of which was 2 cm thick. The exposure factors used were the same as would be selected by the AEC for an equivalent breast thickness of 60 mm. One set of sixteen images was acquired in 2D mode at the AEC selected dose level. In tomosynthesis mode one set of sixteen images was acquired at the AEC selected dose level, and two further sets at approximately half and double this dose level.

The tomosynthesis images were sorted by selecting from each image the focal plane in best focus corresponding to the actual height of the CDMAM above the breast support table. The set of conventional images and the three sets of tomosynthesis planes were read and analysed using two software tools: CDCOM version 1.6† and CDMAM Analysis version 1.4‡. Due to the non-uniformity of the unfiltered tomosynthesis focal planes, it was necessary to flatfield them prior to reading, otherwise CDCOM either failed to read the images or gave poor results. The flatfielding was achieved by cropping each image close to the useful area of the CDMAM and then padding out to achieve an image size with dimensions equal to a power of two. A Butterworth filter was applied in the frequency domain to remove the higher frequencies, including the grid and contrast details of the CDMAM. The original image was then divided by the filtered image and the pixel values rescaled. This was repeated using the planes immediately above and below the expected plane of best focus to ensure that the CDMAM result quoted corresponded to the best image quality obtained. It should be noted that the currently available version of CDCOM is designed to work with 2D images in the DICOM MG format, and will not work directly with tomosynthesis images in the DICOM BTO format, which is available from later Hologic Dimensions software versions.

2D image quality assessed using the CDMAM applies to an equivalent breast thickness of 60 mm. This can be related to the image quality at other thicknesses by comparing the CNRs measured for a range of thicknesses. The European protocol§ gives the relationship between threshold contrast and CNR measurements, which enables calculation of a target CNR value for a particular level of image quality, which can be compared to CNR measurements made for other breast thicknesses. Contrast for a particular gold thickness is calculated using Equation 2, and target CNR is calculated using Equation 3.

\[
\text{Contrast} = 1 - e^{-\mu t}
\]

(2)

where \(\mu\) is the effective attenuation coefficient for gold, and \(t\) is the gold thickness.

* UMC St. Radboud, Nijmegen University, Netherlands
‡ CDMAM analysis UK v1.4, NCCPM, Guildford, UK
\[
\text{CNR}_{\text{target}} = \frac{\text{CNR}_{\text{measured}} \times \text{TC}_{\text{measured}}}{\text{TC}_{\text{target}}}
\]  

where \( \text{CNR}_{\text{measured}} \) is the CNR for a 60 mm equivalent breast, \( \text{TC}_{\text{measured}} \) is the threshold contrast calculated using the threshold gold thickness for a 0.1 mm diameter detail as measured using the CDMAM at the same dose as used for \( \text{CNR}_{\text{measured}} \), and \( \text{TC}_{\text{target}} \) is the calculated threshold contrast corresponding to the threshold gold thickness required to meet either the minimum acceptable or achievable level of image quality as defined in the UK standard.

The European protocol\(^2\) also defines a limiting value for CNR, which is calculated as a percentage of the threshold contrast for minimum acceptable image quality, and varies with thickness. Target CNR values for minimum acceptable and achievable levels of image quality and European limiting values for CNR were calculated for comparison with the CNR results presented in section 3.1.

2.4 Geometric distortion and reconstruction artefacts

An assessment was made of the relationship between reconstructed tomosynthesis focal planes and the actual geometry of the volume that they represent. 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, positioned horizontally at various heights within a 60 mm thick 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, the number of adjacent planes in which the ball was also seen, and to quantify the variation in appearance of the ball between focal planes.

This analysis was automated using a software tool developed at NCCPM for this purpose. This software is in the form of a plug-in for use in conjunction with ImageJ.\(^6\)

2.4.1 Height of best focus

The height of the focal plane in which each ball was best in focus was identified for each ball. 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.

\(^6\) http://rsb.info.nih.gov/ij/
2.4.2 Positional accuracy within focal plane

The x (perpendicular to chest wall edge) and y (parallel to chest wall edge) co-ordinates within the image were found for each ball. The mean distances between adjacent balls were calculated using the pixel spacing quoted in the DICOM image header, and compared to the actual separation of balls within the phantom in order 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 discernable distortion of the image within the focal plane.

2.4.3 Appearance of the ball in adjacent focal planes

Changes to appearance of a ball between focal planes were assessed visually and are described in the results section of this report.

In order 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 three dimensional volume. The software tool was used, in effect, to find the x, y, and z dimensions of a rectangular volume around each ball which would enclose all pixels with values exceeding 50% of the maximum pixel value. The actual method used was to create a composite x-y image using the maximum pixel values from all focal planes. A composite x line was then created using the maximum pixel from each column of the x-y composite plane, and a full width half maximum FWHM measurement in the x direction was made by fitting a polynomial spline. This was repeated in the orthogonal direction to produce the y-FWHM, and again using vertical re-sliced planes to find the z-FWHM. 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 ball imaged for the purpose) was used as a measure of the inter-plane resolution, or z-resolution.

The FWHM in the x- and y-directions of the image of the ball were also measured in the plane of best focus, in order to compare against the composite x- and y-FWHM measurements, so that any apparent shift or spread in the appearance of the ball through a series of adjacent focal planes could be quantified.

2.5 Alignment

Alignment measurements were carried out for reconstructed tomosynthesis images.

The alignment of the X-ray beam to one focal plane of the reconstructed tomosynthesis volume was assessed at the height of the centre of rotation of the X-ray beam at the surface of the breast support table. This was done using self-developing film and graduated markers positioned on each edge of the X-ray beam. The alignment at the lateral edges was only measured at this height because, at other heights, the movement of the tube during the scan would cause the lateral edges of the X-ray beam to move between projections.
The alignment of the imaged volume to the compressed volume was also assessed. Missed tissue at the chest wall edge was assessed at heights of 0, 6, and 10 cm above the table using graduated markers aligned vertically above the chest wall edge of the table. In order to assess vertical alignment, small high contrast markers were placed on the breast support table and on the underside of the compression paddle, and the image planes were inspected to check whether all markers were brought into focus within the reconstructed tomosynthesis volume.
3. Results

3.1 Dose and contrast to noise ratio under AEC control

Measurements of HVL and tube output were made on the midline at the standard position, 4 cm from the chest wall edge of the breast support platform. The paddle was in the beam and was raised well above the ion chamber. These measurements are summarised in Table 3. When measurements were made on this unit, both with the paddle in contact with the upper surface of the ion chamber, and with the paddle raised well above the ion chamber, the increase in dose measured with the paddle in contact was 3%.

<table>
<thead>
<tr>
<th>kV</th>
<th>Target</th>
<th>Filter</th>
<th>HVL</th>
<th>Tube output µGy/mAs at 1m</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>W</td>
<td>Rh</td>
<td>0.48</td>
<td>11.4</td>
</tr>
<tr>
<td>28</td>
<td>W</td>
<td>Rh</td>
<td>0.52</td>
<td>16.0</td>
</tr>
<tr>
<td>31</td>
<td>W</td>
<td>Rh</td>
<td>0.55</td>
<td>20.4</td>
</tr>
<tr>
<td>31</td>
<td>W</td>
<td>Ag</td>
<td>0.57</td>
<td>27.4</td>
</tr>
<tr>
<td>34</td>
<td>W</td>
<td>Ag</td>
<td>0.59</td>
<td>33.8</td>
</tr>
<tr>
<td>25</td>
<td>W</td>
<td>Al</td>
<td>0.44</td>
<td>20.1</td>
</tr>
<tr>
<td>28</td>
<td>W</td>
<td>Al</td>
<td>0.50</td>
<td>29.3</td>
</tr>
<tr>
<td>31</td>
<td>W</td>
<td>Al</td>
<td>0.55</td>
<td>39.4</td>
</tr>
<tr>
<td>34</td>
<td>W</td>
<td>Al</td>
<td>0.60</td>
<td>50.4</td>
</tr>
<tr>
<td>37</td>
<td>W</td>
<td>Al</td>
<td>0.65</td>
<td>62.3</td>
</tr>
<tr>
<td>40</td>
<td>W</td>
<td>Al</td>
<td>0.70</td>
<td>75.2</td>
</tr>
<tr>
<td>43</td>
<td>W</td>
<td>Al</td>
<td>0.74</td>
<td>89.0</td>
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Under AEC control (Autofilter), different of thicknesses of PMMA were imaged in both 2D and tomosynthesis modes to find the exposure factors selected for each equivalent breast thickness. These results were used to calculate the conventional 2D and tomosynthesis doses as shown in Tables 4 and 5, and presented graphically in Figure 2.

The conventional 2D CNR measurements for a 0.2 mm thickness of aluminium foil are shown in Table 4. The CNRs measured for the same contrast target are shown for both the reconstructed tomosynthesis images and for the central (zero degree) 2D projection images in Table 5. The 2D and tomosynthesis CNR results are also presented graphically in Figures 3 and 4. Figure 3 includes the target levels of CNR required for the NHSBSP minimum acceptable and achievable levels of 2D image quality (3.4 and 5.0 respectively), as calculated using the CDMAM results (section 3.2), and also the European limiting value of CNR.
Table 4  Dose measurements for conventional 2D images under AEC control

<table>
<thead>
<tr>
<th>PMMA (mm)</th>
<th>Equivalent breast thickness (mm)</th>
<th>kV</th>
<th>Target / filter</th>
<th>mAs†</th>
<th>MGD†* (mGy)</th>
<th>NHSBSP dose limit (mGy)</th>
<th>CNR</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>21</td>
<td>25</td>
<td>W / Rh</td>
<td>50</td>
<td>0.65</td>
<td>1.0</td>
<td>10.9</td>
</tr>
<tr>
<td>30</td>
<td>32</td>
<td>26</td>
<td>W / Rh</td>
<td>72</td>
<td>0.86</td>
<td>1.5</td>
<td>9.6</td>
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<td>40</td>
<td>45</td>
<td>28</td>
<td>W / Rh</td>
<td>94</td>
<td>1.19</td>
<td>2.0</td>
<td>8.7</td>
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<td>45</td>
<td>53</td>
<td>29</td>
<td>W / Rh</td>
<td>115</td>
<td>1.49</td>
<td>2.5</td>
<td>8.2</td>
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<tr>
<td>50</td>
<td>60</td>
<td>31</td>
<td>W / Ag</td>
<td>139</td>
<td>2.04</td>
<td>3.0</td>
<td>8.2</td>
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<tr>
<td>60</td>
<td>75</td>
<td>31</td>
<td>W / Ag</td>
<td>152</td>
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<td>4.5</td>
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<tr>
<td>70</td>
<td>90</td>
<td>34</td>
<td>W / Ag</td>
<td>146</td>
<td>2.93</td>
<td>6.5</td>
<td>6.1</td>
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†The mAs and MGD values quoted here include the pre-exposure pulse (tubeload 5 mAs for indicated thickness less than 50 mm, 10 mAs for 50 mm or more), which is not included in the image. *These MGD values were calculated using output measurements made with the paddle raised well above the ion chamber. In order to correct to a more precise measurement including scatter from the paddle, a multiplying factor of 1.03 should be applied.

Table 5  Dose measurements for tomosynthesis images under AEC control

<table>
<thead>
<tr>
<th>PMMA (mm)</th>
<th>Equivalent breast thickness (mm)</th>
<th>kV</th>
<th>Target / filter</th>
<th>mAs*</th>
<th>MGD† (mGy)</th>
<th>CNR in reconstructed tomosynthesis image</th>
<th>CNR in central projection#</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>21</td>
<td>26</td>
<td>W / Al</td>
<td>36</td>
<td>0.91</td>
<td>29.7</td>
<td>5.07</td>
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<tr>
<td>30</td>
<td>32</td>
<td>28</td>
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<tr>
<td>40</td>
<td>45</td>
<td>30</td>
<td>W / Al</td>
<td>46</td>
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<tr>
<td>45</td>
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<td>W / Al</td>
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<td>75</td>
<td>36</td>
<td>W / Al</td>
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<td>3.30</td>
<td>14.3</td>
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</tr>
<tr>
<td>70</td>
<td>90</td>
<td>42</td>
<td>W / Al</td>
<td>64</td>
<td>4.22</td>
<td>10.9</td>
<td>2.16</td>
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</tbody>
</table>

*The mAs recorded here is the total mAs including the pre-exposure pulse (tube load 5 mAs), which is not included in the reconstructed image. †These MGD values were calculated using output measurements made with the paddle raised well above the ion chamber. In order to correct to a more precise measurement including scatter from the paddle, a factor of 1.03 should be applied. ‡The dose for the individual projection from which this CNR is calculated is one fifteenth of the total image dose from which the reconstructed tomosynthesis CNR is calculated.
Technical evaluation of Hologic Selenia Dimensions digital breast tomosynthesis system

Figure 2  PMMA mean glandular doses for 2D and tomosynthesis images under AEC control

Figure 3  Measured 2D CNR for images obtained under AEC control compared with limiting values for this system to meet 2D image quality standards, as defined in the NHSBSP and European standards.
CNR for tomosynthesis images obtained under AEC control. Measurements are shown for both the central projection, for which the dose is one fifteenth of the total, as well as for focal planes within the reconstructed tomosynthesis image.

The variation of tomosynthesis CNR with dose is shown in Table 6 and Figure 5.

<table>
<thead>
<tr>
<th>PMMA (mm)</th>
<th>Equivalent breast thickness (mm)</th>
<th>kV</th>
<th>Target / filter</th>
<th>mAs</th>
<th>MGD (mGy)</th>
<th>CNR in reconstructed DBT image</th>
<th>CNR in central projection*</th>
</tr>
</thead>
<tbody>
<tr>
<td>45</td>
<td>53</td>
<td>31</td>
<td>W / Al</td>
<td>16</td>
<td>0.50</td>
<td>9.3</td>
<td>1.77</td>
</tr>
<tr>
<td>45</td>
<td>53</td>
<td>31</td>
<td>W / Al</td>
<td>30</td>
<td>0.93</td>
<td>12.9</td>
<td>2.48</td>
</tr>
<tr>
<td>45</td>
<td>53</td>
<td>31</td>
<td>W / Al</td>
<td>60</td>
<td>1.87</td>
<td>17.9</td>
<td>3.72</td>
</tr>
<tr>
<td>45</td>
<td>53</td>
<td>31</td>
<td>W / Al</td>
<td>120</td>
<td>3.74</td>
<td>25.5</td>
<td>5.15</td>
</tr>
</tbody>
</table>

*CNR in a single projection for which the dose is one fifteenth of the total dose for the tomosynthesis image.

A power fit was applied to the relationships between CNR and dose for reconstructed focal planes and projections in Figure 5. The variation of projection CNR with tube angle is shown for three equivalent breast thicknesses in Figure 6.
3.2 Image quality measurements

The threshold gold thickness detection curve is shown in Figure 7 for sixteen conventional 2D images of the CDMAM acquired at the same dose as would be obtained under AEC control for an equivalent breast thickness of 60 mm.
Figure 7  Threshold gold thickness detail detection curves for conventional images taken at the dose selected under AEC control. The beam quality selected was 31 kV W/Rh.

In Figure 8 the tomosynthesis CDMAM curves are shown for the sets of sixteen images that were assessed using the flat-fielded slice in best focus from each image. The tomosynthesis CDMAM performance was assessed at the same dose as obtained under AEC control for a 60 mm equivalent breast and again at half and twice this dose.

The 2D and tomosynthesis image quality results shown in Figures 7 and 8 are summarised in Table 7.
Figure 8  Threshold gold thickness detail detection curves for tomosynthesis images acquired using the exposure factors selected under AEC control and at half and double this dose level. The beam quality selected was 33 kV W/Al.

Table 7  Measured threshold gold thicknesses for 2D and tomosynthesis CDMAM images compared to the NHSBSP standards for 2D image quality

<table>
<thead>
<tr>
<th>Detail diameter (mm)</th>
<th>2D AEC dose (mGy)</th>
<th>DBT AEC dose (mGy)</th>
<th>DBT half AEC dose (mGy)</th>
<th>DBT double AEC dose (mGy)</th>
<th>Minimum standard for 2D</th>
<th>Achievable standard for 2D</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1</td>
<td>0.635</td>
<td>1.125</td>
<td>1.690</td>
<td>0.879</td>
<td>1.680</td>
<td>1.100</td>
</tr>
<tr>
<td>0.25</td>
<td>0.173</td>
<td>0.215</td>
<td>0.276</td>
<td>0.178</td>
<td>0.352</td>
<td>0.244</td>
</tr>
<tr>
<td>0.5</td>
<td>0.086</td>
<td>0.092</td>
<td>0.119</td>
<td>0.072</td>
<td>0.150</td>
<td>0.103</td>
</tr>
<tr>
<td>1.0</td>
<td>0.044</td>
<td>0.045</td>
<td>0.062</td>
<td>0.034</td>
<td>0.091</td>
<td>0.056</td>
</tr>
</tbody>
</table>

The 2D threshold gold thickness for a 0.1 mm diameter detail was used to calculate target CNR values of 3.4 and 5.0 for minimum acceptable and achievable levels of image quality using an equivalent attenuation coefficient of 0.120 for the beam quality selected (31 W/Rh). These target CNR levels are shown compared to measured CNR values in Figure 3.
3.3 Geometric distortion and resolution between focal planes

The geometric phantom was imaged with the balls at heights of 7.5, 32.5, and 57.5 mm above the breast support table. An image was also acquired with the test tool attached to the underside of the paddle positioned such that the indicated breast thickness was 100 mm, so the balls were at a nominal height of 97.5 mm above the table. However, without compression, the paddle sloped down slightly towards the chest wall edge.

3.3.1 Height of best focus

For the three images where the geometric test tool was within the PMMA stack on the breast support table, the height of best focus for each ball was found to correspond closely to (i.e. to be within 1 mm of) the actual height of the balls above the table, with a variation of no more than 1 mm across the image. This indicates that the reconstructed focal planes are parallel to the surface of the table, with no vertical distortion.

In the image of the test tool attached to the bottom of the compression paddle, the height of best focus matched the nominal height of the balls at the rear of the image and decreased towards the chest wall edge of the image by 2 to 3 mm due to the tilt of the paddle without compression.

3.3.2 Positional accuracy within focal plane

The mean distances calculated between balls using the pixel spacings from the DICOM headers were 52.0 mm in both the x and y directions. These compare to an actual separation of 50.0 mm between balls, indicating a 4% scaling error. The maximum deviations from the mean separations were 0.2 mm in the x and y directions for all images, compared to the test object manufacturing specification of a non-cumulative positioning accuracy of +/-0.1 mm. These results indicate that there is no discernable geometric distortion within the focal plane.

3.3.3 Appearance of the ball in adjacent focal planes

The image of a 1 mm diameter aluminium ball is well defined in the plane of best focus, with no artefact. As one moves to adjacent focal planes the image of the ball becomes fainter, and stretches into a line parallel to the chest wall edge of the image, as shown in Figure 9.

Figure 10 shows the focal planes re-sliced into vertical planes in the x-z and y-z orientations.
Figure 9. Views from focal planes at different heights of a 1 mm aluminium ball, 11 cm from the chest wall edge in the central area of a DBT image. The views shown are taken from focal planes at 2 mm intervals, from 24 mm below to 24 mm above the plane corresponding to the actual height of the ball.

Figure 10. Vertically resliced planes through the centre of a 1 mm aluminium ball, 11 cm from the chest wall edge in the central area of a DBT image. The x-z plane is on the left and the y-z plane is on the right.
Results of the automated analysis for all balls in all the images at heights of 7.5, 32.5, 57.5, and 97.5 mm above the breast support table are presented in Table 8. The variations of these measurements with position within the reconstructed image are presented graphically in Figures 11 to 15.

The difference between x- or y-FWHM measurements of a ball in the single plane corresponding to the apparent position of the ball, and the composite x- or y-FWHM measurements using the maximum pixel values from all planes gives a measure of any apparent shift or spread of the image of the ball between planes, which is also shown in Table 8.

The composite FWHM in the direction perpendicular to the chest wall is seen in Figure 11 to have no significant dependence on position within the image. The composite FWHM in the direction parallel to the chest wall edge is seen in Figure 12 to have no significant dependence on position within the image either.

The composite z-FWHM measurements give a measure of the inter-plane or z-resolution for the tomosynthesis image. This is seen in Figures 13, 14, and 15 to have slight dependence on position within the image. The composite z-FWHM increases very slightly with distance from the centre of the chest wall edge, and decreases slightly with increasing height above the breast support table.

Table 8  Mean dimensions in terms of FWHM for 1 mm diameter aluminium balls and their associated reconstruction artefacts

<table>
<thead>
<tr>
<th></th>
<th>FWHM within plane of best focus (range)</th>
<th>Composite FWHM using all planes (range)</th>
<th>Apparent shift or spread between focal planes (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>X (perpendicular to chest wall edge)</strong></td>
<td>0.88 mm (0.84 to 0.93)</td>
<td>0.89 mm (0.86 to 0.93)</td>
<td>0.01 mm (-0.01 to 0.04)</td>
</tr>
<tr>
<td><strong>Y (parallel to chest wall edge)</strong></td>
<td>0.88 mm (0.83 to 0.91)</td>
<td>0.94 mm (0.89 to 0.99)</td>
<td>0.05 mm (0.01 to 0.09)</td>
</tr>
<tr>
<td><strong>Z (vertical)</strong></td>
<td>11.0 mm (9.9 to 12.2)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 11  Composite FWHM in the x-direction (perpendicular to the chest wall edge) for each 1 mm diameter aluminium ball, plotted against distance from the chest wall edge of the image.

Figure 12  Composite FWHM in the y-direction (parallel to the chest wall edge) for each 1 mm diameter aluminium ball, plotted against lateral distance from the middle of the chest wall edge of the image.
Figure 13  Composite FWHM in the z-direction (vertical) for each 1 mm diameter aluminium ball, plotted against distance from the chest wall edge of the image.

Figure 14  Composite FWHM in the z-direction (vertical) for each 1 mm diameter aluminium ball, plotted against lateral distance from the middle of the image.
Figure 15  Composite FWHM in the z-direction (vertical) for each 1 mm diameter aluminium ball, plotted against height above the table.

3.4 Alignment

The alignment of the X-ray field to the focal plane at the surface of the breast support table is shown in Table 9. The X-ray field overlaps the chest wall edge and the lateral edges of this reconstructed focal plane by no more than the 5 mm limit which is applied to conventional mammography.

Table 9  Alignment of X-ray field to reconstructed tomosynthesis image

<table>
<thead>
<tr>
<th>Height above table</th>
<th>X-ray field to reconstructed tomosynthesis image* (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Front</td>
</tr>
<tr>
<td>0 cm</td>
<td>4</td>
</tr>
</tbody>
</table>

*A positive value indicates that the X-ray field extends beyond the edge of the image

The alignment of the reconstructed tomosynthesis volume to the compressed volume was assessed at the base and top of the image, as well as at the chest wall edge. The amount of missed tissue at the chest wall edge was 4 mm at heights of 0, 6, and 10 cm above the breast support table, which is within the 5 mm limit which is applied to conventional mammography. All markers distributed across the surface of the breast support table and the underside of the compression paddle were brought into focus in planes near the bottom or top of the image, showing that nothing is missed at the base or top of the reconstructed volume.
4. Discussion

4.1 Dose and CNR

The MGD to the standard breast model for a range of equivalent breast thicknesses from 20 mm to 90 mm were compared to the existing NHSBSP limits for conventional 2D mammography. In both 2D and tomosynthesis modes the doses were well within these dose limits (except for the smallest equivalent breast thickness, where the tomosynthesis dose is close to the limit). The MGD to a 53 mm equivalent breast thickness was 1.49 mGy and 1.81 mGy for 2D and tomosynthesis respectively, compared to the NHSBSP dose limit for 2D mammography of 2.5 mGy for this thickness.

In 2D mode under AEC, the CNR for all equivalent breast thicknesses exceeded the value required to meet the NHSBSP standard for achievable image quality. As is usually the case in digital mammography, the CNR for 2D imaging was significantly reduced as the breast thickness increased but remained better than the achievable limit.

Regarding the CNR measurements made in reconstructed tomosynthesis focal planes, it is expected that such measurements will be highly dependent on the degree of smoothing and scaling inherent within the reconstruction algorithm. Any interpretation of absolute CNR values in relation to image quality therefore needs to be treated with caution. However, it is interesting to observe that the focal plane CNR decreases as the breast thickness increases to a greater extent than is the case for 2D CNR. It is assumed that this effect is largely due to the greater amount of scatter reaching the detector in the tomosynthesis projections due to the absence of a grid.

CNR measurements were also made in the raw unprocessed tomosynthesis projections, but in comparing these it must be remembered that the dose per projection is a fraction (in this case one fifteenth) of the total tomosynthesis dose. Projection CNR was found not to change significantly with projection angle within the narrow range of tube angles on this system. Over a greater range of tube angles, some variation in CNR with projection angle would be expected due to changes in contrast and noise.

The variation of tomosynthesis CNR with dose was assessed. A power fit applied to the relationships between CNR and dose for reconstructed focal planes and projections gave an index close to 0.5 for both, indicating that quantum noise is the dominant noise source in the tomosynthesis images.
4.2 Image quality

Image quality was assessed in 2D mode using the CDMAM test object. Under AEC control, the 2D threshold gold thickness curve exceeds the achievable level of image quality for all detail sizes.

In the absence of a suitable test object for assessing tomosynthesis imaging performance, images were also acquired of the CDMAM in tomosynthesis mode. Under AEC control, the tomosynthesis curve is close to the achievable level of image quality that is applied to 2D mammography. However, this result takes 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 according to the angular range at which projections are acquired. At half and double the normal AEC dose, the threshold gold thickness increases and decreases respectively, as expected.

A standard test object that would allow a realistic and quantitative comparison of tomosynthesis image quality between systems or between 2D and tomosynthesis modes is not yet available. 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 such a test object, an extensive clinical trial is the only current method available for evaluating whether the tomosynthesis performance of a particular system is likely to be clinically adequate.

4.3 Geometric distortion and reconstruction artefacts

Assessment of geometric distortion images demonstrated that reconstructed tomosynthesis focal planes are parallel to the surface of the breast support table with no vertical distortion. Within the focal plane, comparison of measured and actual separations between imaged details demonstrated that there is no geometric distortion apart from an overall scaling error of 4%, due to an inaccuracy in the pixel spacing quoted in the image DICOM headers used in the calculation. Hologic have stated that the pixel spacing quoted in the DICOM header has been corrected in the later software version 1.7.

In tomosynthesis images of 1 mm aluminium balls within a PMMA block, the balls appeared well defined and circular within the plane of best focus, with no artefact. Moving between focal planes, the reconstruction artefact associated with each ball was seen to persist and to stretch into a faint line parallel to the chest wall edge of the image.

The spread within focal planes of reconstruction artefacts associated with the balls did not vary with position of the ball within the image and the maximum extent of the 50% contour level in background corrected pixel values around each ball in all planes did not exceed that in the plane of best focus by any significant amount (i.e. the difference remained less than the pixel spacing of 0.1 mm). Due to the geometry of the diverging primary X-ray beam, one would
expect the reconstruction artefacts to extend away from the centre of the chest wall edge of the image with increasing distance from the X-ray tube focal spot. Hologic have compensated for this magnification effect between focal planes by varying the pixel size with focal plane height such that reconstruction artefacts appear to extend vertically in the plane perpendicular to the chest wall edge when viewed within the stack of reconstructed focal planes. A spread of the reconstruction artefacts is expected in the direction of tube motion (parallel to the chest wall edge of the image) over a distance increasing with the projection angular range used by the system. Although a line is seen parallel to the chest wall edge as one moves away from the plane of best focus, the maximum extent of the 50% contour in this direction was no more than 0.1 mm greater than the extent in the plane of best focus.

The 50% contour extended vertically between focal planes, giving a mean inter-plane resolution of 11 mm for the 1 mm diameter balls. Balls of greater or lesser diameter would result in more or less extensive reconstruction artefacts, and thus the measure of inter-plane resolution would be correspondingly larger or smaller. A tomosynthesis system employing a wider range of projection angles would be expected to have improved inter-plane resolution with less persistence between focal planes. Inter-plane resolution did not vary by any more than 10% with vertical or horizontal position of the balls.

4.4 Alignment

It is not possible to assess alignment of the irradiated volume to the imaged volume because the lateral parts of the volume are partially irradiated as the X-ray field moves during the tomosynthesis scan. However an assessment can be made at the chest wall edge and, for the lateral sides, at the height of the centre of rotation (in this case, at the surface of the breast support table), where the edges of the X-ray beam remain static. At these positions the X-ray beam extended beyond the edges of the reconstructed focal plane by no more than the 5 mm limit which is applied to 2D mammography.

Assessment of alignment of the tomosynthesis imaged volume to the compressed volume indicated that 4 mm of tissue is missed at the chest wall edge at heights of 0 to 10 cm above the breast support table, which is within the 5 mm limit for 2D mammography. There was no missed tissue at either the top or bottom of the reconstructed image, as focal planes extend sufficiently close to the top and bottom of the imaged volume for all tissue to be within focal range. The Hologic system design is such that five additional 1 mm planes are reconstructed above the height of the indicated compressed breast thickness, allowing for any inaccuracy in calibration or tilt of the compression paddle.
5. Conclusions

Tests of both 2D and tomosynthesis technical performance were carried out. 2D performance met current NHSBSP standards for digital mammography, with image quality better than the achievable target level. No performance standards have yet been set for digital breast tomosynthesis systems and it is not yet possible to predict clinical tomosynthesis performance from these results.

Measurements were made of the tomosynthesis MGD to the standard breast model, and were found to be approximately 20% higher than the doses measured in 2D mode for an average sized breast. These tomosynthesis doses are well within the NHSBSP dose limits for 2D mammography.

Any decision to approve the use of tomosynthesis in screening or assessment in the NHS Breast screening programme will depend on a review of the available evidence and a practical evaluation by the NHSBSP.
References


