NHS
Cancer Screening Programmes

Practical evaluation of Hologic Selenia Dimensions digital breast tomosynthesis system

NHSBSP Equipment Report 1401

July 2014

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Published: July 2014
PHE publications gateway number: 2014025

Document Information	
Title	Practical evaluation of Hologic Selenia Dimensions digital breast tomosynthesis system
Policy/document type	Equipment Report 1401
Electronic publication date	February 2014
Version	1
Superseded publications	None
Review date	None
Author/s	EHL Mungutroy, JM Oduko, JC Cooke, WJ Formstone
Owner	NHSBSP
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 and subsequently recalled for assessment
Target audience	Radiologists, Radiographers, Programme Managers, Physicists
Archived	Current document

Contents

Acknowledgements

The authors are grateful to all the staff at the Jarvis Breast Centre, Guildford, for their co-operation in the evaluation of the unit at their site.

The authors are also grateful to the TOMosynthesis with digital MammographY (TOMMY[1]) trial chief investigator for permission to use a subset of the assessment data collected during the trial.

Executive summary

The purpose of this evaluation was to assess the practical performance of the tomosynthesis mode of the Hologic Selenia Dimensions mammography unit for use within the NHSBSP, in the assessment process of recalled women.

This evaluation covers use of the Hologic Selenia Dimensions between September and November 2012. Use of the SecurView DX reporting workstation and the SecurXchange mini-PACS for image storage was included.

In general, the radiographers liked the system, found it easy to use, and their workflow was not limited by the extra processes involved in tomosynthesis.

The readers were generally positive about the practicalities and usefulness of tomosynthesis, although some also made comments suggesting a few improvements that they would like to see implemented. The visualisation of different types of lesions seen with tomosynthesis was the same or better than with 2-D. Fewer asymmetric densities were described, probably due to the facility for tomosynthesis to “unwrap” positional shadows.

A dose survey was carried out for both the 2-D and tomosynthesis components of the examinations. Average mean glandular dose for 50-60 mm breasts was found to be 1.87 and 2.28 mGy for 2-D and tomosynthesis images respectively, well within the dose limits for 2-D mammography.
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1. Introduction

1.1 Evaluation centre and timeline

The evaluation centre is the Jarvis Breast Centre, an NHSBSP unit inviting approximately 57,000 women per year for screening, of whom 45,000 are screened. Approximately 2,100 assessments are carried out per year. The centre meets relevant national quality standards for breast screening and meets the criteria for evaluation centres outlined in the Guidance Notes for Equipment Evaluation[2]. The centre was one of the sites participating in the TOMMY trial of tomosynthesis in assessment and the Hologic Selenia Dimensions unit was installed for the purpose of this trial. A subset of the data collected for the trial has been used for this evaluation, covering the period September to November 2012. At the start of this period, the system had been in use for 14 months, so that both readers and radiographers had considerable experience.

1.2 Equipment evaluated

The Selenia Dimensions digital breast tomosynthesis (DBT) system has a tungsten target, with rhodium and silver filters for two-dimensional (2-D) imaging and an aluminium filter for tomosynthesis imaging. It has an amorphous selenium detector, manufactured by Hologic, and a high transmission cellular (HTC) grid that is withdrawn automatically during tomosynthesis exposures. Software version 1.4.2 was in use during the period of the evaluation.

A practical evaluation of the Selenia Dimensions in normal 2-D operation was published in 2010[3]. The technical performance of the Hologic Selenia Dimensions system in 2-D operation with the original and with the more recently updated automatic exposure control (AEC) software has previously been assessed and reported[4,5]. A report on the technical performance of the tomosynthesis system has recently been published[6]. During tomosynthesis exposures the tube head rotates in an arc from -7.5 to +7.5 degrees, either side of the central axis, while making 15 short exposures called “projections”. All the imaging in this evaluation was “combo” exposures, which comprise a series of tomosynthesis exposures, followed by a 2-D exposure in the zero-degree position, all in the same compression. The automatic exposure control (AEC) mode used was AutoFilter, in which the system selects the most appropriate kV, target and filter, based on separate pre-exposures for tomosynthesis and for 2-D imaging.

The operator console consists of an integrated colour touch screen display for workflow and administrative tasks. Operators can log in through fingerprint recognition or by password using the keyboard located in an integral sliding drawer. The console also features a trackerball, a rotating wheel for scrolling through series of tomosynthesis images, and a barcode scanner for patient selection from a worklist. A 3 megapixel (MP) greyscale monitor is mounted on a swing arm for the display of images. There is an

integrated uninterruptible power supply. The radiation protection screen is integrated into the console assembly.

Figure 1 shows the Hologic Selenia Dimensions with tomosynthesis face shield and acquisition workstation.

Figure 1. Hologic Selenia Dimensions with tomosynthesis face shield

The special face shield for tomosynthesis remains stationary, for safety reasons, during angular movement of the gantry in tomosynthesis mode. Details of the face shield mounted on the Dimensions are shown in Figure 2.

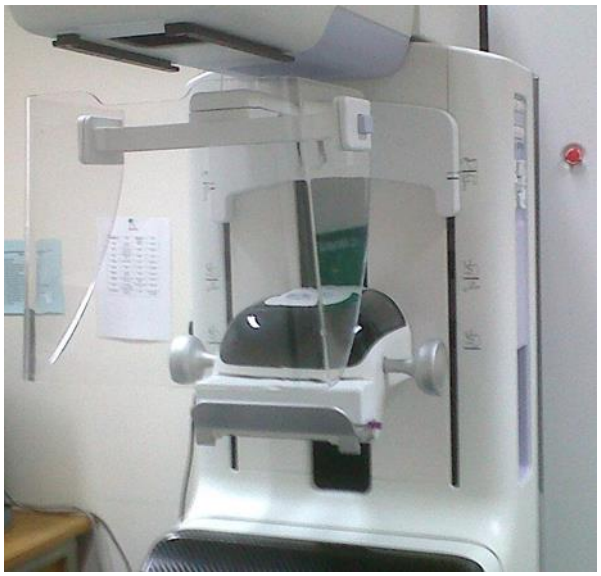

Figure 2. Additional view of tomosynthesis face shield on Selenia Dimensions

The tomosynthesis images are reconstructed planes spaced at 1mm intervals, with the total number of planes equal to the compressed breast thickness in mm plus 5. The maximum compressed thickness for a tomosynthesis scan is 244mm. The projection images and the reconstructed planes appear on the acquisition workstation after each acquisition.

A SecurXchange mini-PACS was installed to store the tomosynthesis images, and a SecurView DX workstation for viewing and reporting on the images. Further details of these are in Section 9.

1.3 Objectives

The primary focus of the evaluation was to determine the performance and usability of the Hologic Selenia Dimensions tomosynthesis system for the assessment of women who have been recalled for further examination following their mammographic screening.

The detailed objectives were as follows:

- to evaluate the usefulness of the system in assessment, and report on the readers' views of image quality and practical aspects of reading the images
- to assess the practical aspects of use and report on the operators' views and experience
- to assess the performance and reliability of the equipment when in use for tomosynthesis
- to report on radiation dose to the breast for the women imaged during the evaluation

2. Acceptance testing, commissioning and performance testing

2.1 Acceptance testing and commissioning

The Selenia Dimensions unit had already been in use for 14 months at the start of the evaluation. The system was installed by Hologic over three weeks in June 2011 and installation was completed on schedule. Installation included integration with the local PACS. Acceptance testing and commissioning[7] was carried out by the local physics service, the Regional Radiation Protection Service (RRPS), based at the Royal Surrey County Hospital. They were assisted by staff of the National Coordinating Centre for the Physics of Mammography (NCCPM), who had developed performance tests on the tomosynthesis imaging capability[8]. The tests included measurement of dose and image quality, in both conventional and tomosynthesis modes.

2.2 Six-monthly performance testing

The tomosynthesis tests were repeated on a six-monthly basis as part of the trial for which the equipment was originally installed. The 2-D performance of the system was tested at six-monthly intervals as usual. The reporting monitors of the SecurView workstation were also tested. The physics reports for all these tests (carried out in August 2012, just before the evaluation period) are included at Appendices 1 and 2.

3. Routine quality control

Routine quality control (QC) was undertaken in accordance with the relevant NHSBSP guidelines[9] relevant to 2-D exposures, and in accordance with the tomosynthesis trial's guidelines. Different radiographers carried out these tests from day to day.

3.1 Results of daily tests

A 4.5cm thick block of Perspex was imaged under AEC control for the daily QC tests. The values of signal-to-noise ratio (SNR) and mAs for 2-D imaging, and mAs for tomosynthesis imaging, are shown in Figures 3 to 5. Almost all the values recorded lie within the recommended remedial limits. Those few points which lie outside the remedial limits for the mAs (marked in red on the graphs) correspond to occasions when the kV selected automatically was different from the normal value. This could occur when the compressed breast thickness was slightly different from the norm, due to slightly different compression being applied.

There was also a daily check of the acquisition monitor, and an inspection of the image for artefacts. The monitor was always satisfactory and no artefacts were seen.

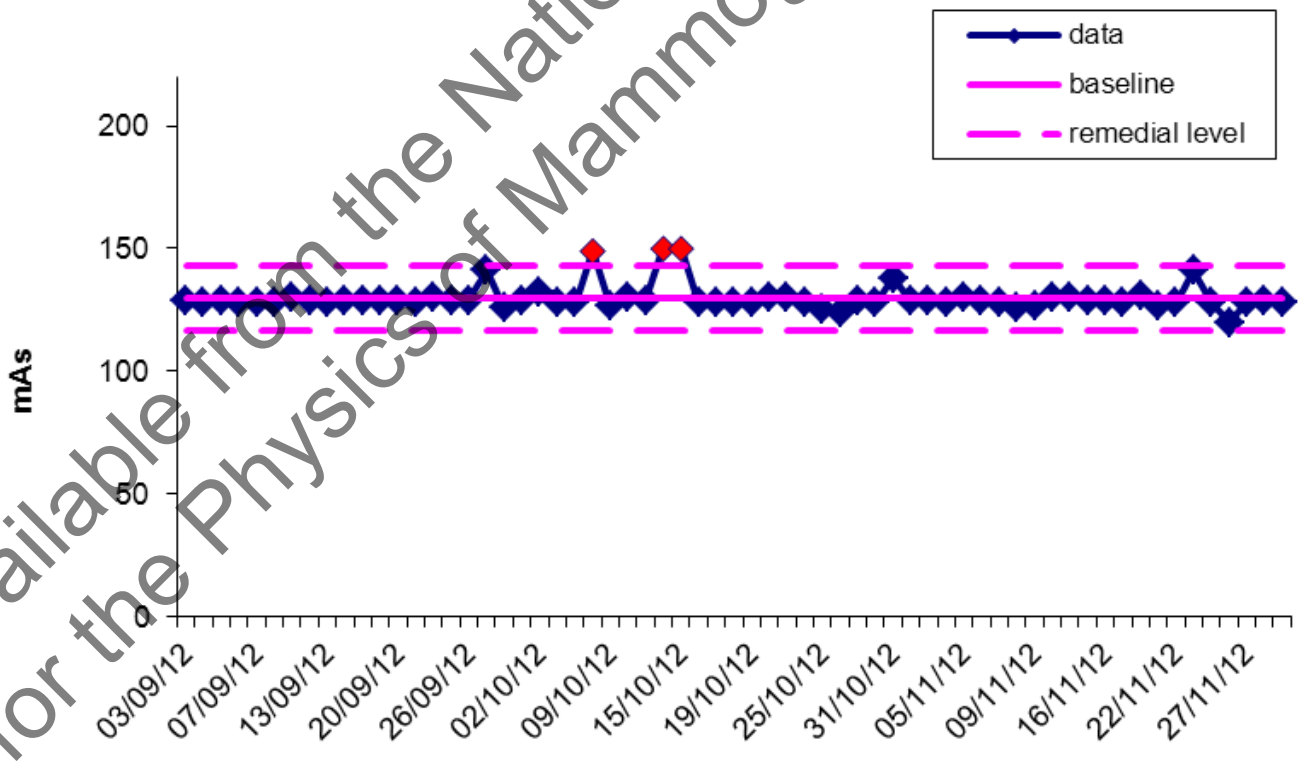

Figure 3. mAs recorded daily for 4.5cm of Perspex for 2-D imaging

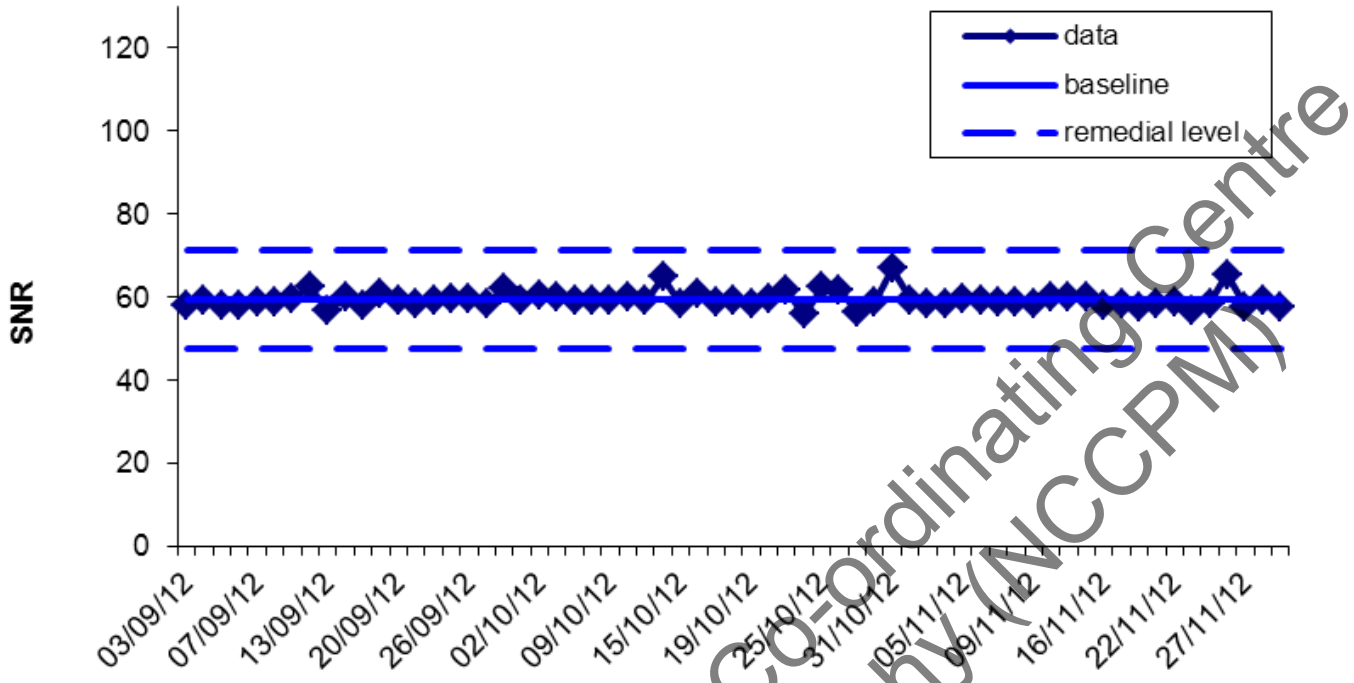

Figure 4. Daily SNR measurements for 4.5cm of Perspex for 2-D imaging

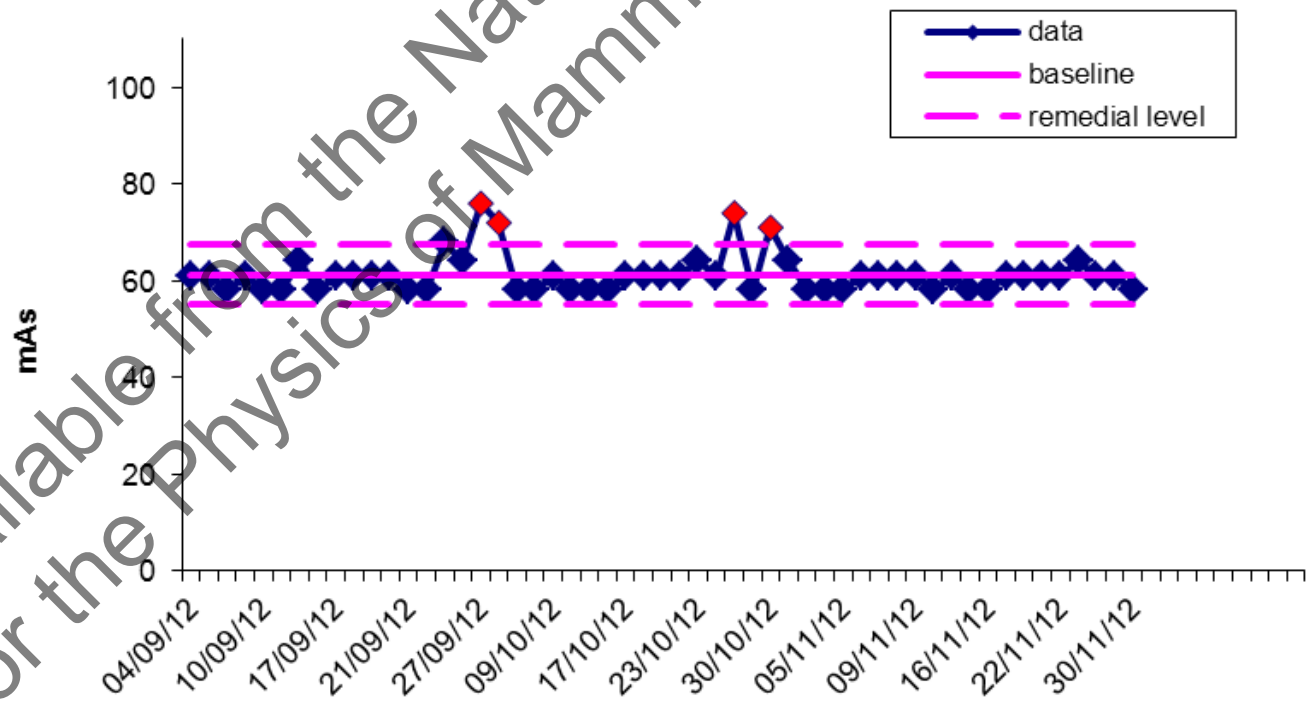

Figure 5. mAs recorded daily for 4.5cm of Perspex for tomosynthesis

3.2 Results of weekly tests

For weekly routine QC the 4.5cm block of Perspex contained a small square of aluminium 0.2mm thick, and the contrast-to-noise ratio (CNR) was determined in 2-D imaging mode. SNR was also found, for a reconstructed tomosynthesis plane. The results are shown in Figures 6-7. All results lie within the ± 20% remedial limits.

For the uniformity test, the maximum difference in mean pixel value (between centre and corners) was calculated and it shows complete stability.

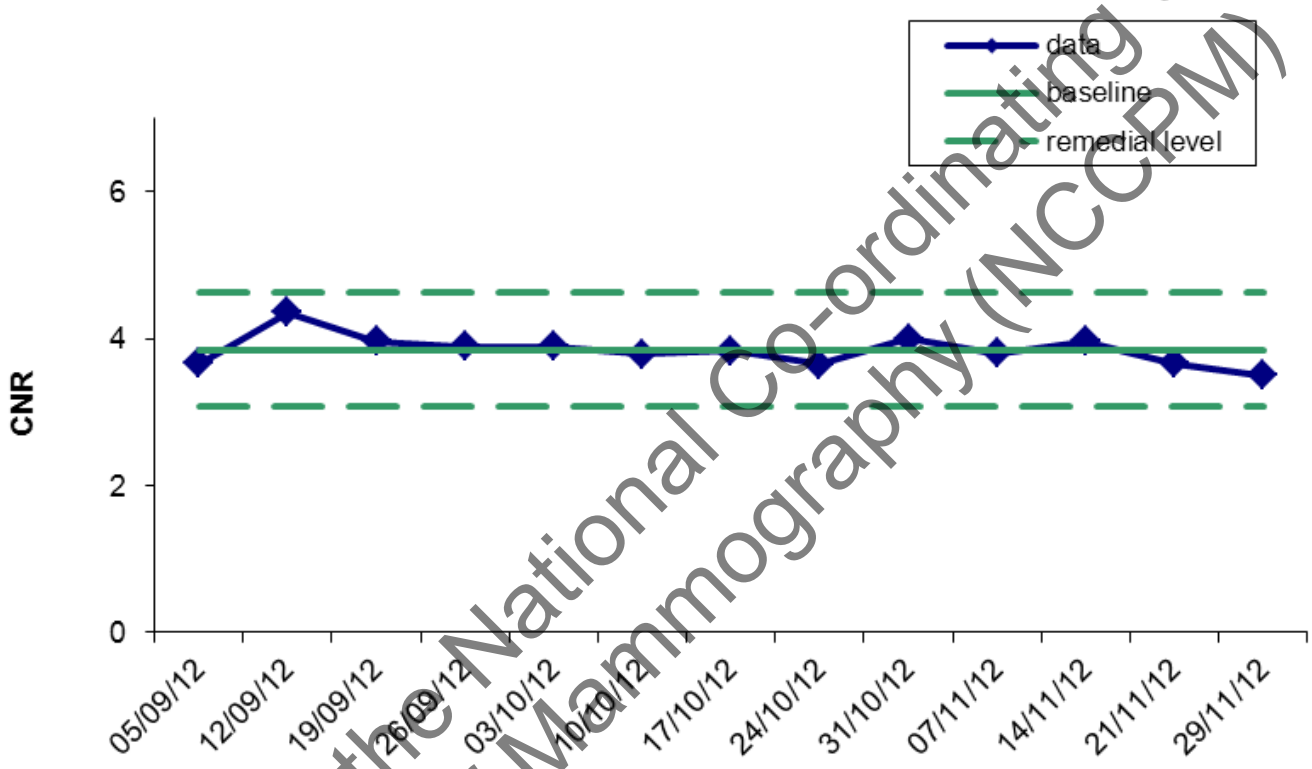

Figure 6. Weekly CNR measurements for an aluminium square in 4.5cm of Perspex, for 2-D imaging

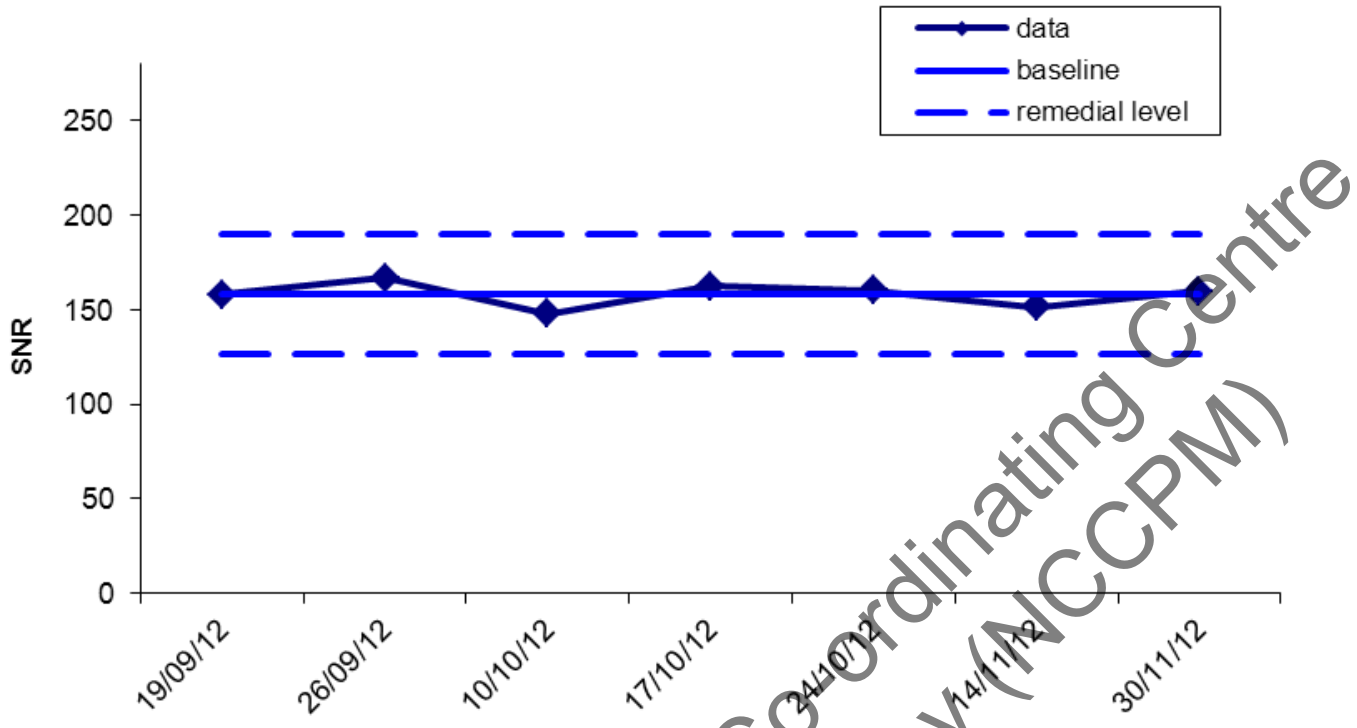

Figure 7. Weekly SNR measurements for 4.5cm of Perspex for tomosynthesis

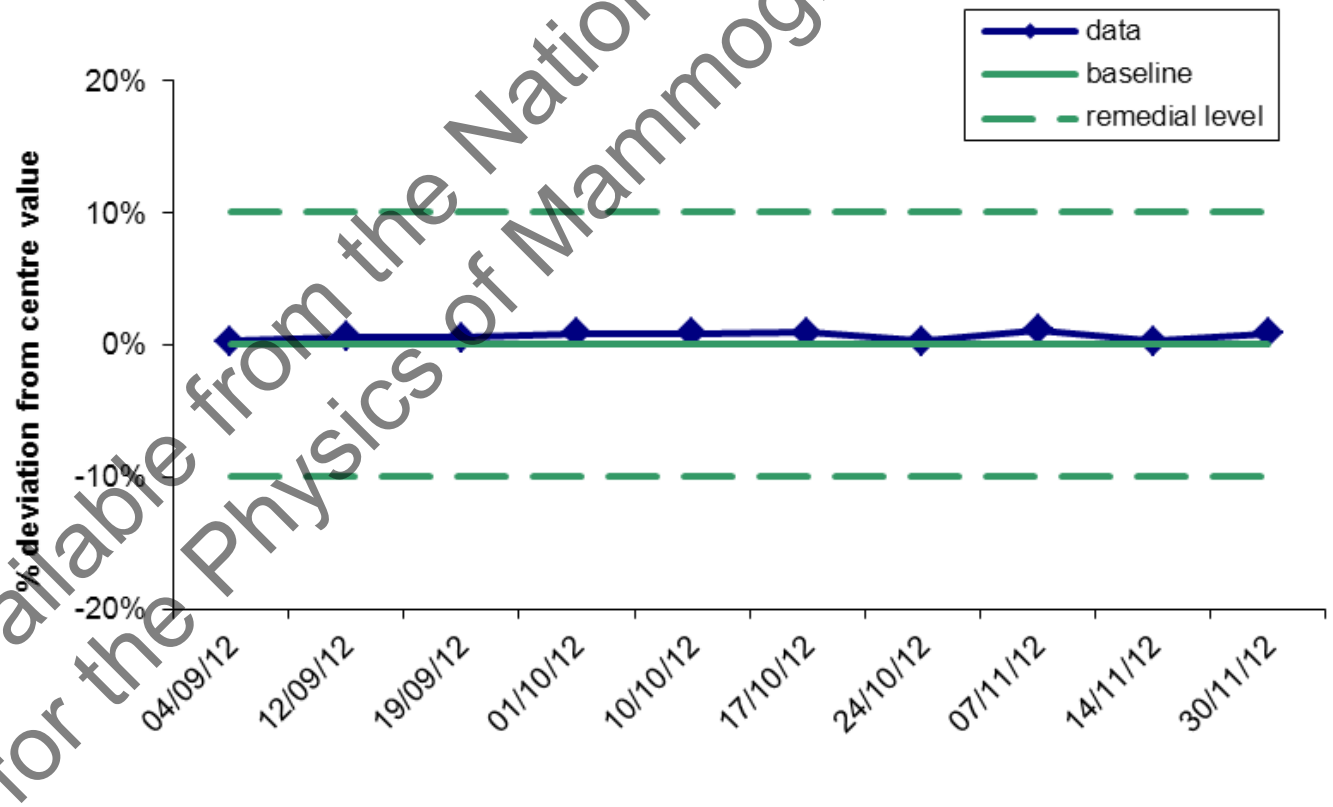

Figure 8. Weekly test of uniformity

3.3 Results of monthly tests

For the monthly tests, Perspex blocks of thickness 2cm and 7cm were exposed under AEC control and the mAs recorded for both 2-D imaging and tomosynthesis. The SNR and CNR were also determined for both thicknesses of Perspex, for 2-D imaging. The results are shown in Figures 9-16; they are for the whole year (2012), otherwise the graphs would have only three points for the evaluation period September to November, which is not enough to show longer-term stability. The results lie within the remedial limits of ± 10% for mAs and ± 20% for SNR and CNR.

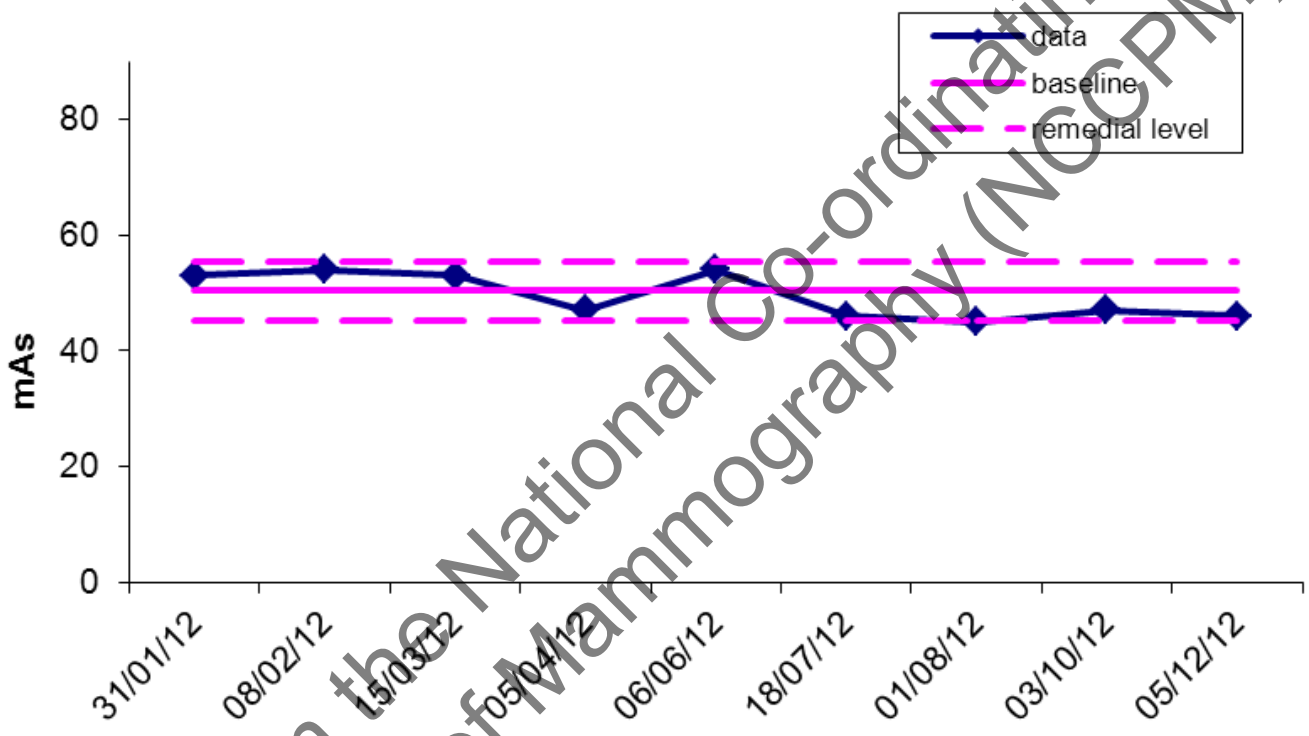

Figure 9. mAs recorded monthly for 2cm Perspex for 2-D imaging

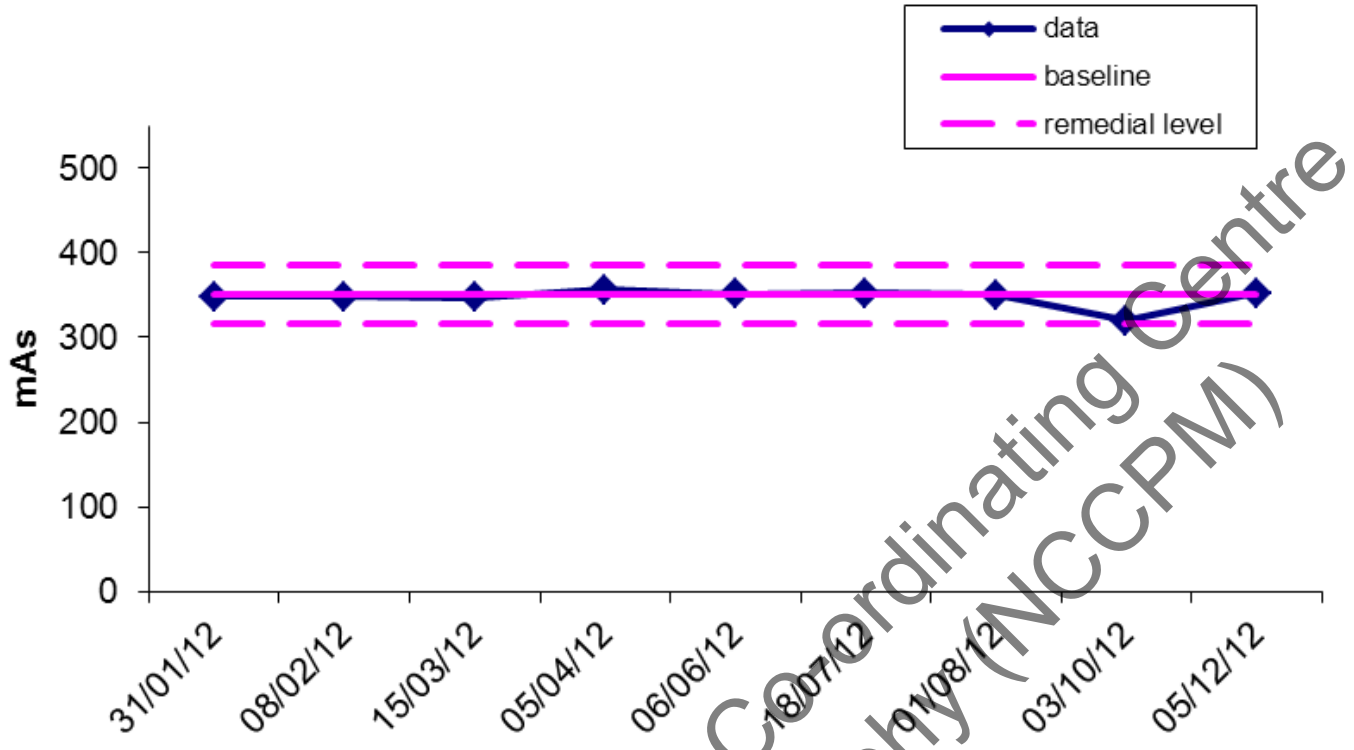

Figure 10. mAs recorded monthly for 7cm Perspex for 2-D imaging

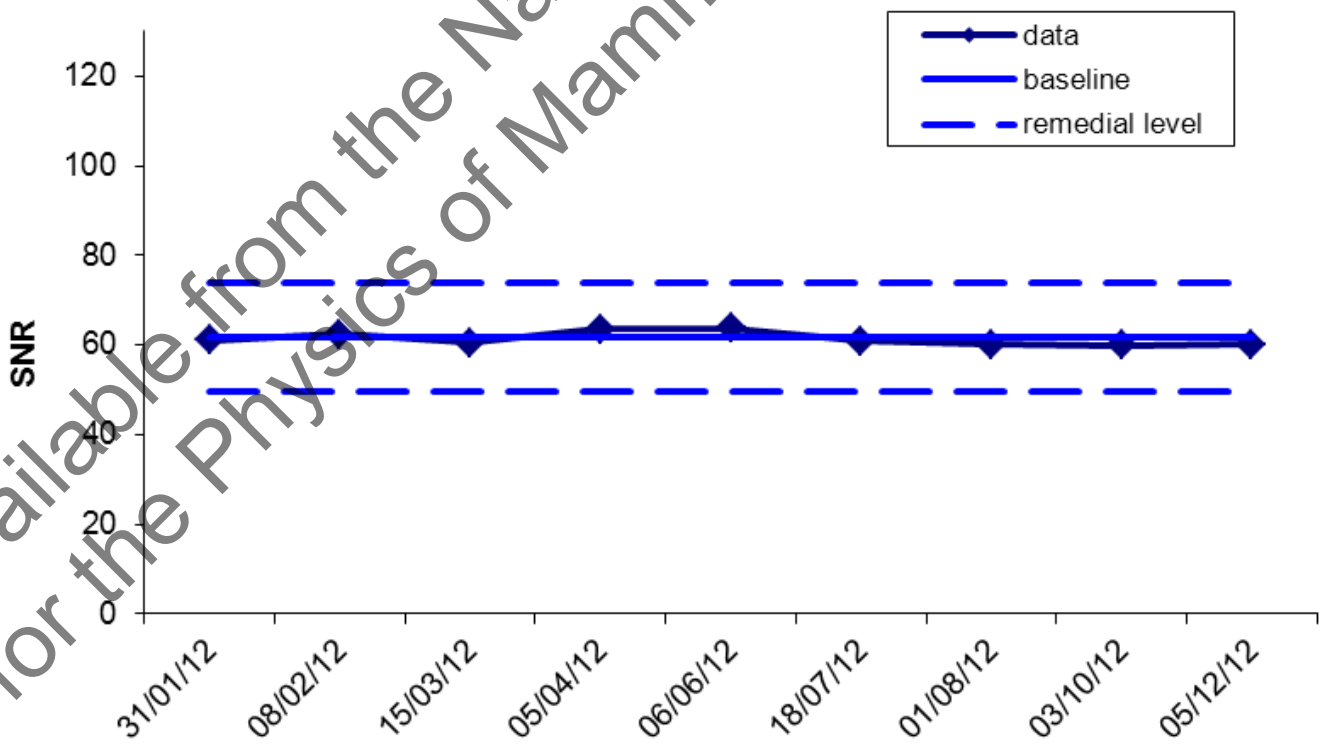

Figure 11. Monthly SNR measurements for 2cm Perspex for 2-D imaging

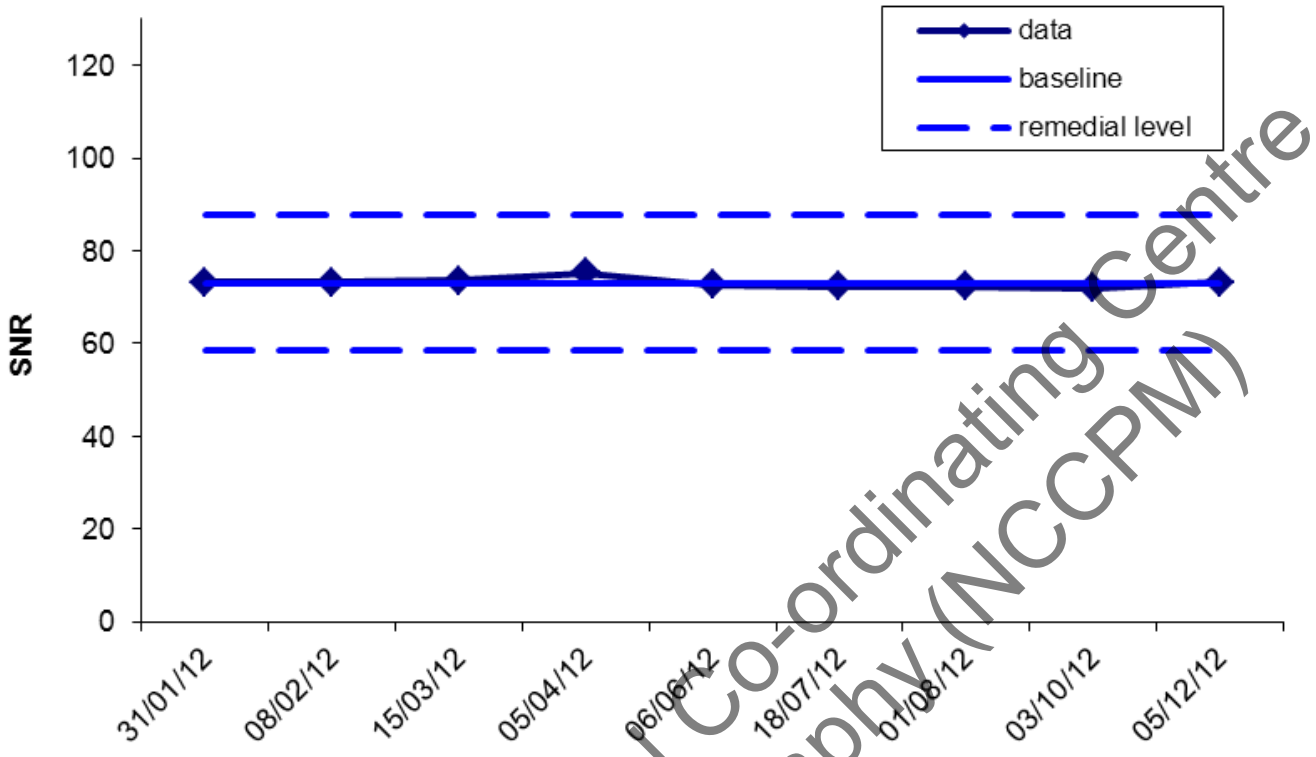

Figure 12. Monthly SNR measurements for 7cm Perspex for 2-D imaging

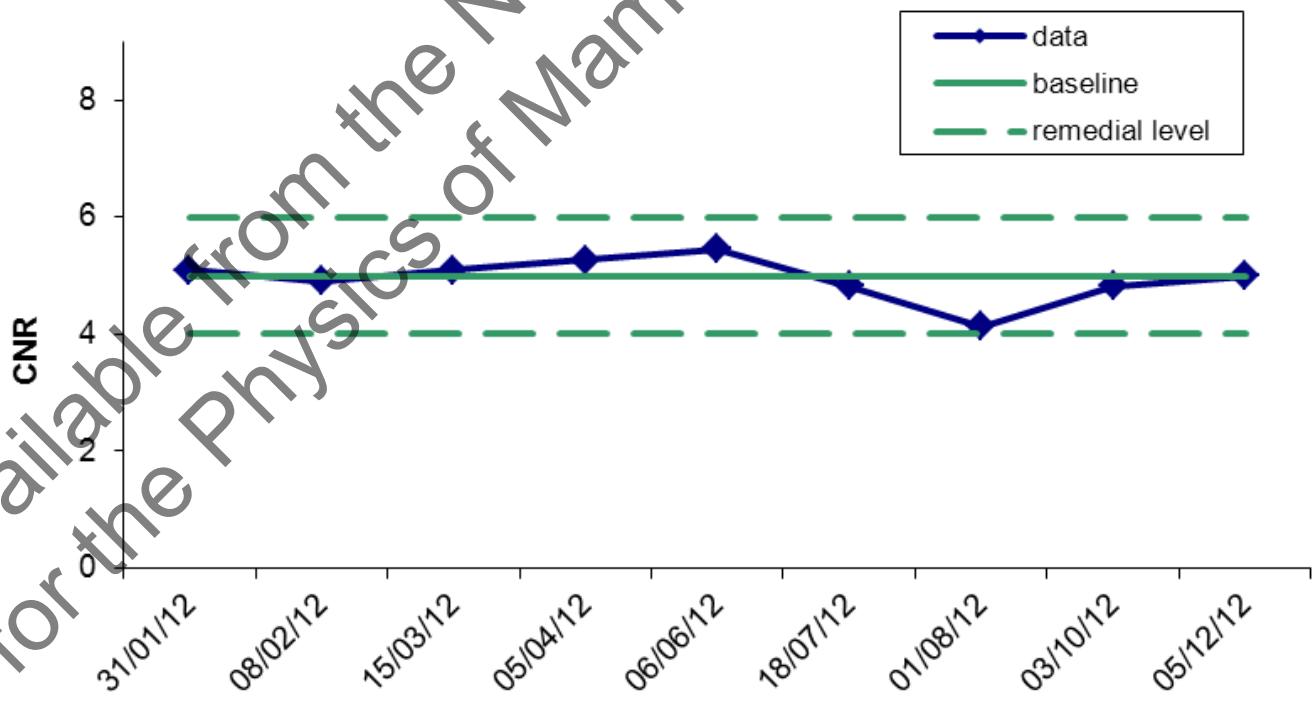

Figure 13. Monthly CNR measurements for 2cm Perspex for 2-D imaging

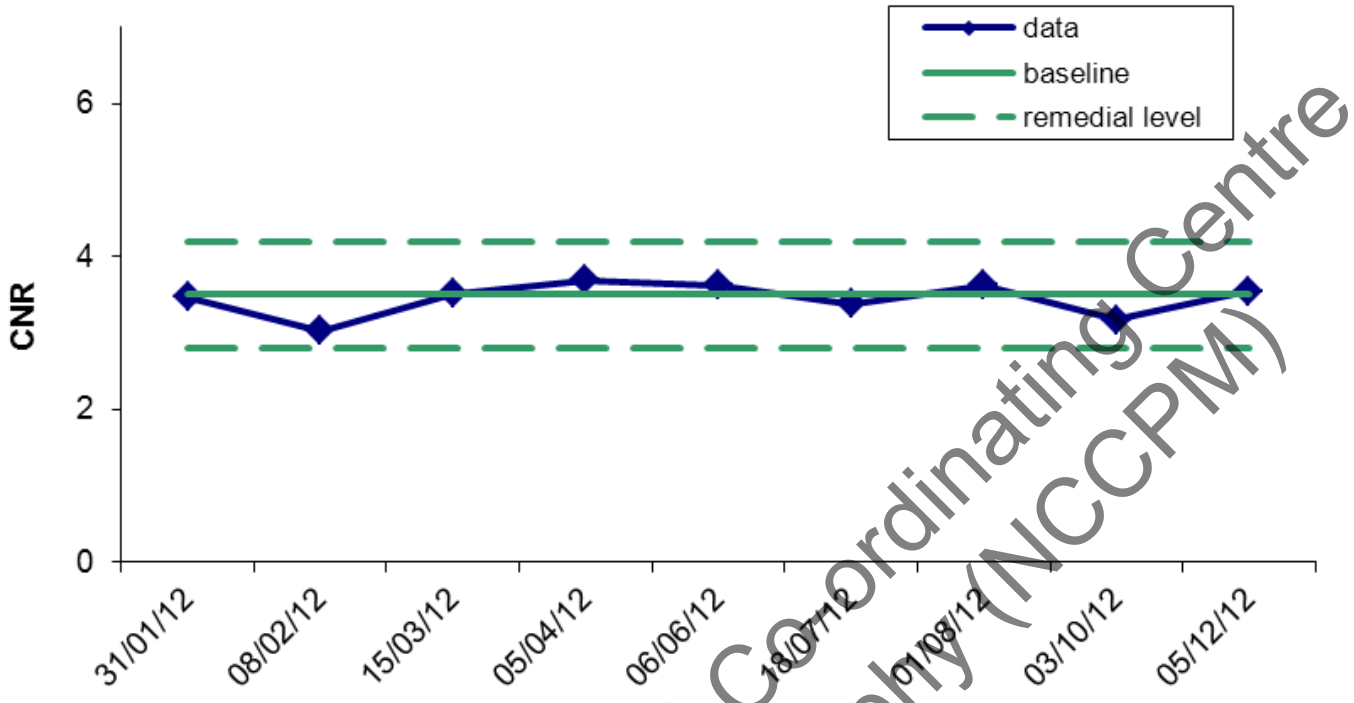

Figure 14. Monthly CNR measurements for 7cm Perspex for 2-D imaging

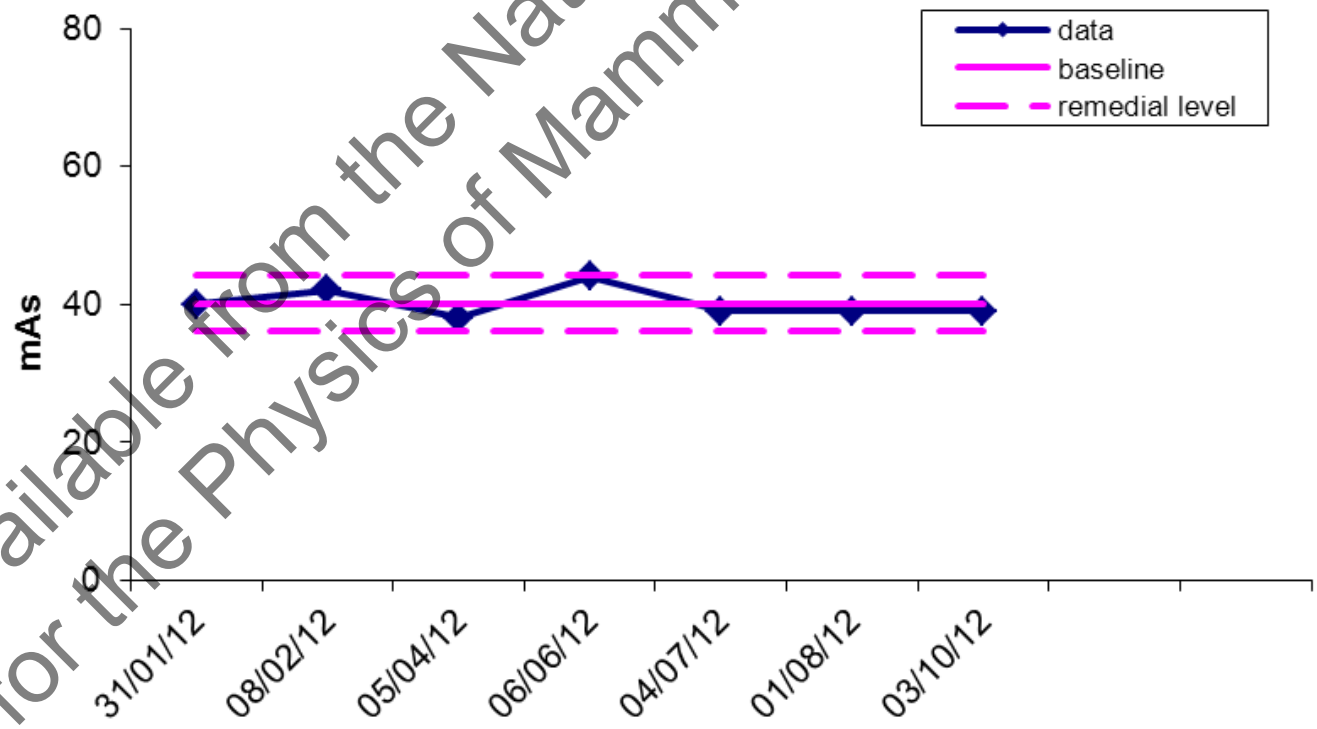

Figure 15. mAs recorded monthly for 2cm Perspex for tomosynthesis

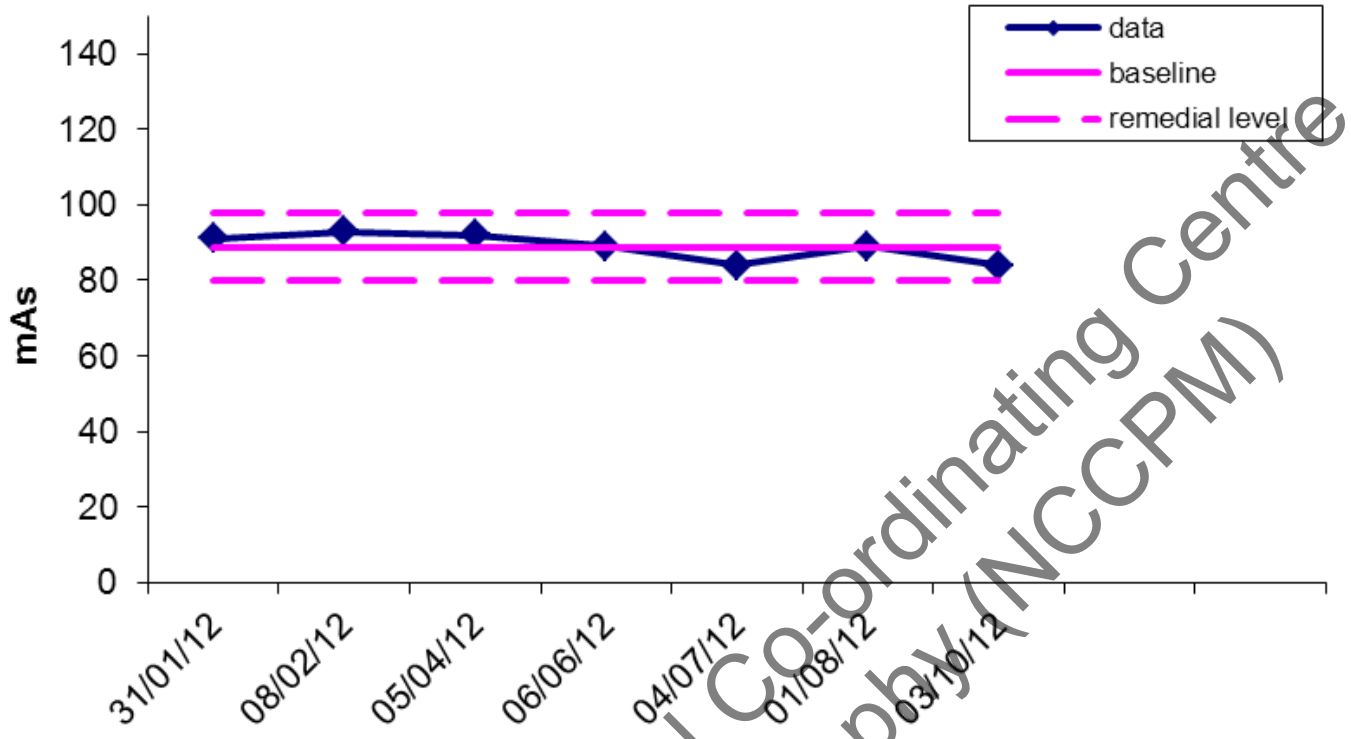

Figure 16. mAs recorded monthly for 7cm Perspex for tomosynthesis

4. Data on assessments conducted

4.1 Clinical dose audit

For the purposes of the trial, both breasts were imaged with “combo” exposures in both cranio-caudal (CC) and medio-lateral oblique (MLO) projections. A combo exposure consists of a tomosynthesis exposure (15 views), followed by a 2-D exposure in the same compression.

The exposure data from 277 women, who had been recalled for assessment following their NHSBSP screening examinations, were obtained from the DICOM[10] headers of the images using specially written software[11]. These were entered into a modified version of the NHSBSP dose calculation software. The doses were analysed from both 2-D images and tomosynthesis images of the combo exposures.

The detailed results of the dose survey, for the 2-D and tomosynthesis parts of the exposure, are presented in Appendices 3 and 4 respectively. The average mean glandular dose (MGD) and compressed breast thickness (CBT) are summarised in Table 1 below. MGDs were calculated using data published by Dance et al.[12, 13]

Table 1. Average values of MGD and CBT for the different components of a combo exposure

View	Group of women	Average MGD (mGy) for 2-D	Average MGD (mGy) for tomosynthesis	Average CBT (mm)
CC	all	2.15	2.77	61
MLO	all	2.22	2.80	61
MLO	CBT 50-60 mm	1.87	2.28	56

The evaluation centre has adopted the national dose diagnostic reference level (DRL) of 3.5mGy for an MLO image of the 50-60 mm breast[14]. There are no limiting values set yet for tomosynthesis but this 2-D figure may be used for comparison. The dose survey results for the Hologic Selenia Dimensions tomosynthesis system are well below this level in each imaging mode. The average MGD for 50-60 mm breasts was 1.87mGy for the 2-D exposure and 2.28 mGy, approximately 30% higher, for the tomosynthesis exposure. The total of 4.15mGy is only slightly greater than the 3.5mGy DRL for one image.

4.2 Comparison of organ dose with calculated MGD

The calculated MGDs were compared with the doses displayed on the acquisition workstation and stored in the DICOM header of each image as “organ dose”. These are plotted against each other in Figures 17 and 18. The gradient of each graph is close to 1.0 for both 2-D and tomosynthesis exposures. These displayed and stored values could therefore be used for dose surveys (or if required for any individual woman) without the usual need for extensive calculation based on exposure parameters and X-ray tube output.

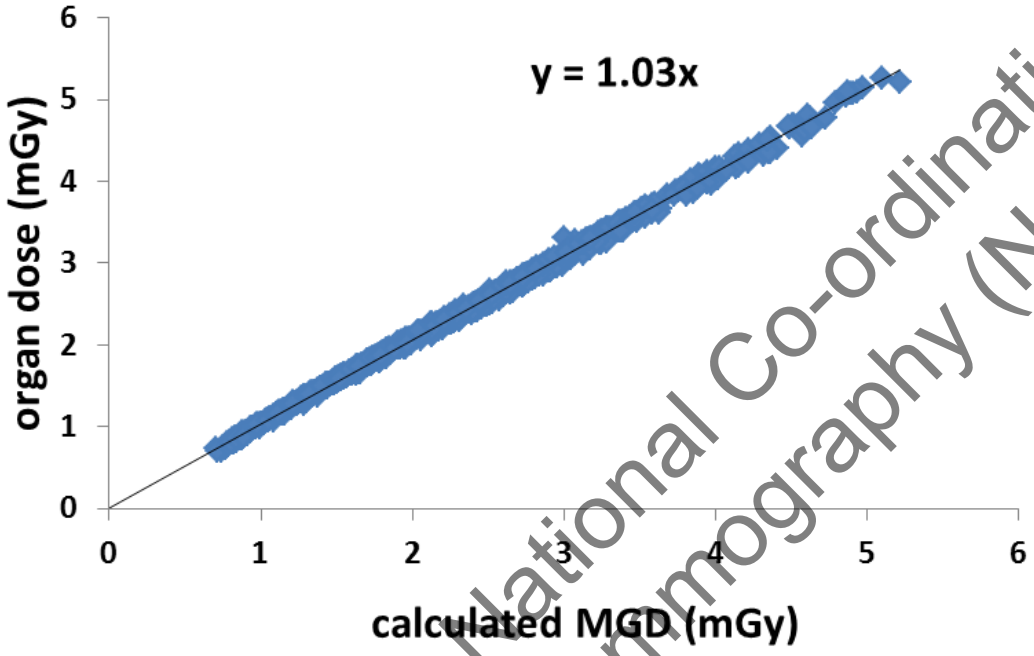

Figure 17. Organ dose from DICOM header vs calculated MGD for 2-D

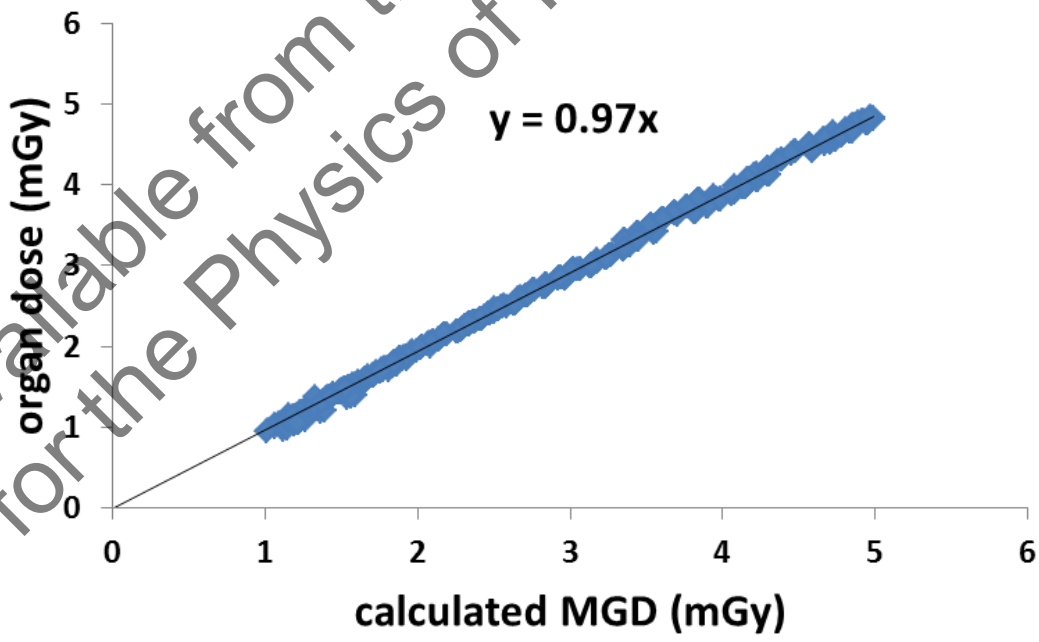

Figure 18. Organ dose from DICOM header vs calculated MGD for tomosynthesis

4.3 Breast density

As part of the clinical trial, readers assigned an estimated value for percentage breast density to each woman whose images they viewed. The figures from the clinical trial for the subset of data used for this evaluation were grouped to give numbers assessed as fatty (0 – 33% density), mixed (34 – 66% density), and dense (67 – 100%). The proportions found in the 277 cases in the evaluation were:

- fatty: 119 out of 277 – 43%
- mixed: 135 out of 277 – 49%
- dense: 23 out of 277 – 8%

These results are shown in Figure 19 below.

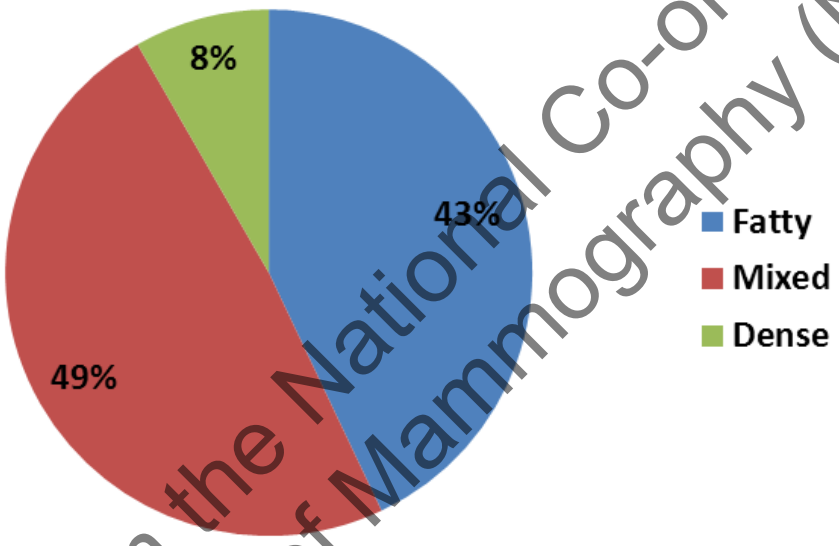

Figure 19. Reader estimates of breast density

4.4 Imaging times

Total assessment times for each woman are not presented here, as the research trial included the process of consenting the woman and answering any questions she had. The timings of the tomosynthesis examinations for assessment were determined by using software to extract from the DICOM headers the start time of the whole examination and the start time of each individual exposure. This is not the same as the length of each exposure which is of the order of 1.2 seconds for a 2-D exposure of an average breast, and 6 seconds in total for a series of tomosynthesis exposures (AEC pre-pulse followed by 15 exposures each 35-40 milliseconds long). The tomosynthesis exposures alone take four seconds.

Timings of exposures of a phantom were measured with a stopwatch to determine how long the different steps took, including the time taken for images to appear on the screen, and the time when the next exposure became possible. The results of these timings are given in Table 1 below. The evaluation used combo exposures, but timings for tomosynthesis and 2-D exposures are also presented here for comparison.

Table 2. Stopwatch timings in seconds for exposures of 45 mm of Perspex. All timings are from when the operator presses the exposure button, and are cumulative. The time when compression is released is indicated by (R)

Type of exposure	combo	tomosynthesis	2-D
Start of exposure	2	2	2
End of tomosynthesis exposure (timing includes pre-pulse)	8	8 (R)	-
Start of 2-D component of combo	12	-	-
End of 2-D exposure	14 (R)	-	4 (R)
First image appears on screen	5	5	15
Last tomosynthesis image appears on screen	23	22	-
Unit is ready for next exposure (cycle time)	37	35	27

The time between the beginning of one acquisition and the start time of the next acquisition could be identified from the DICOM headers. This time includes repositioning the woman and moving the tube head to either the opposite oblique view or the cranio-caudal view. On average the first combo sequence to the start of the next image took 59 seconds and the subsequent three combo images took 110 seconds. In the assessment setting, it is unlikely that all four views would be imaged. The total time for two views would be approximately 169 seconds.

Clearly it is the positioning which is the determining factor in the timing of exposures, rather than the Selenia Dimensions, which is ready for the next combo exposure approximately 37 seconds from the start of the previous one.

4.5 Timings for image reading by radiologists

The tomosynthesis images were mainly reported by five consultant radiologists and one senior associate specialist. For the assessments, mammography images were read on a Hologic SecurView DX reporting workstation, using a workflow keypad specially designed for the workstation (see section 9.2). This enabled the user to access the tomosynthesis tools either on the keypad or with the mouse on the workstation. Tomosynthesis images acquired on the Selenia Dimensions unit were stored on the SecurXchange mini-PACS. The 2-D images from the combo exposure and any spot compression images taken on

the unit were displayed on the SecurView and also stored on the Sectra PACS used by the centre. The original 2-D screening images were only displayed on the Sectra reporting workstation.

While the clinical trial was in progress the SecurView DX workstation was positioned next to the Sectra workstation in the clinic review area to enable the image readers to access all images from the patient during the assessment session. This allowed the tomosynthesis images to be read at the same time as the screening images. A personalised work flow for reporting images on the SecurView DX was not customised for this part of the study. The radiologists reported each case as it was available and manipulated the images and display settings on an individual case basis. Once the tomosynthesis images were available on the SecurView DX workstation switching from 2-D to tomosynthesis images was rapid (under one second). Changing between different images, display modes and viewing spot compression was also rapid. Reviewing and reporting on the tomosynthesis images took a variable amount of time, depending on the complexity of the case, density of the breast and confidence of the reader. It was not possible to estimate how long this image review took but an informal discussion with the readers reported between five and 10 minutes per patient. This generally included a review with a colleague as part of the assessment process.

Part of the TOMMY study was retrospective reading of batches of images ranging from 20-40 cases. These batches were read as tomosynthesis with 2-D, tomosynthesis with synthesized 2-D (C-View^{TM}) or 2-D only. It became apparent that a personalised work flow was essential to enable rapid and efficient reading of images. A reporting workflow was agreed by all the readers and was implemented with the support of the application specialist. This enabled more rapid reading and easier throughput of work. All readers stated that reading 2-D and tomosynthesis images together took significantly longer than reading standard 2-D screening images, although the reading time decreased with increasing reader experience. It should be noted that all cases reviewed had been recalled from the initial screening visit and therefore readers were cautious in their reading and were expecting lesions to be present, some of which were extremely subtle. All lesions that were seen were reported onto specific forms and at least ten separate data items recorded, with a new form completed if multiple lesions were detected. On average, the radiologists reported on 20 such cases in an hour.

4.6 Clinic workflow

For the purposes of the clinical trial, the Selenia Dimensions was sited in a room located in the administrative wing of the centre. Radiographers had to bring the woman round from their normal work area in the clinical wing, which is where all the screening and assessments normally take place. They also had to go through a 15 minute process of consenting the patient for the study, which added extra time to the clinics. All the radiographers agreed that these processes had an effect on the clinic workflow, as shown in their responses to the evaluation questionnaire (see Appendix 6).

No individually timed session was conducted during the evaluation because of these administrative complications. Various image timings are given in sections 4.4 and 4.5 above.

4.7 Visibility with tomosynthesis

For each lesion detected in the evaluation, readers gave their assessment of whether it was seen clearly, seen but not very well, or not seen. The results are presented in Figure 20. In the tomosynthesis images, approximately 50% fewer asymmetric densities were visualised than in the 2-D images. This is to be expected, as scrolling through the tomosynthesis planes will unwrap positional shadows and demonstrate normal appearing glandular tissue in asymmetric distribution.

Circumscribed masses have margins more clearly defined in a greater number of cases when visualised with tomosynthesis. When a benign appearing mass is visualised with a plane through the centre of the mass, overlapping normal glandular tissue is less well seen allowing the clearer definition of a smooth margin. For distortions and spiculated masses, the irregular margins and long spiculation were more clearly identified with the tomosynthesis technique. A few well-defined masses were identified on tomosynthesis which were not clearly appreciated on 2-D imaging. During the evaluation period, 35% of distortions and 4% of spiculated masses were more clearly seen with tomosynthesis than in the 2-D images. Round masses tended to be visualised as cysts or fibro-adenomas when scanning with ultrasound. The radial distortions or spiculated masses were shown to represent either radial scars or unexpected invasive malignancy.

There is no difference in the perception of micro-calcification when using tomosynthesis and no difference in assessment of the size, shape and configuration of the particles or the cluster. In the calcification cases, it was harder to appreciate the whole size of the cluster in tomosynthesis without using the slab facility for widening the slice thickness of the images.

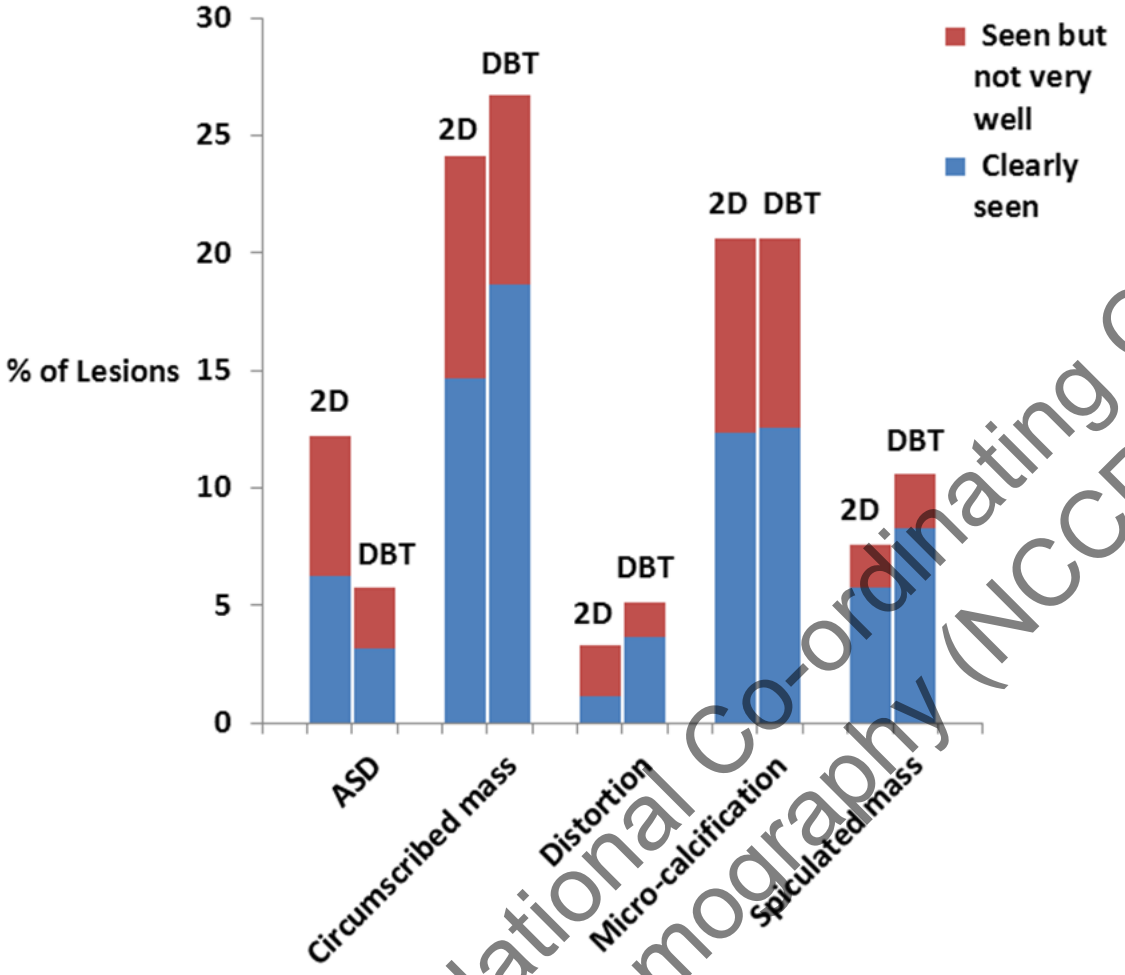

Figure 20. Visibility with tomosynthesis and with 2-D imaging

4.8 Diagnostic value of tomosynthesis vs. 2-D

A total of 303 lesions were identified in the 277 assessment cases examined during the evaluation period. As part of the TOMMY trial, data comparing diagnostic value of tomosynthesis vs. 2-D was collected, using a five-point scale. The results for the evaluation subset, taken from the study, are shown in Figure 21 below.

In more than half (58%) of lesions the readers judged the diagnostic value of both imaging modes as the same. Tomosynthesis was considered better (or much better) for 37% of the lesions, and worse (or inadequate) in only 5% of them. There was a total of 13 lesions in the latter category, 11 of which were micro-calcifications, one an asymmetric density and one a distortion.

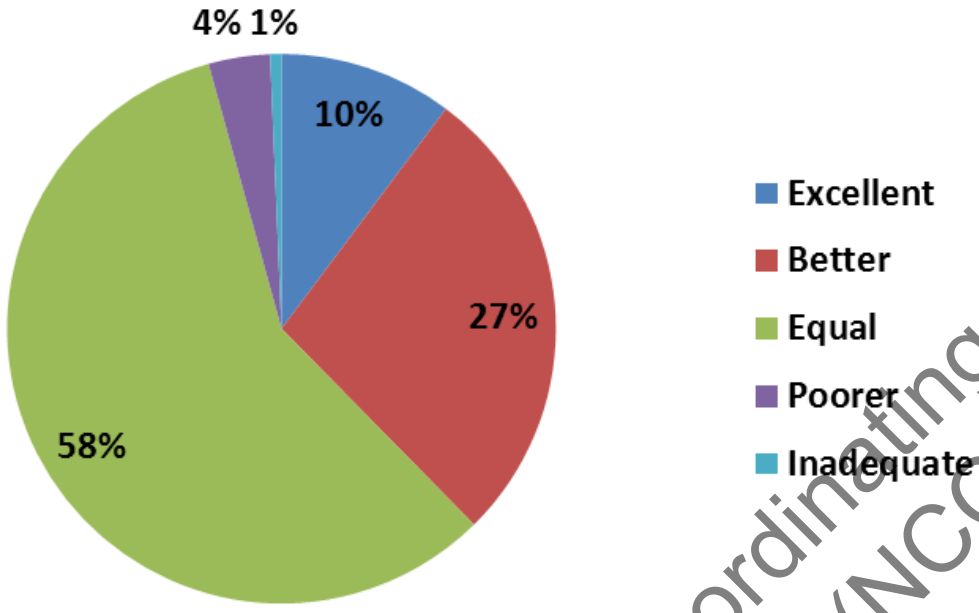

Figure 21. Readers' assessment of the diagnostic value of tomosynthesis compared to 2-D imaging

5. Equipment reliability

The equipment was generally reliable during the assessment evaluation period. Only one fault was recorded on the NHSBSP Equipment Fault Report Forms during the period: the compressed breast thickness was not being displayed. This was in November 2012 and is recorded at Appendix 5. It was resolved by recalibration of the thickness. There was no equipment downtime due to the fault or the recalibration.

One software error was recorded in the X-ray room's communication book, which was resolved locally by the radiographer. No other software errors were recorded during the evaluation period.

The Selenia Dimensions did not experience any downtime during the three-month evaluation period. There was some downtime prior to the evaluation period while the system was still bedding down.

6. Electrical and mechanical robustness

There were no safety issues, and no electrical or mechanical problems were encountered during the evaluation period, other than the single fault reported in section 5.

7. Radiographers' comments and observations

A new standard evaluation form no 11 (a copy of evaluation form 9 in the evaluation guidelines which had been modified for use with tomosynthesis systems) was used to collect the views of radiographers regarding the use of tomosynthesis for assessment. A total of 14 out of 20 questionnaires were returned. The responses are amalgamated in the table at Appendix 6 with the main points explained below.

The equipment was installed in a room that was some distance away from the other X-ray rooms, off a separate corridor. This was perceived as an inconvenience, but it was not related to the system under evaluation. Similarly, because use of the equipment was part of a research trial, there was an additional time commitment related to explanations and consent issues, which also contributed to the operators' overall experience but was not due to the practical use of the Selenia Dimensions tomosynthesis system. There was no other IT equipment in the room, apart from the unit and its acquisition workstation. If there had been, it might have helped with some of the issues raised by the respondents.

7.1 Operator's manual

Hologic provided two large manuals: a user manual and a quality control manual. Half the respondents considered that they were good (3) or average (4) while the others either did not use them or did not know about them. A single respondent qualified them as complex, and found the cleaning information vague and unhelpful.

An in-house developed set of instructions was in use and was preferred by the large majority, with only one person saying she was not happy with it. One wanted a more detailed version.

When comparing the manuals to those for 2-D imaging, of those who responded, one thought they were better and four thought they were the same.

7.2 Training

The applications training for tomosynthesis use was delivered by Hologic to the senior radiographers and those who were to train other staff. The training was cascaded to others over a period of time as described in Section 11.

The training was considered excellent (2), good (8) or average (1) by those who responded. One commented that they were already using similar units for 2-D imaging and were therefore already familiar with their general operation.

The training for the acquisition workstation was regarded as excellent (1), good (8) or average (1).

The results of the comparison with 2-D was that it was judged better (1) or the same (9) on both training-related questions.

7.3 Ease of use of the unit

Respondents rated this as excellent (7) or good (7). This was probably helped by their familiarity with the unit from the 2-D Dimensions systems that they already used in their routine work.

7.4 Ease of fitting of the tomosynthesis faceplate

This was rated as excellent (1), good (12) or average (1). No additional comments were made relating to fitting or removing this add-on to the unit.

7.5 QC testing for tomosynthesis

The QC tests were developed for the TOMMY trial, and some were more complex than the new guidelines which have been developed for routine use in the NHSBSP[15]. Only one respondent rated this special QC testing as easy, but many considered it time-consuming. The others rated it as average (9) with four rating it as difficult. One said that it took some time getting used to the tests and it would have been better if there was a PC available in the X-ray room. Another commented that the export of QC data to disk was time-consuming. Two others said they rarely performed the QC in person and did not become familiar enough with it. Another pointed out that the radiographer who was doing the QC testing was a resource unavailable for clinical work during the considerable time taken for the testing. An additional comment from another radiographer was that early clients could not be offered tomosynthesis because of the time taken for QC testing.

The time for the daily QC testing with the TOMMY protocol took on average 30 minutes. With the new NHSBSP guidelines, this time is expected to be cut down to about 15 minutes.

With regards to weekly calibration, respondents rated this as average (7), difficult (4) or easy (3).

Very few responded to the question about the QC for the SecurView workstation. Those who did rated it as easy (1), average (2) or difficult (1). One radiographer thought that it was normally done by physics staff, while another said that no training had been given for doing this task.

7.6 Compression times for tomosynthesis

All respondents thought that compression times for the tomosynthesis exposures were acceptable. When compared to the acceptability of compression times for 2-D exposures, six said it was the same with four rating it worse.

Two commented that the clients either did not complain or made no negative comments. Two others commented that the tomosynthesis imaging took longer.

7.7 Limit to patient throughput for tomosynthesis

The majority of respondents commented that the time taken to explain about the gantry movement, and the consenting of the woman for the trial study together with the paperwork that they had to do before the examination, increased considerably the time taken for each examination and limited patient throughput. One also mentioned a queue of patients during busy clinics as a result. Whilst this situation was correct for the trial study, which required additional processes, these would not normally be required for routine assessments.

Among the respondents, nine thought patient throughput was limited while five disagreed. One commented that the location of the X-ray room and the time taken for any additional assessment views meant that it took longer overall. Another one commented that the unit was fine, but the explanation and consenting took a long time.

When compared to 2-D imaging, those who responded said throughput was the same (1) or worse (6).

While these comments about patient throughput in the trial were rather negative, there were no comments that suggested the unit itself was directly the cause of the limitations.

7.8 Comfort level for the women for tomosynthesis

Explanations for the gantry movements and exposure times were given to the women. Women were not asked formally to assess the comfort or otherwise of tomosynthesis. These ratings are based on the radiographers' own perceptions and any comments volunteered by individual women. The radiographers rated the comfort of women as excellent (1), good (8) or average (4).

7.9 Range of controls and indicators for tomosynthesis

All the expected controls were present and the respondents all said that they were easy to find and use.

When comparing with 2-D imaging, those radiographers who responded said they were the same for all controls.

7.10 Image appearing at the acquisition workstation and image storage for tomosynthesis

The time for the image to appear at the acquisition workstation was rated excellent (2), good (7) or average (4). One mentioned that the images were very quick to appear. When compared to 2-D imaging, timing was judged the same by those (10) who responded.

The time for storage of the images was rated excellent (2), good (6) or average (4). One thought that images coming in from outside the centre to the SecurView (for the TOMMY trial) affected its normal operation. When compared to 2-D imaging, it was judged the same (3) with no other responses.

The time for image auto-deletion was rated good (1), average (2) or no response. Most commented that it was never done or not allowed.

7.11 Image handling and processing facilities at the acquisition workstation for tomosynthesis

When rating the image handling and processing facilities at the acquisition workstation, scrolling through the image levels was rated as excellent (2), good (10) or average (1). Seven assessed it as the same as for 2-D imaging.

Radiographers rated the image processing facilities as excellent (2) or good (10). When comparing to 2-D imaging, ten rated them the same, with no other responses.

Use of query/retrieve at the workstation to bring back prior images was rated good (7), average (2) or satisfactory (1). When compared to 2-D imaging, radiographers judged it better (1), the same (6) or worse (1). One comment made was that having a PC in the X-ray room helps with the setting up for assessment.

7.12 Ease of use of the human interface facilities at the acquisition workstation

There was no issue with using the keyboard. Four judged the ease of use as excellent, with eight judging it good and two average. When comparing to 2-D imaging, 11 rated it the same.

Of those who responded about the touchscreen, ease of use was judged as excellent (3), good (7) or average (1). Again, ten rated it the same as for 2-D with no other response. One said that there was a need for a rigid protocol to ensure that an incorrect name is not selected from the worklist with the touchscreen.

Similarly, four found it easy to use the trackerball, with eight considering it good and two average. When compared to 2-D imaging, eleven judged it the same, with no other response.

The wheel for scrolling through the tomosynthesis planes was rated by respondents as excellent (4), good (9) or average (1).

7.13 Image quality for tomosynthesis

Image quality at the acquisition workstation was deemed to be excellent (3), good (9) or average (2).

Radiographers rated the overall image quality of the system in tomosynthesis mode as excellent (3) or good (11).

7.14 Level of confidence in the unit for tomosynthesis

The respondents rated their level of confidence in the unit for tomosynthesis as excellent (3) or good (11). Compared to 2-D imaging, one judged it better with ten the same.

7.15 Hazards

All respondents agreed that there was no hazard to themselves due to operating the unit in tomosynthesis mode. When comparing potential hazards to 2-D imaging, nine said there was no difference, with no other response.

Nine radiographers said there were no hazards to the woman with the unit operating in tomosynthesis mode.

7.16 General comments

A number of general comments were made on the questionnaire by radiographers. Most of those who responded generally enjoyed using the Dimensions in tomosynthesis mode and did not find any issue with the unit itself. Among their comments were:

- generally easy to use in tomosynthesis mode
- unit easy to use. Clients found it acceptable, however a good level of explanation was necessary
- enjoyed using the equipment – clients seemed very satisfied
- there were greater electrical, electronic and mechanical consequences if the exposure switch was released prematurely when compared to equipment used for 2-D screening
- data volume for image storage needs to be taken into consideration for the local PACS

- once trained and using regularly – routine performance was similar to normal mammography. Slightly longer to perform examination purely down to management, but this did not have an adverse effect on women or radiographer

8. Radiologists' comments and observations

Another new evaluation form (based on evaluation form 9 of the evaluation guidelines) was used to collect the views of radiologists regarding the use of tomosynthesis for assessment. All six of the questionnaires sent out were returned. The responses are amalgamated in the table at Appendix 7.

The comments on workflow and on setting hanging protocols should be seen in the light of the fact that radiologists are not expected to administer workstation settings. The responsibility for this rests with the local PACS management team, who are normally charged with ensuring that the readers have the hanging protocol set-up they need. Comments on calcifications are made in several sections below. The reservations expressed by some readers should be considered in the context of their equal detectability in 2-D and tomosynthesis, as reported in Section 4.6.

While the majority of respondents' answers were "good", it should be noted that some comments (such as the time taken to view many image planes) apply to tomosynthesis in general rather than to the Selenia Dimensions in particular.

8.1 Operator manual

Only two readers had used the manual, and they judged it as excellent.

8.2 Applications training for tomosynthesis

At the start of the study, none of the readers had used any other tomosynthesis mammography system, but all had attended a formal training course externally at Kings College Hospital. Five said the applications training provided by the supplier was good.

8.3 Use of reporting station controls for tomosynthesis

Most respondents rated the use of the mouse/trackerball, keyboard and keypad as good or average, with one person having found the keyboard and keypad excellent.

8.4 Image handling tools for tomosynthesis

Regarding the use of ordinary image handling tools (such as zoom) for tomosynthesis, three found these good and one each found them average, satisfactory or poor. One

reader thought the zoom capability limited and one would have preferred whole image zoom.

Three considered the special tomosynthesis image handling tools (ciné, slider etc) to be good, one average and one satisfactory.

8.5 Visibility and usability of icons on screen for tomosynthesis

The on-screen icons were assessed as good (3) or average (3).

8.6 Slab thickness change when viewing tomosynthesis images

All readers used the facility to change the slab thickness when viewing tomosynthesis images, with two mentioning its usefulness for calcifications.

8.7 Reading/reporting workflow in tomosynthesis mode

Four thought the workflow was good. Two considered it poor, and explained their view with reference to the longer reading times for tomosysnthesis images than for 2-D.

8.8 Time for image to appear on screen in tomosynthesis mode

For both new patient selection and in-examination change, two readers rated the time taken as excellent and three as good. The remaining two responses were satisfactory and poor, respectively.

8.9 Recording on NBSS for tomosynthesis images

The assessment findings were recorded on NBSS (National Breast Screening System, the NHSBSP information system), as Phase II had been implemented at the centre. There were no special provisions for recording tomosynthesis findings.

8.10 Adjustment of reporting monitors to suit the user

One found this easy, two average and two difficult.

8.11 Navigation between tomosynthesis planes

Five found this easy and one average.

8.12 Hanging protocols for tomosynthesis

Two readers found setting up and changing hanging protocols average, and two found it difficult. However, this is not normally their responsibility, as explained above.

8.13 Image quality of tomosynthesis images

Three readers considered the image quality excellent, two good and one average.

8.14 Overall image quality (sharpness and contrast) of tomosynthesis images

Four readers thought the sharpness was good, while contrast was rated as good (1) or average (3).

8.15 Overall satisfaction in use for assessment

Readers' overall opinion of the tomosynthesis system for assessment was excellent (3), good (2) or average (1).

8.16 General comments

Radiologists made a number of general comments on the questionnaire. Each of the following comments was made by single (different) individuals:

- tomosynthesis enables better assessment of distortions and better identification of round masses
- calcifications thought to be difficult to see
- viewing was time-consuming for large dense breasts with many image planes
- found it hard to look at the images while scrolling through
- would like to see the ciné loop facility improved

9. Information systems

9.1 Workflow configuration

The Selenia Dimensions unit and the SecurView DX reporting workstation were installed by Hologic on the imaging VLAN (local area network) and integrated into the local Sectra PACS to allow for storage of the images.

The Dimensions was connected to NBSS so that the worklist was displayed at the workstation.

Only the 2-D images could be stored on the Sectra PACS, as the tomosynthesis images were too large and, although in standard DICOM format, were encoded in a special format which could not be displayed by the PACS.

Hologic installed a separate SecurXchange mini-PACS on the imaging VLAN to store all imaging information from the Dimensions and to route the images to the SecurView DX reporting workstation. These included the 2-D “For Processing” (raw), the “For Presentation” (processed) images, the tomosynthesis projections and the reconstructed planes.

In normal operation, the Dimensions only pushed the 2-D images to the Sectra PACS, but pushed both the 2-D and tomosynthesis images to the SecurXchange. Whenever a patient examination was carried out, the SecurXchange automatically sent all the “For Presentation” 2-D and tomosynthesis images to the SecurView DX to be available for clinical review by the radiologists.

The workflow diagram is given in Figure 22. The red arrow indicates the path for Query/Retrieve when used to bring priors and any magnification views to the SecurView DX workstation.

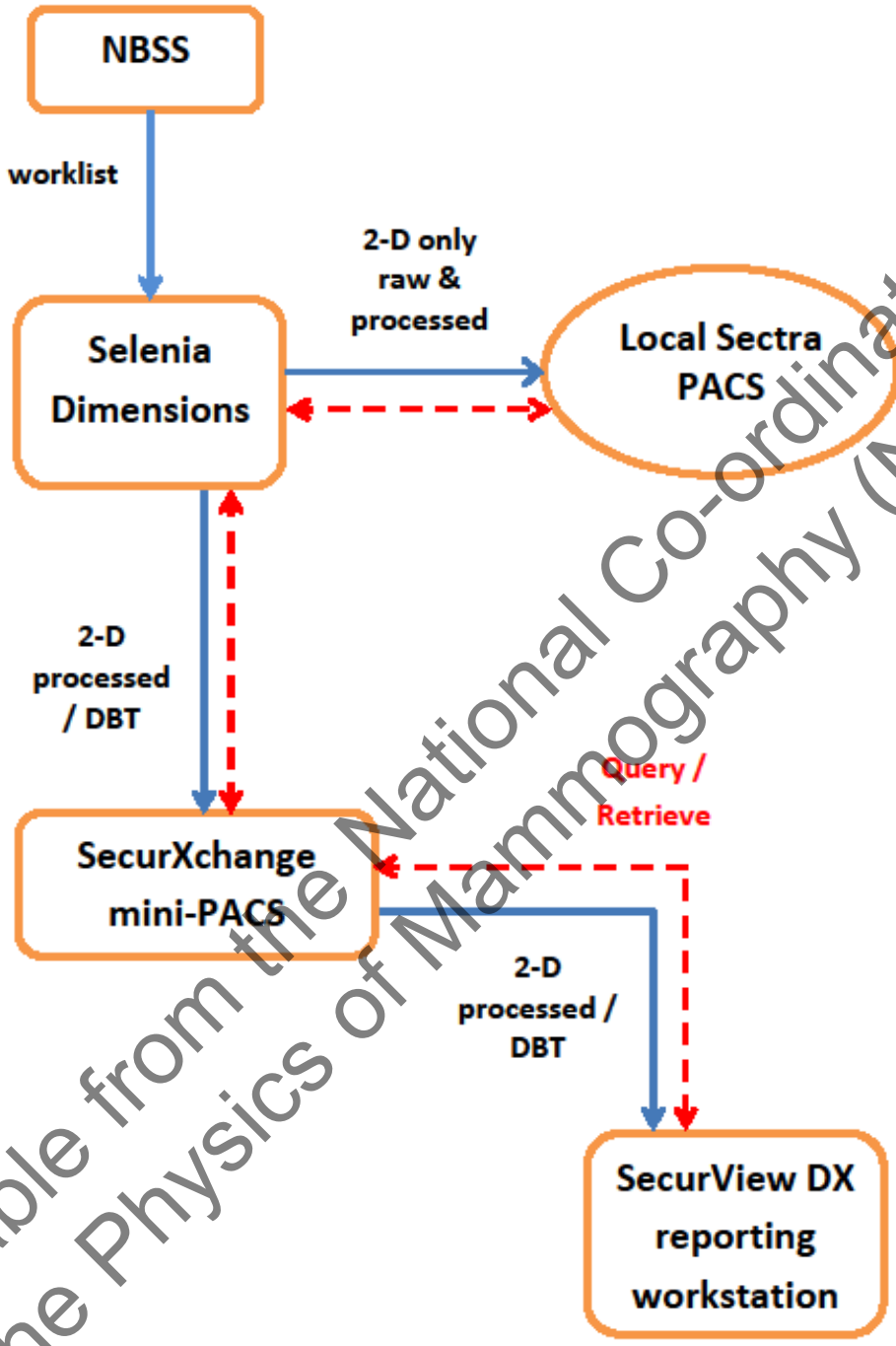

Figure 22. Workflow diagram for images

9.2 Hologic SecurView DX reporting workstation

The SecurView DX reporting workstation consists of a computer where images are cached on the local hard drive, with two 5 MP LCD greyscale monitors and a dedicated mammography workflow keypad. It uses a dedicated Mammography Based Image Review Software.

The configuration in use in the centre did not have any additional 1.3 MP colour monitor for connecting to the local network to retrieve NBSS information.

The SecurView DX was connected to the SecurXchange to view the tomosynthesis images and also to the local Sectra PACS, enabling DICOM Query Retrieve functionality for prior 2-D images.

The Hologic SecurView DX is shown in Figure 23.

Figure 23. Hologic SecurView DX reporting workstation

Figure 24 shows the Hologic mammography workflow keypad dedicated for use with tomosynthesis images. This keypad works in tandem with the SecurView workstation and some radiologists preferred its use. It was found to be very useful for switching between 2-D and tomosynthesis reading, and for using the roll bar to scroll between the tomosynthesis planes.

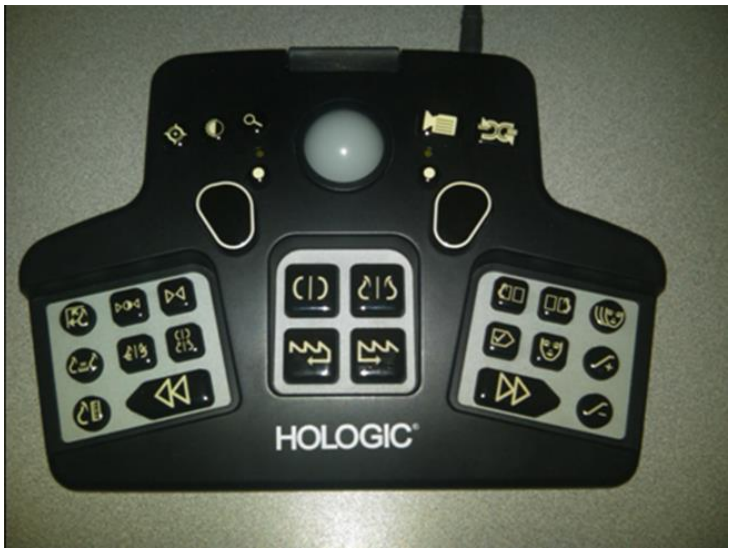

Figure 24. Hologic tomosynthesis workflow keypad

9.3 Image sizes

The “For Processing” 2-D images were 64MB or 104MB for the two views of both breasts, depending on image size (18cm x 24cm or 24cm x 30cm). The corresponding “For Presentation” sizes were also 64MB or 104MB.

The tomosynthesis images were in a special “SC” format. At the time of the trial, neither Hologic nor the Sectra PACS supported the DICOM standard for tomosynthesis images (BTO) for storage or display. The image sizes varied with the thickness of the breasts (and hence the number of reconstructed planes), but on average, were 340MB for the two views of both breasts. Images in BTO format, which is now available, would be substantially larger, of the order of four times or more larger ie approximately 1360MB for the same four views, but could be stored on any compatible PACS.

Image storage for tomosynthesis images will have a major impact on PACS storage in future and needs to be an essential consideration if implemented for routine use.

10. Confidentiality and security issues

The evaluation complied fully with NHS Cancer Screening Programmes' Confidentiality and Disclosure Policy[16]. In addition, the women who were assessed during this evaluation had also given their written consent to the use of the data which was gathered as part of a clinical trial.

All electronic patient data was stored on NBSS and the images were stored on the local Sectra PACS and the SecurXchange mini-PACS. Access to each of these systems is restricted to authorised users only by password protection.

Access to the Selenia Dimensions acquisition workstation is controlled by typing a username and password or fingerprint recognition. Access to the SecurView DX is also password protected with individual readers having their own passwords. The images on the workstation were not the primary record and the workstation's own software was not used to record any reports.

11. Training

The radiologists attended the training course which was available at King's College Hospital at the time. The course content was as follows:

a. Principles of tomosynthesis
b. Tomosynthesis appearances of normal/benign/malignant cases
c. Hands-on reading of test sets
d. 2-D vs. tomosynthesis imaging comparison
e. Practical self-assessment of test sets with feedback

Most of the readers in the centre who were working on the trial study attended this course several months before the installation of the equipment at the centre.

Applications training for the radiologists was also provided at the centre by Hologic at the time of installation. Most of the readers involved in the evaluation attended this course. A refresher/update course some time after they had started reading might have been beneficial in increasing awareness of the use of the workflow and tomosynthesis facilities of the SecurView DX reporting station.

Applications training was provided by Hologic at the time of installation. This training was given to lead radiographers and trainers principally, and was then cascaded down to all radiographers who worked on the trial study. It took some time before all of the staff were trained, due to work patterns (rotation to vans and to the centre).

As there were other Selenia Dimensions already in operation in the centre for 2-D imaging, all radiographers were familiar with the normal day-to-day operation of the unit.

12. Conclusions and recommendations

The overall assessment of the practicality and usefulness of the Hologic Selenia Dimensions tomosynthesis system for assessment was very positive. The radiographers found it generally easy to use and were satisfied with timings and image quality at the acquisition workstation. Connection with NBSS to provide assessment worklists was satisfactory. The readers were mostly satisfied with the tomosynthesis images and workflow, although a few possible areas for improvement were noted.

Comparison of the detection of different types of lesion in 2-D and tomosynthesis yielded the somewhat surprising result that there was no difference in the detection of calcifications. While fewer asymmetric densities were seen with tomosynthesis, for other types of lesions more were seen with tomosynthesis than with 2-D imaging.

The equipment was found to be very reliable during the period of the evaluation. Mean glandular doses for both 2-D and tomosynthesis imaging were found to be well below the national DRL.

The Hologic Selenia Dimensions was found to be suitable for use in assessments in the NHSBSP.

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Appendix 1: Physics routine survey report

Regional Radiation Protection Service NHS

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Mammography Physics Routine Survey Report

Tommy Trial Unit

Jarvis Breast Screening Centre

1 Introduction

A routine radiation protection and performance survey of the digital mammography equipment was undertaken in August 2012. The X-ray equipment was tested in accordance with the requirements of the Ionising Radiations Regulations 1999 and NHS BSP 33, 'Quality Assurance Guidelines for Medical Physics Services'. Engineering controls, safety features and warning signals provided by the employer were also checked as part of the survey.

The performance of the equipment was checked using procedures described in IPEM89 "The Commissioning and Routine Testing of Mammographic X-ray Systems" and NHSBSP publication 0604 "Commissioning and Routine Testing of Full Field Digital Mammography Systems". Performance was compared with NHSBSP standards and the Recommended Standards for the Routine Performance Testing of Diagnostic X-Ray Imaging Systems (IPEM91).

2 Equipment

Mammography Unit: Hologic Selenia Dimensions

3 Conclusions and Recommendations

Detailed results are given in the attached summary. Where results exceed remedial criteria these are reflected in the recommendations given below.

Flag	*Recommendations*	*Local Action Taken (where required)*	*Sign & Date*
R/A	The X-ray beam overlaps the back and sides of the detector by more than 5mm for both the 18x24 and 24x30 field sizes in contact mode and the overlap on the right hand side is up to 12mm. The engineer should be asked to check and adjust the alignment so it is between 0-5mm overlap on all sides of the detector as soon as possible.		

Note: You are advised to warn service companies in advance of any issues that require investigation at the next service so that they can schedule additional time for the engineer.

Mary Simon
Principal Physicist
28th August 2012

Lesley Leavesley
Principal Physicist

Key:
R Immediate action required R/A To be resolved as soon as practicable A To be addressed A/G Points to note G Satisfactory

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Regional Radiation Protection Service

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Mammography Routine Performance Report
Results Summary

Location	*Jarvis BSC* *X-ray Room Tommy Trial*	***Survey Date***	08/08/2012

Equipment

X-ray Set	Hologic	Selenia Dimensions
Detector	DR Hologic	 Selenia Dimensions
Small Field Digital	n/a	n/a

Survey Results

1 Radiation Protection

Measurement	Criteria	Baseline	Result	OK	Comments
X-ray unit				✔	
Room Protection				✔	
Local Rules	Up to date, on display			✔	
Room Warning Lights	Functioning			✔	

2 Tube and Generator

Measurement	Criteria	Baseline	Result	OK	Comments
Tube Voltage (kV)	Max error ±1kV		0.7	✔	
Tube Output (µGy/mAs@50cm)					
28kV MoMo BF	>120 + 70% of baseline			☐	N/A
28kV MoRh BF				☐	N/A
28kV RhRh BF				☐	N/A
28kV WRh BF		74	69	✔	
28kV WAg BF		75	71	✔	
28kV MoMo FF				☐	N/A
28kV WRh FF		61	54	✔	
Output Rate (MoMo)	>7.5 mGy/sec			☐	N/A
Focal Spot (mm)					
BF Mo	150% of nominal value	Nominal BF: 0.3		☐	N/A
BF Rh				☐	N/A
BF W			0.31	✔	
FF Mo		Nominal FF: 0.1		☐	N/A
FF Rh				☐	N/A
FF W				☐	N/A

3 X-ray Set

Measurement	Criteria	Baseline	Result	OK	Comments
Patient Compression					
Max (kg)	15 - 20 kg		19.3	✔	
Maximum error (kg)	2 kg		1.3	✔	
Change over 30s	Should be no change			✔	
CBT indicator max error (mm)	±5 mm at 100 N		3.0	✔	
Edge of bucky alignment (mm)	Within 5 mm			☐	N/A

4 Alignment

Measurement	Criteria	Baseline	Result	OK	Comments
X-ray to Light Alignment (mm)	±5mm at all edges		F B L R	✔	
Mag BF W			0 -2 1 -1		
24x30 BF W			0 0 2 0		
18x24 BF W			0 -3.5 0 -1.5		
X-ray to Detector Alignment	0-5mm overlap all sides		F B L R	☐	1
Mag BF W			1 4 2 5		
24x30 BF W			2 8 7 12		
18x24 BF W			2 10 5 12		

5 Detector Performance

Measurement	Criteria	Baseline	Result	OK	Comments
Detector Response					
Air Kerma (µGy) at PV= 400	20% change frm baseline	113.7	113	✔	
Noise	10% change frm baseline	6	5.90	✔	
SNR	10% change frm baseline	57.7	59.2	✔	
Limiting Resolution (lp/mm)	<75% of baseline	8.9	7.1	✔	
SWCTF(perp) at 1, 4, 8lp/mm	10% change frm baseline	0.36 0.23 0.13	0.36 0.24 0.13	✔	
SWCTF(para) at 1, 4, 8lp/mm	10% change frm baseline	0.36 0.23 0.12	0.37 0.24 0.13		
Spatial Discontinuity	None			✔	
Image Retention	Retention factor <0.3		0.01	☐	
Uniformity	<10% variation		DR 4.1 CR Centre-side Left-right	✔	

6 Image Quality

Measurement	Criteria	Baseline	Result	OK	Comments
TORMAX					
Perpendicular lp/mm	Significant difference			✔	
Parallel lp/mm	from baseline				
Contrast (%) 6mm		0.58	0.58		
Contrast (%) 0.5mm		2	2.7		
Contrast (%) 0.25mm		2.7	2.7		
TORMAM	Significant difference				
Diff from Baseline	from baseline		Unchanged	✔	

7 AEC Performance

Measurement	Criteria	Baseline	Result	OK	Comments
AEC Repeatability (%)	5% max dev from mean		1.0	✔	
Back up Timer	Functioning		mAs BF: FF:	✔	

18x24											
CNR - variation with PMMA	10% change frm baseline	Settings			CNR	Settings			CNR	✔	
2 cm		25	W	Rh	10.11	25	W	Rh	10.69		
3 cm		26	W	Rh	9.38	26	W	Rh	9.65		
4 cm		28	W	Rh	8.52	28	W	Rh	8.59		
4.5 cm		29	W	Rh	7.89	29	W	Rh	8.23		
5 cm		31	W	Rh	7.97	31	W	Rh	8.19		
6 cm		31	W	Ag	7.60	31	W	Ag	7.81		
7 cm		34	W	Ag	6.45	34	W	Ag	6.27		

Mag											
CNR - variation with PMMA	10% change frm baseline	Settings			CNR	Settings			CNR	✔	
2 cm		25	W	Rh	8.24	25	W	Rh	8.19		
3 cm											
4 cm						30	W	Rh	5.82		
4.5 cm		31	W	Rh	5.29	31	W	Rh	5.23		
5 cm											
6 cm		34	W	Ag	3.70	34	W	Ag	3.48		

8 Mean Glandular Dose

Measurement	Criteria	Baseline				Result				OK	Comments
18x24											
MGD (mGy) at thickness	25% change frm baseline	Settings			MGD	Settings			MGD		
2cm	<1mGy	25	W	Rh	0.58	25	W	Rh	0.62	✔	
3cm	<1.5mGy	26	W	Rh	0.81	26	W	Rh	0.85	✔	
4cm	<2mGy	28	W	Rh	1.14	28	W	Rh	1.11	✔	
"Standard breast" 4.5cm	<2.5mGy	29	W	Rh	1.38	29	W	Rh	1.40	✔	
5cm	<3mGy	31	W	Rh	1.95	31	W	Rh	1.93	✔	
6cm	<4.5mGy	31	W	Ag	2.64	31	W	Ag	2.52	✔	
7cm	<6.5mGy	34	W	Ag	3.00	34	W	Ag	2.80	✔	

Comments

1 The X-ray beam overlaps the back and sides of the detector by more than 5mm for both the 18x24 and 24x30 field sizes in contact mode.

Reported By: ***Lesley Leavesley***
Principal Physicist

Appendix 2: Physics performance testing report for clinical trial

National Coordinating Centre for the Physics of Mammography NHS

SIX-MONTHLY REPORT ON TECHNICAL PERFORMANCE OF TOMOSYNTHESIS EQUIPMENT FOR TOMMY TRIAL

Clinical site:	Jarvis Breast Sceening Centre
Equipment tested:	Hologic Selenia Dimensions and SecurView workstation
Date of testing:	8th August 2012
Tested by:	Mary Simon, Lesley Leavesley

INTRODUCTION

This report summarises conventional and tomosynthesis aspects of technical performance of the mammographic X-ray unit and of the reporting monitors used for the TOMMY trial. The full range of conventional digital mammography physics tests is carried out on each unit in accordance with NHSBSP0702 and IPEM 89 and reported separately. This report duplicates some aspects of the conventional report and includes additional tomosynthesis results.

PART A

Summary of results

Test	Summary of results	Comment
1. Tube output and HVL measurements	Within 5% of baseline	Satisfactory
2. Compressed breast thickness indication accuracy	Within 0.2cm	Satisfactory
3. Dose and CNR under AEC control	2D doses within 10% of baseline. Tomo doses within 5% of baseline. 2D CNR max 6% change from baseline. Tomo CNR in QC mode is variable for larger thicknesses.	1
4. Tomo geometric distortion and z-resolution	Maximum displacement 0.2mm in the horizontal plane and 1mm vertically. Mean z-resolution 10.4mm	Satisfactory
5. Image quality	2D CDMAM similar to baseline Tomo CDMAM appears poorer than baseline in QC mode	2
6. SecurView Reporting monitors	Viewing conditions and monitor performance within acceptable limits	Satisfactory

Comments

1. When the software was upgraded in April it was noticed that the noise in tomo QC images of larger thicknesses of PMMA had subtly changed in appearance. Hologic were informed and they assured us that these changes were due to a software bug affecting tomo QC images but not affecting clinical tomo images (apparently the two undergo separate and different processing). Further checks on CNR images taken using a clinical exposure protocol show noise that is normal in appearance.
2. Tomo CDMAM images appear poorer than baseline for the larger detail sizes. The apparent change may be to be linked to the QC noise issue mentioned above, in which case clinical performance is likely to be unaffected.

Recommendations

None.

Celia Strudley
17/09/12

Performance report on TOMMY equipment at Jarvis, August 2012 Page 1 of 6

PART B

Detailed results

1. Tube output and HVL measurements

Measurements of tube output were made covering the clinical range of beam qualities and the HVL was checked at one tube voltage for each target filter combination. Measurements were made with the paddle in place (raised well above the dosemeter in accordance with NHSBSP0702) for the purpose of MGD calculation.

Results were compared against baseline measurements made by NCCPM at the start of the trial. Doses measured using different dosemeters may vary by up to 5%. Where tube output and HVL measurements differ by no more than 5% from measurements made by NCCPM at the start of the trial, the original measurements are used for the MGD calculations.

Table 1 *HVL and tube output measurements*

kV	target	filter	Measured HVL mmAl	Baseline for HVL (NCCPM)	Difference from baseline	Measured µGy/mAs at 1m	Baseline for output (NCCPM)	Difference from baseline
25	W	Rh				**10.0**	10.1	-1%
31	W	Rh	**0.57**	0.55	4%	**17.8**	18.2	-2%
31	W	Ag	**0.64**	0.62	2%	**19.0**	19.6	-3%
34	W	Ag				**23.7**	24.3	-2%
26	W	Al				**19.5**	19.8	-2%
31	W	Al				**34.7**	35.9	-3%
42	W	Al				**71.6**	75.5	-5%

2. Compressed breast thickness indication accuracy

The accuracy of the compressed breast thickness indication was checked using a method similar to that used by Hologic engineers when calibrating the system. This method employs a smaller piece of PMMA than that prescribed in IPEM89 and thus more closely resembles the clinical situation.

The remedial level specified in IPEM89 is 0.5cm, but generally 0.3cm or better can be achieved.

Table 2 *Compressed breast thickness accuracy measurements*

paddle size	actual thickness cm	indicated thickness cm	error cm
18x24	2.0	2.1	0.1
18x24	5.0	5.1	0.1
18x24	7.0	7	0.0
24x29	2.0	2.2	0.2
24x29	5.0	5.2	0.2
24x29	7.0	7.2	0.2

3. AEC dose and CNR

Images were taken under AEC control (AutoFilter mode) of a range of thicknesses of PMMA containing 0.2mm Al foil in order to assess doses and CNRs across the range of thicknesses. An airgap was left between the top of the PMMA and the paddle so that the indicated thickness matched the appropriate equivalent breast thickness for each thickness for PMMA.

The remedial levels specified in NHSBSP0702 for conventional mammography are 25% change in dose and 10% change in CNR. For the TOMMY trial we expect to keep doses within 10% and CNR within 5% of baseline values.

Table 3a *Dose and CNR under AEC control for conventional exposures*

Equivalent breast thickness (mm)	kV target filter	mAs	MGD (mGy)	Baseline MGD	Difference from baseline	CNR	Baseline CNR	Difference from baseline
21	25WRh	55	**0.63**	0.58	10%	**11.7**	11.3	4%
32	26WRh	84	**0.88**	0.81	9%	**10.6**	10.3	3%
45	28WRh	105	**1.18**	1.14	3%	**9.5**	9.5	0%
53	29WRh	128	**1.46**	1.38	6%	**9.0**	8.9	1%
60	31WRh	157	**2.05**	1.95	5%	**8.9**	9.1	-2%
75	31WAg	196	**2.75**	2.64	4%	**8.6**	8.7	-2%
90	34WAg	192	**3.07**	3.00	2%	**6.8**	7.3	-6%

Table 3b *Dose and CNR under AEC control for tomosynthesis exposures*

Equivalent breast thickness (mm)	kV target filter	mAs	MGD (mGy)	Baseline MGD	Difference from baseline	CNR	Baseline CNR	Difference from baseline
21	26WAl	42	**0.93**	0.88	5%	**30.4**	30.1	1%
32	28WAl	44	**1.08**	1.08	0%	**22.9**	23.0	-1%
45	30WAl	54	**1.52**	1.52	0%	**20.2**	19.6	3%
53	31WAl	68	**2.00**	2.00	0%	**21.2**	19.4	10%
60	33WAl	69	**2.42**	2.42	0%	**20.3**	17.7	14%
75	36WAl	84	**3.63**	3.63	0%	**16.4**	16.0	3%
90	42WAl	74	**4.48**	4.48	0%	**11.3***	12.0	-6%

**The result quoted here is for a repeat exposure. The initial result obtained was 5.1*

The CNR results have become variable in QC tomo mode for the greatest PMMA thicknesses since the software upgrade in April 2012. Narrow windowing and magnification revealed that the texture of the noise has changed. Hologic assured us in April that the changes we observed in noise in QC images was due to a software bug which affects processing of QC images but does not affect processing of clinical images. On a subsequent visit further tests of CNR using a clinical exposure protocol show that the noise is of normal appearance. A series of six repeat CNR measurements with 7cm PMMA in clinical mode gave a mean of 2.97 with a maximum deviation of 2%, whereas in clinical mode the mean was 10.4 with a maximum deviation of 6%. We have no baseline for CNR measurements from images acquired using a clinical exposure protocol.

4. Tomosynthesis geometric distortion and z-resolution

Tomosynthesis geometric distortion and z-resolution were assessed by sequentially imaging a test tool at heights of 7.5, 32.5 and 57.5mm within a stack of PMMA with an overall thickness of 60mm. The test tool contains a rectangular array of 1mm aluminium balls at 50mm intervals. A software tool was then used to measure the deviation of each ball within the reconstructed tomosynthesis image from its actual position in the x, y and z directions. The FWHM of each ball was also measured in the vertical direction to determine the z-resolution. The accuracy of the pixel size shown in the image header for each tomosynthesis slice was checked by using it to calculate the distance between balls and comparing with the actual distance between balls.

Table 4 *Summary of geometric distortion and z-resolution results*

Height above table	7.5mm	32.5mm	57.5mm
Maxiumum distortion parallel to tube axis (mm)	0.1	0.1	0.2
Maxiumum distortion perpendicular to tube axis (mm)	0.1	0.1	0.1
Maximum distortion in vertical plane (mm)	1	1	1
Resolution in vertical plane (FWHM) (mm)	10.9	10.5	9.8
Scaling error		4%	

5. Image quality (Threshold contrast detail detection)

Sixteen conventional and sixteen tomosynthesis images were taken of a CDMAM test object in order to assess image quality. The images were read automatically and the results and CDMAM curves are shown below. The baselines quoted are for the same CDMAM.

Table 5a *CDMAM results for conventional images*

Diameter (mm)	Predicted Human Gold Thickness	2 SE	Baseline Predicted Human Gold Thickness	2 SE
0.10	0.860	0.059	0.893	0.065
0.13	0.490	0.031	0.578	0.035
0.16	0.323	0.021	0.393	0.024
0.20	0.236	0.016	0.265	0.019
0.25	0.174	0.012	0.202	0.014
0.31	0.131	0.009	0.158	0.011
0.40	0.106	0.007	0.123	0.008
0.50	0.089	0.007	0.106	0.008
0.63	0.077	0.006	0.090	0.007
0.80	0.063	0.006	0.070	0.006
1.00	0.052	0.006	0.060	0.006

Table 5b *CDMAM results for tomosynthesis images*

Diameter (mm)	Predicted Human Gold Thickness	2 SE	Baseline Predicted Human Gold Thickness	2 SE
0.10	1.538	0.109	1.424	0.098
0.13	0.949	0.057	0.764	0.052
0.16	0.603	0.040	0.498	0.036
0.20	0.431	0.030	0.374	0.027
0.25	0.319	0.022	0.299	0.020
0.31	0.238	0.017	0.208	0.014
0.40	0.189	0.013	0.142	0.010
0.50	0.156	0.011	0.113	0.009
0.63	0.126	0.011	0.094	0.008
0.80	0.102	0.009	0.074	0.007
1.00	0.084	0.009	0.057	0.007

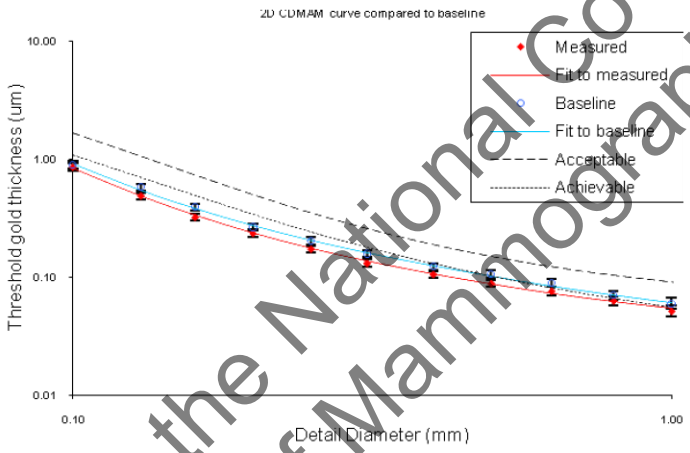


Figure 5a *CDMAM curves for conventional images*

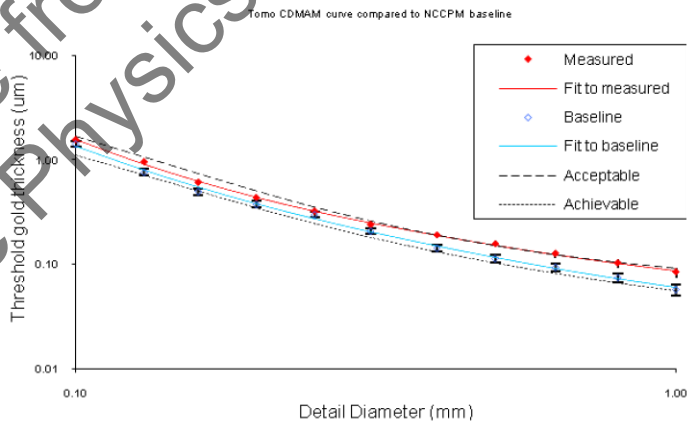


Figure 5b *CDMAM curves for tomosynthesis images*

6. Reporting monitor performance

The performance of the reporting monitors attached to the SecurView workstation was checked and is summarised below.

Normal viewing conditions:	Lights switched off in immediate area	
Reflections in monitors	No	
Illuminance (lux) under normal viewing conditions	**7.8**	Remedial action should be taken if illuminance exceeds 10 lux

	Left	Right	Remedial level
Minimum luminance (cd/m^2)	1.04	1.05	>1.5
Maximum luminance (cd/m^2)	551	556	<450
Maximum deviation from DICOM standard	2.2%	1.9%	>10%
Luminance ratio	530	529	<300
Difference between monitors	1%		>5%
Uniformity	3.2%	2.3%	>30%
5% on 0% and 95% on 100% visible?	Yes	Yes	
Are all resolution gratings visible?	Yes	Yes	
Are any disturbing artefacts seen?	No	No	

Appendix 3: 2-D clinical breast dose survey

NHSBSP Breast Dose Survey

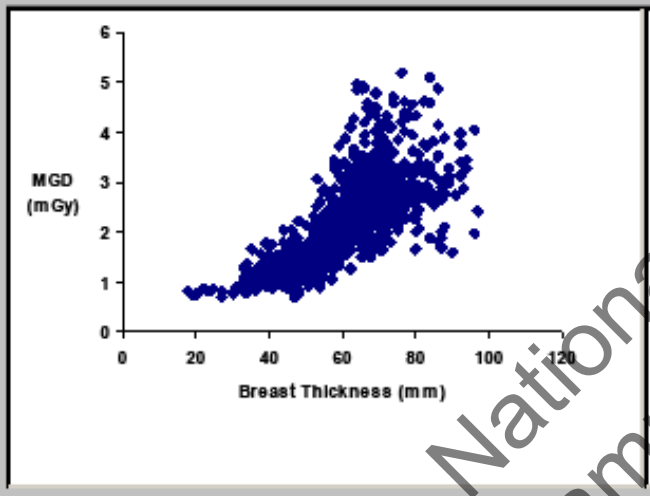
Survey No:	29
Centre:	Jarvis Centre
Date of first exam:	03/09/2012
Date of last exam:	29/11/2012
X-ray make	Hologic
Model:	Selenia Dimensions
Local Id:	
Installation:	fixed
kV mode:	auto
Type of data:	assessment

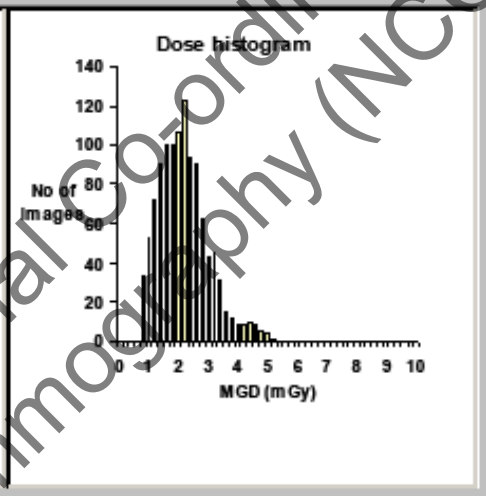
Tomo mode: 2D

MGD to standard breast

Auto/manual kV:	auto	PMMA thickness:	45mm
Auto/AEC setting:	AutoFilter	MGD mAs:	121.0
kV set:	29	HVL (mm):	0.530
Target:	W	MGD (mGy):	1.44
Filter:	Rh		

Physics Service	NCCPM
Physicist	





Count of images

view	main images	extra images
CC	552	6
MLO	552	5

Average doses for main images

view	no of images	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	552	0.71	5.21	2.15	61
MLO	552	0.71	4.97	2.22	61

Average doses per assessment examination

	no of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
Two view	277	0.86	9.71	4.38

Average dose for 50-60mm thick breasts

view	no of images	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
MLO	160	1.87	0.07	56

Summary of X-ray factors selected

Anode	Filter	kV	Images
W	Ag	30	121
W	Ag	31	62
W	Ag	32	30
W	Ag	33	24
W	Ag	34	10
W	Ag	35	3
W	Rh	25	7
W	Rh	26	17
W	Rh	27	37
W	Rh	28	139
W	Rh	29	115
W	Rh	30	192
W	Rh	31	181
W	Rh	32	177

Appendix 4: DBT clinical breast dose survey

NHSBSP Breast Dose Survey

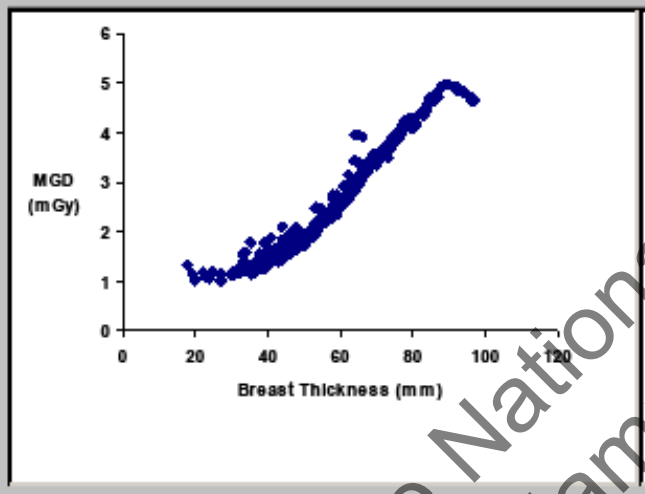
Survey No:	30
Centre:	Jarvis Centre
Date of first exam:	03/09/2012
Date of last exam:	29/11/2012
X-ray make	Hologic
Model:	Selenia Dimensions
Local Id:	
Installation:	fixed
kV mode:	auto
Type of data:	assessment

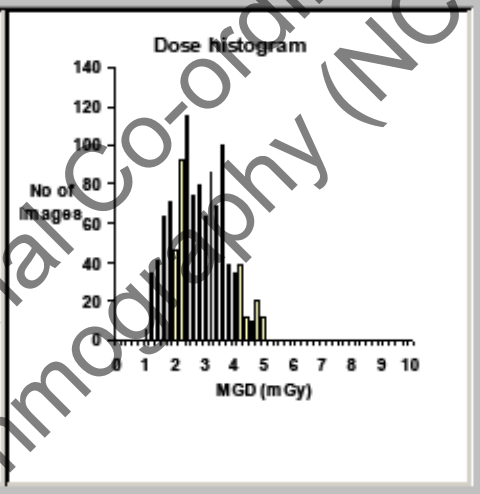
Tomo mode: Tomo

MGD to standard breast

Auto/manual kV:	auto	PMMA thickness:	45mm
Auto/AEC setting:	AutoFilter	MGD mAs:	66.0
kV set:	28	HVL (mm):	0.570
Target:	W	MGD (mGy):	2.08
Filter:	Al		

Physics Service: NCCPM
Physicist:





Count of images

view	main images	extra images
CC	552	1
MLO	552	

Average doses for main images

view	no of images	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	552	1.02	4.99	2.77	61
MLO	552	1.01	4.99	2.80	61

Average doses per assessment examination

	no of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
Two view	277	1.20	9.89	5.55

Average dose for 50-60mm thick breasts

view	no of images	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
MLO	160	2.28	0.04	56

Summary of X-ray factors selected

Anode	Filter	kV	Images
W	Al	26	7
W	Al	27	3
W	Al	28	15
W	Al	29	102
W	Al	30	71
W	Al	31	112
W	Al	32	191
W	Al	33	179
W	Al	34	177
W	Al	35	120
W	Al	36	62
W	Al	38	29
W	Al	40	24
W	Al	42	10
W	Al	43	3

Appendix 5: Fault reports requiring engineer visits

Date	Fault	Solution
27/11/12	Compression thickness not reading	Compression thickness paddle angle recalibrated

Appendix 6: Radiographers' answers to questionnaire

	Comments and observations	Comparison to 2-D
How do you rate the supplier's operator manual (if used)?	7 N/A, 3 good , 4 average One qualified it as complex with cleaning information vague and unhelpful. Some thought it was average to good. The others either did not use it or did not know about it.	9 N/A, 1 better, 4 same
Did you prefer an in-house simplified version?	13 yes , 1 no Most preferred this as a step by step guide, with only one not happy with it. One said that it could be more detailed.	
How good was the clinical applications training for tomosynthesis provided by the supplier for :		
Modality?	3 N/A, 2 excellent ,8 good, 1 average As only available to senior radiographers and trainers, took some time to cascade to others. One said they already had similar units and were already familiar with them.	4 N/A, 1 better, 9 same
Acquisition Workstation?	4 N/A, 1 excellent, 8 good, 1 average	4 N/A, 1 better, 9 same
How do you rate the unit's ease of use for tomosynthesis?	7 excellent, 7 good	
How easy was it to fit/remove the tomosynthesis faceplate?	1 excellent, 12 good, 1 average	
How do you find carrying out the :		
Special QC tests for	1 easy, 9 average, 4 difficult	

tomosynthesis?	One said it took some time getting used to and would have been better if a PC was available in the X-ray room. One said it was easy but took time. One said it was time-consuming with the export to disc. Two said they only rarely did it in person and did not become familiar enough with it. One pointed out that the radiographer was not available for clinical work while doing the QC.	
calibration tests for tomosynthesis?	3 easy, 7 average, 4 difficult	
SecurView workstation QC?	10 N/A, 1 easy, 2 average, 1 difficult One said it was done by QC staff. One said there was no training given.	
Were the compression times acceptable for each exposure? (If not, explain in comments)	14 yes One said that clients did not complain. Two said it took longer and one said that they did not get any negative comments.	4 N/A, 6 same, 4 worse
Did the unit performance limit patient throughput?	9 yes, 5 no One mentioned the location in the centre, and the time for additional views meant that it took longer. A number mentioned that the explanation about the gantry movement, the consent required for the study trial and the paperwork increased the throughput time. One also mentioned the build-up of a queue in times of busy clinics.	7 N/A, 1 same, 6 worse
How do you rate the comfort of women during	1 N/A, 1 excellent, 8 good, 4 average	

tomosynthesis exposures, including acceptability of gantry motion?		
Range of controls and indicators (on-screen icons) for tomosynthesis:		
Were all the expected controls present?	14 yes One mentioned that icons could be more obvious.	2 N/A, 12 same
Were they easy to find?	14 yes	2 N/A, 12 same
Were the icons easy to use?	14 yes One mentioned the need for more practice.	3 N/A, 11 same
How do you rate the time for :	1 N/A, 2 excellent, 7 good, 4 average	4 N/A, 10 same
an image to appear at the acquisition workstation?	One mentioned the images were very quick to appear.	
storage of the image?	2 N/A, 2 excellent, 6 good, 4 average One mentioned that the impact of images coming in from external sources to the SecurView slowed down the image storage.	11 N/A, 3 same
auto-deleting an image?	11 N/A, 1 good, 2 average Most commented that it was never done or not allowed	
How do you rate image handling at the acquisition workstation:		
scrolling through the image levels?	1 N/A, 2 excellent, 10 good, 1 average	7 N/A, 7 same
the processing facilities?	2 N/A, 2 excellent, 10 good	4 N/A, 10 same
use of query/retrieve?	4 N/A, 7 good, 2 average, 1 satisfactory	6 N/A, 1 better, 6 same, 1 worse

	One thought using a PC would be better than using Q/R to get prior images as they had been used to with 2-D imaging. One would have liked to be able to retrieve after the client file was open.	
How easy was it to use, for tomosynthesis, the		
Keyboard?	4 easy, 8 good, 2 average	3 N/A, 11 same
Touchscreen?	3 N/A, 3 easy, 7 good, 1 average	4 N/A, 10 same
	One thought it is easier to make mistakes without a rigid protocol in place. One pointed out that the response on the touchscreen was fairly quick because the data volume on the tomosynthesis workstation was less than on the centre's other Dimensions which are in constant use.	3 N/A, 11 same
	4 easy, 8 good, 2 average	
Tracker ball?	4 easy, 9 good, 1 average	
Wheel for scrolling through the tomosynthesis planes?		
How do you rate the following:		
Image quality at the acquisition workstation for tomosynthesis images?	3 excellent, 9 good, 2 average	
Overall image quality of this system in tomosynthesis mode?	3 excellent, 11 good	
What was your level of confidence in the unit?	3 excellent, 11 good	

Were there any potential hazards with use in tomosynthesis mode to:	
you?	13 no
the woman?	9 no
Any additional comments on general or imaging performance in tomosynthesis mode	Generally easy to use in tomosynthesis mode. Time consuming if changing back and forth for full assessment. Unit easy to use. Clients found it acceptable however a good level of explanation was necessary. QC test took a long time and were a bit arduous. Some breakdown occurred and the supplier's response was slow causing downtime. Enjoyed using the equipment - clients seemed very satisfied. There was greater electrical / electronic / mechanical consequences if exposure switch was released prematurely. For screening a simple robust solution is required. Data volume for image storage needs to be taken into consideration for the local PACS. Once trained and used - routine performance similar to normal mammography. Slightly longer to perform examination purely down to management - but did not have an adverse effect on women or radiographer.

Appendix 7: Radiologists' answers to questionnaire

	Comments and dbservations
How good were the operator manual instructions for tomosynthesis? (State N/A if not applicable/not used)	4 N/A; 2 excellent One had not seen the manual
How good was the application training for tomosynthesis provided by the supplier?	1 N/A; 5 good.
Did you attend any external training course for tomosynthesis? If so, please state where in comments.	All attended the course at Kings College Hospital.
How do you rate the use of the reporting workstation controls for tomosynthesis?	
Mouse/trackerball	2 N/A; 3 good; 1 average
Keyboard	1 excellent; 2 good; 3 average
Keypad	1 excellent; 4 good; 1 average
How do you rate the image handling tools (zoom, etc.) for tomosynthesis?	3 good; 1 average; 1 satisfactory; 1 poor One thought the zoom capability limited and another one would have preferred whole image zoom.
How do you rate the special tomosynthesis image handling tools (slider, ciné, etc.)?	1 N/A; 3 good; 1 average; 1 satisfactory One thought image loading was slow while another preferred to use the mouse wheel which was found easier to stop/start.
How do you rate the visibility and usability of on-screen icons for tomosynthesis?	3 good; 3 average
Did you sometimes change the slab thickness when reviewing the tomosynthesis images?	All made use of it with 2 mentioning its use in identifying calcifications.

How do you rate the reading/reporting flow pattern in tomosynthesis?	4 good; 2 poor One thought it too slow, which, although not an issue for assessment, would be an issue for screening.
How do you rate the time for an image to appear on the screen in tomosynthesis mode?	
New patient selection	2 excellent; 3 good; 1 satisfactory
In-examination change	2 excellent; 3 good; 1 poor
How easy was it to record findings for tomosynthesis on NBSS?	5 N/A ;1 difficult
How easy is it to adjust the height and angle of the reporting monitors to suit the user?	1 N/A; 1 easy; 2 average; 2 difficult One adjusted the chair.
How easy was it to navigate between the tomosynthesis planes?	5 easy; 1 average
How easy was it to set up different hanging protocols in tomosynthesis?	2 N/A; 2 average; 2 difficult One highlighted the need for specialist training and one said they had had no training for it.
How easy was it to change from one hanging protocol to another in tomosynthesis?	2 N/A; 2 difficult ; 2 average
What is your impression of the quality of images provided by the tomosynthesis system?	3 excellent; 2 good; 1 average
What is your opinion on the following on the whole image quality provided by the tomosynthesis system:	
Contrast?	2 N/A; 1 good; 3 average

Sharpness?	2 N/A; 4 good One said good for masses and spiculations. Three had reservations about calcifications. One said slabbing could help with calcifications.
What is your overall level of satisfaction with using this tomosynthesis system for assessments?	3 excellent; 2 good; 1 average
Any additional comments on general or imaging performance of the system for tomosynthesis	Strengths of tomosynthesis: • better assessment of distortions • better identification of round masses. Ciné loop needs improvement for everyday use. Calcifications difficult to see and evaluate – may require different protocols. Workstation uncomfortable and hanging protocols difficult to change once selected. Image viewing time-consuming for large dense breasts with many levels. Hard to look at image while scrolling through levels.

Appendix 8: Manufacturer's comments

The manufacturer has added the following comments that are not part of the current evaluation, but do provide further information about the equipment.

- with reference to imaging times (section 4.4) Hologic's official timings for different phases of exposure (4.5 cm Perspex) are as follows:

Table 3. Stopwatch timings in seconds for different phases of exposure of 4.5cm Perspex. (Hologic measurements)

	2-D	tomosynthesis	Combo: 2-D + tomosynthesis
Exposure time	maximum 2 seconds	4 seconds	10-12 seconds
Preview time	4-6 seconds	2 seconds	2 seconds for tomosynthesis 4-6 seconds for 2-D
Cycle time (time between two exposures)	25 seconds	25 seconds	25 seconds

- while not part of this equipment review, a subsequent software release (C-View) allows performing a combo mode procedure without requiring an actual 2-D exposure as the 2-D image can be generated from the tomosynthesis data. The elimination of the 2-D exposure shortens the acquisition time and patient compression time, and reduces radiation dose for a combo procedure by about half. The performance of C-View has been reported as part of the Oslo trial[17,18,19]
- with reference to section 4.5, in regards to reading time, there is now evidence that reading times decrease with experience in reading tomosynthesis studies. The Oslo screening trial group recently reported study reading times of approximately 60 seconds per study[20]
- with reference to section 8.16, the ciné loop in the reading software has been improved in SVDX workstation software v8.2