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NHS Breast Screening Programme Equipment Report

Practical evaluation of 'Siemens Inspiration' PRIME digital breast 2D and tomosynthesis system

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About this document

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Contents

Executive summary

The purpose of this evaluation was to assess the practical performance of the tomosynthesis mode of the Siemens Mammomat Inspiration, in the assessment of women recalled from routine screening.

During the evaluation period standard tomosynthesis images were acquired for assessment. In January 2017 the system was updated to HD Tomosynthesis with with EMPIRE , Insight 2D and 3D technology. Subsequently, tomosynthesis images, synthesised 2D views as well as 3D projections were generated for each tomosynthesis examination.

Radiographers trained by the applications specialist found the equipment easy to use and straightforward. Some initial workflow delays were resolved later in the evaluation period. The women's experience in terms of compression times and comfort were considered good.

Readers were positive about the tomosynthesis images, finding them to be of good diagnostic quality. The maximum compressed breast thickness (CBT) that can be reconstructed in tomosynthesis mode is 100mm. For thicknesses above this, the system will allow the exposure but will display a warning that only the lower 100mm will be reconstructed. Any planes above the 100mm will be available but at a lower image quality. There are women with breast thicker than 100mm, albeit small in number.

The system was successfully integrated with the local PACS and NBSS although there were initial integration issues with both systems, leading to slowing of clinical workflow in the early stages.

A dose survey was carried out for 2 view tomosynthesis. The average mean glandular dose for a 50 to 60 mm breast was 1.48 mGy and 1.59 mGy for 2D and tomosynthesis images respectively before the upgrade. The corresponding figures were 1.40 mGy and 1.63 mGy respectively following the update with the EMPIRE and PRIME 2D and 3D technology. These figures are well within the dose limits for 2D mammography and also within the subsequently published dose limiting figure of 2.5mGy for tomosynthesis.

1. Introduction

1.1 Evaluation centre and timeline

The evaluation was carried out at the South West London Breast Screening Service. This is an NHSBSP unit inviting approximately 70,700 women per year, of whom 45,100 are screened. Approximately 2,300 assessments are carried out per year. The centre meets the relevant national quality standards for breast screening and also meets the criteria for evaluation centres outlined in the NHSBSP Guidance Notes for Equipment Evaluation.[1]

The evaluation took place between September 2016 and May 2017. The Siemens Mammomat Inspiration was installed in August 2016. In January 2017 the system software was upgraded to High Definition Tomosynthesis with EMPIRE (Enhanced Mulitple Parameter Iterative Reconstruction), Insight 2D and 3D.

1.2 Equipment evaluated

The Siemens Mammomat Inspiration with tomosynthesis option is suitable for the acquisition of conventional 2D mammography as well as tomosynthesis images. The system, shown in Figure 1, uses an amorphous selenium-based direct conversion detector. It has a tungsten target with a rhodium and molybdenum filter for both tomosynthesis and 2D exposures, together with a reciprocating grid with a ratio 5:1 and 31 lines/cm.

Software version VB30 L, which included True Tomosynthesis with PRIME, and VB60, including HD Tomosynthesis with EMPIRE, Insight 2D and 3D were in use during the evaluation period.

PRIME is a software based antiscatter solution for digital mammography, whereby the structures within the breast that cause scatter are identified and subtracted. When in use, the mechanical grid automatically slides back and therefore the radiation dose to the breast is reduced.

EMPIRE software uses iterative and machine learning algorithms to reconstruct tomosynthesis images.
With Insight 2D and 3D, synthetic 2D images of the breast are generated from the stack of tomosynthesis planes. Synthetic 3D images of the entire breast are also generated.

The system has 2 automatic exposure control (AEC) modes in both 2D and tomosynthesis exposures:

- OpDose – in which the tube current, exposure time and kV are automatically selected by the system
- AEC – in which the user selects the kV with tube current and exposure time automatically selected by the system. This mode was not used in the evaluation

Tomosynthesis exposures are performed using a large format paddle which is exclusively for use in tomosynthesis. During the tomosynthesis acquisition, the swivel arm covers an angular range from +25° to -25°, with the centre of rotation 30mm above the centre of the breast support table. 25 projections are acquired, at approximately 2-degree intervals, during continuous tube motion. The calculated tube load is divided equally between the 25 projections. The grid is not used during tomosynthesis and collimation is dynamically adjusted to restrict the radiation field.

The system can perform 2D and tomosynthesis acquisitions separately but also 2D/ tomosynthesis combined acquisitions in which a 2D exposure is followed by a tomosynthesis exposure.

Breast Tomosynthesis Object (BTO) converter hardware was installed to allow viewing of the tomosynthesis images on PACS. This is a DICOM Proxy converter box which converts CTO images to BTO images which is DICOM standard for Tomosynthesis images. Further details are provided in Section 9.

Several technical evaluations have been published: the technical evaluation of the 'Siemens Mammomat Inspiration Full Field Digital Mammography system NHSBSP Equipment Report 0909' was published in December 2009.[2] The technical evaluation of 'Siemens Mammomat Inspiration digital breast tomosynthesis system NHSBSP Equipment Report 1306 version 2' was published in January 2015.[3] The technical evaluation of Siemens Inspiration PRIME with VB30L software NHSBSP Equipment Report 1503 was published later in March 2016.[4] In December 2018 the technical evaluation of 'Siemens Mammomat Inspiration digital breast tomosynthesis system – modified detector and software (VB60)' was published.[5]

Figure 1. Siemens Mammomat Inspiration Tomosynthesis system

Figure 2. Siemens Mammomat Inspiration Tomosynthesis with wide and narrow face shields.

1.2.1 X-ray set and workstation

The freestanding mammography gantry is backlit with an integrated LED 'Moodlight' panel which allows choice of soft lighting in a specific colour or continuous, gradual colour change.

There are face shield options including a wide face shield for tomosynthesis and a narrow one for 2D, as illustrated in Figure 2. The face shield rotates with the gantry arm during the tomsynthesis acquisition and the client's head must be clear of the shield during swivel arm movement.

There are 2 compression plates for tomosynthesis. One measures 24cm x 30cm and there is a larger 24cm x 37cm plate.

The operator console comprises a height-adjustable control desk integrated with the Acquisition Workstation (AWS) and a radiation shield. The control desk features a lockable cabinet accommodating the AWS computer. There is a retractable keyboard underneath the desktop. There are 2 adjustable screens, one for the preview image display to check the completeness of the examination performed and another for image display to allow review of previous images. Both these screens are 3 megapixels therefore not of diagnostic resolution.

Exposures are obtained either by pressing a button on the control desk or a foot pedal.

Reconstructed planes are 1mm apart and the number of reconstructions is the compressed breast thickness in mm +1. A maximum of 100 planes can be reconstructed. If a tomosynthesis scan is performed on a greater thickness, a warning is given that only the bottom 100mm will be reconstructed. The women imaged during the evaluation did not exceed this compression depth. Had there been an issue with depth of compression exceeding 100mm, given the Inspiration was being used in assessment rather than for screening, a clinical decision would have been made as to whether the location of the lesion of interest would have been included within the tomosynthesis images.

1.2.2 Other equipment under evaluation

Images were reviewed on existing Philips PACS reporting workstations and no additional equipment was used in the reviewing process. The Siemens Mammomat Inspiration was also used for stereotactic biopsy.

1.3 Objectives of the evaluation

The primary objective of the evaluation was to establish the performance and usability of the Siemens Mammmomat Inspiration tomosynthesis system in the assessment of women recalled for further examination following mammographic screening.

The detailed objectives were to:

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

2. Acceptance testing, commissioning and performance testing

2.1 Acceptance testing and commissioning

The Siemens tomosynthesis sytem was installed in August 2016. Integration with local PACS was phased, with images initially visible on a standalone workstation and then, after 4 weeks, images were made available on PACS.

Acceptance testing and commissioning was carried out by the local physics service.

2.2 Other physics testing

The Radiation Protection Centre Physics report of the physics routine survey is available in appendix 1.

3. Routine quality control

Routine quality control checks were carried out on the equipment in 2D and for tomosynthesis modes during the evaluation period and beyond, following the appropriate NHSBSP guidelines.6,7

3.1 Daily QC tests

For the daily QC test a 4.5cm thick perspex block was imaged under AEC control. The values of mAs and signal-to-noise ratio (SNR) for 2-D imaging, and mAs and SNR for tomosynthesis imaging are shown in Figures 3 to 6. Recorded values for tomosynthesis were all between the appropriate remedial levels. The discontinuity shows a baseline reset to match the change in performance following service visits.

3.1.1 Daily tests – 2D exposure

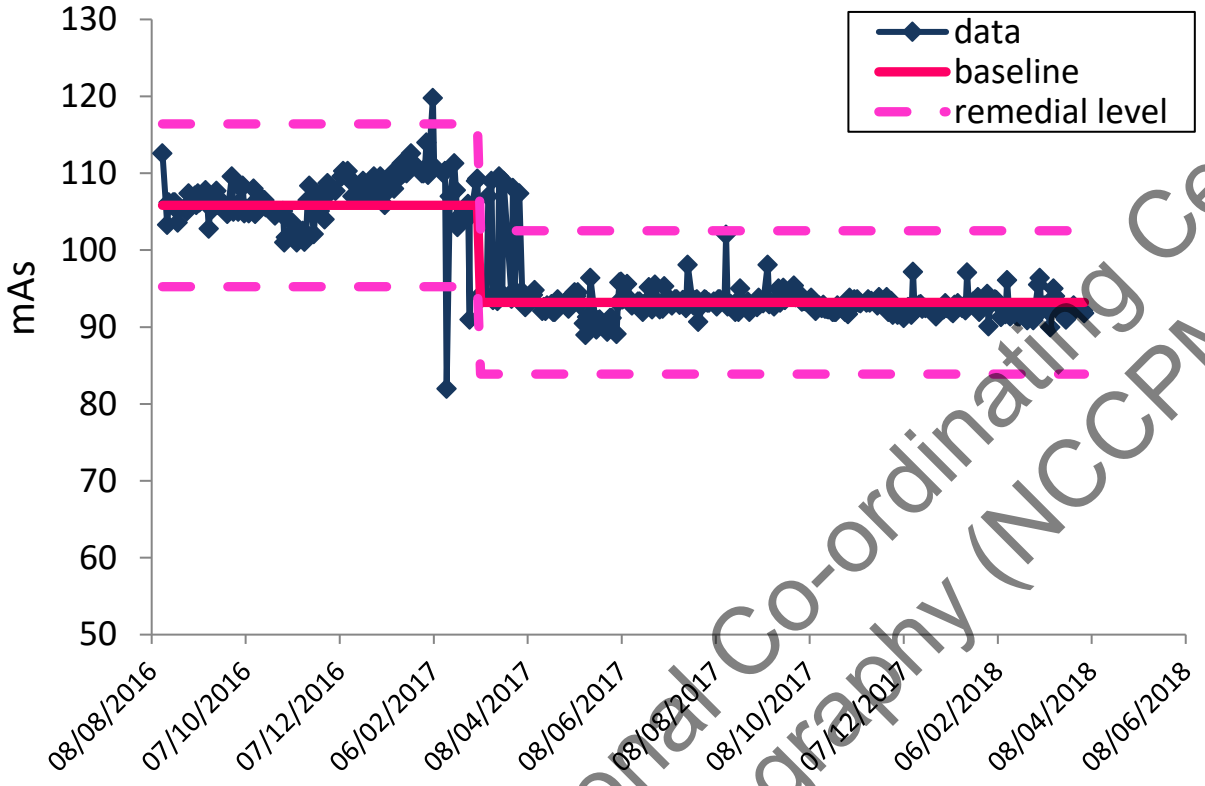


Figure 3. mAs recorded daily for 45mm of Perspex (2D)

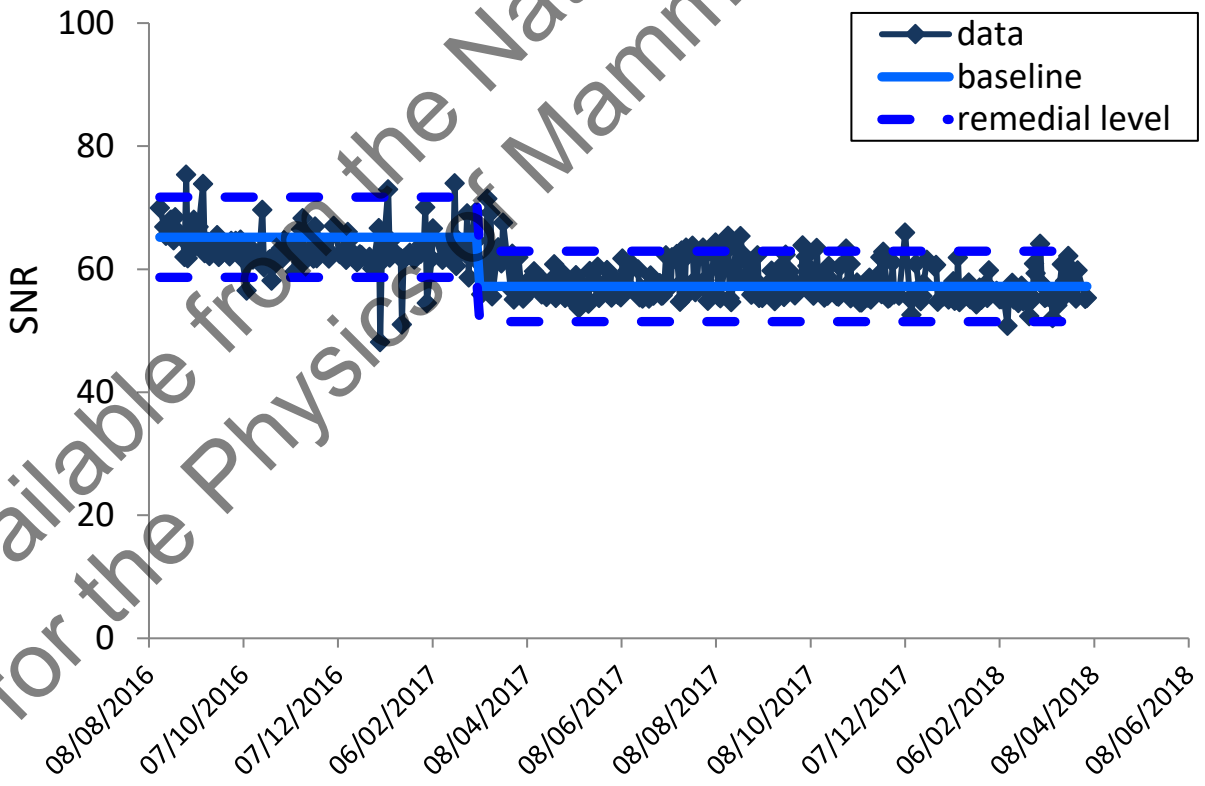


Figure 4. SNR recorded daily for 45mm of Perspex (2D)

3.1.2 Daily tests – tomosynthesis exposure

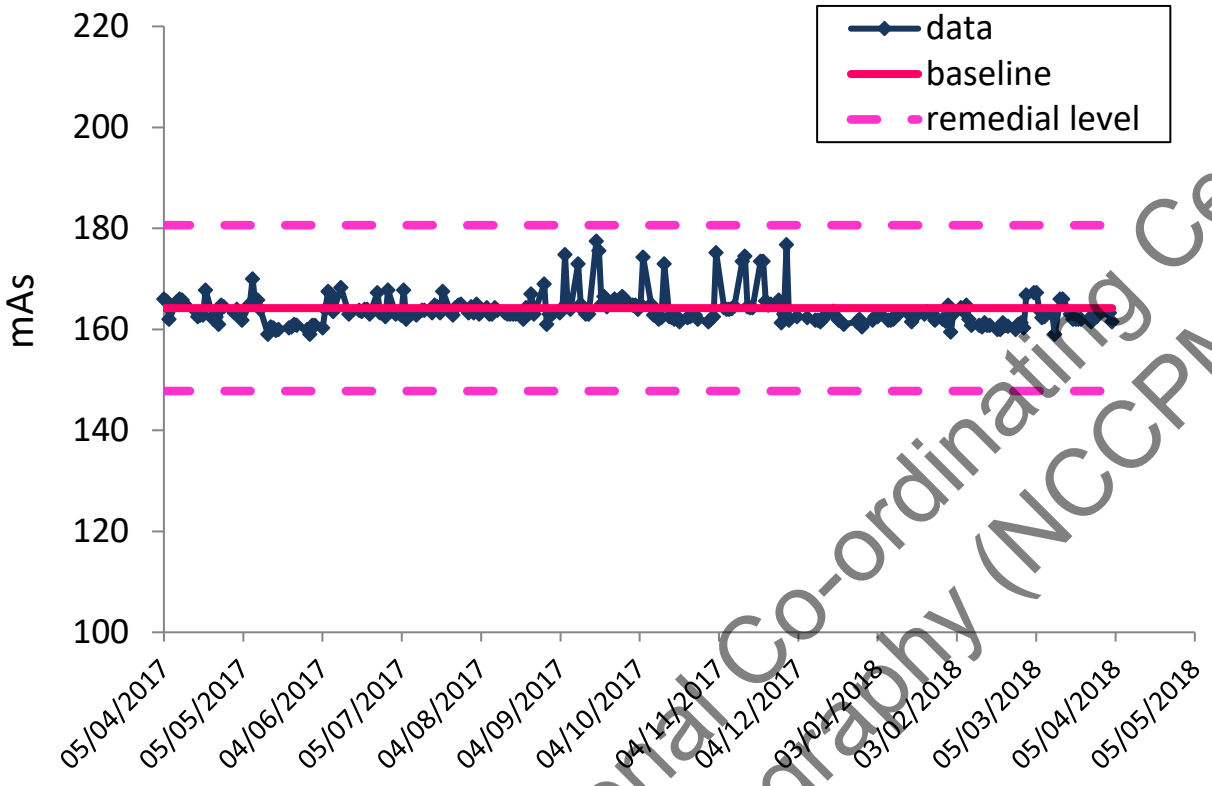


Figure 5. mAs recorded daily for 45mm of Perspex (tomosynthesis)

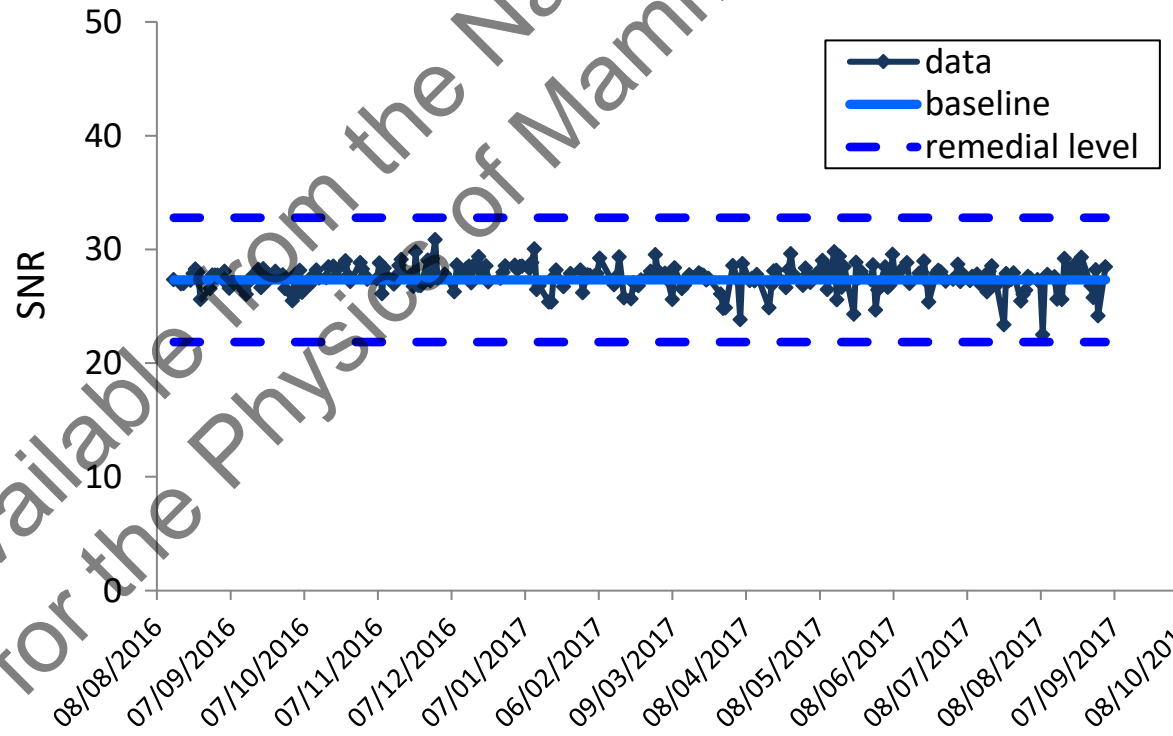


Figure 6. SNR recorded daily for 45mm of Perspex (tomosynthesis)

3.2 Weekly QC tests

The contrast-to-noise ratio (CNR) was obtained by measurements on the image of 0.2mm thick square of aluminium contained within the 4.5cm block of perspex. The results are shown in Figure 7. Most results lie within the +/- 10% remedial limits for 2D with a few only just exceeding this at the upper level, and 2 points significantly different, although no cause was recorded.

3.2.1 Weekly tests – 2D

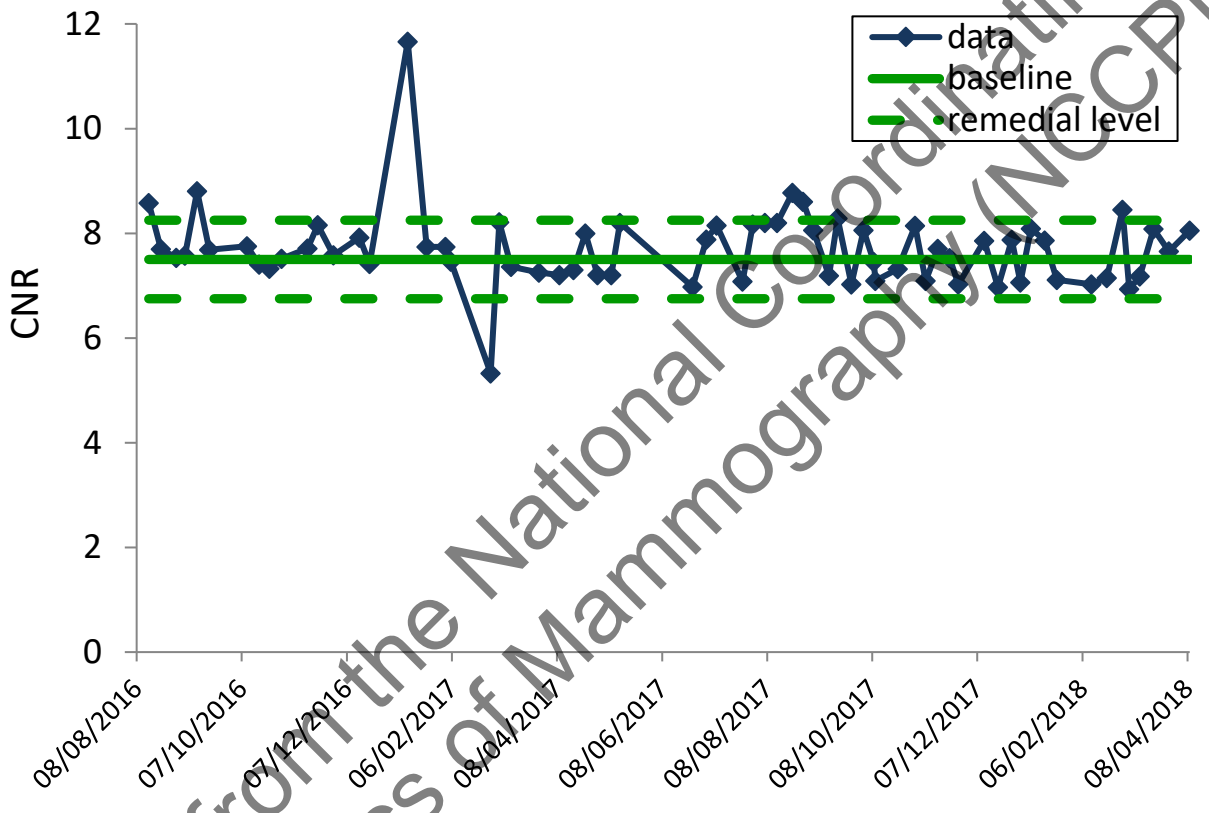


Figure 7. Weekly CNR measurements for 45mm Perspex (2D)

Uniformity tests were carried out on the clinically used target/ filter combination of Tungsten and Rhodium and showed good stability, as shown in Figure 8.

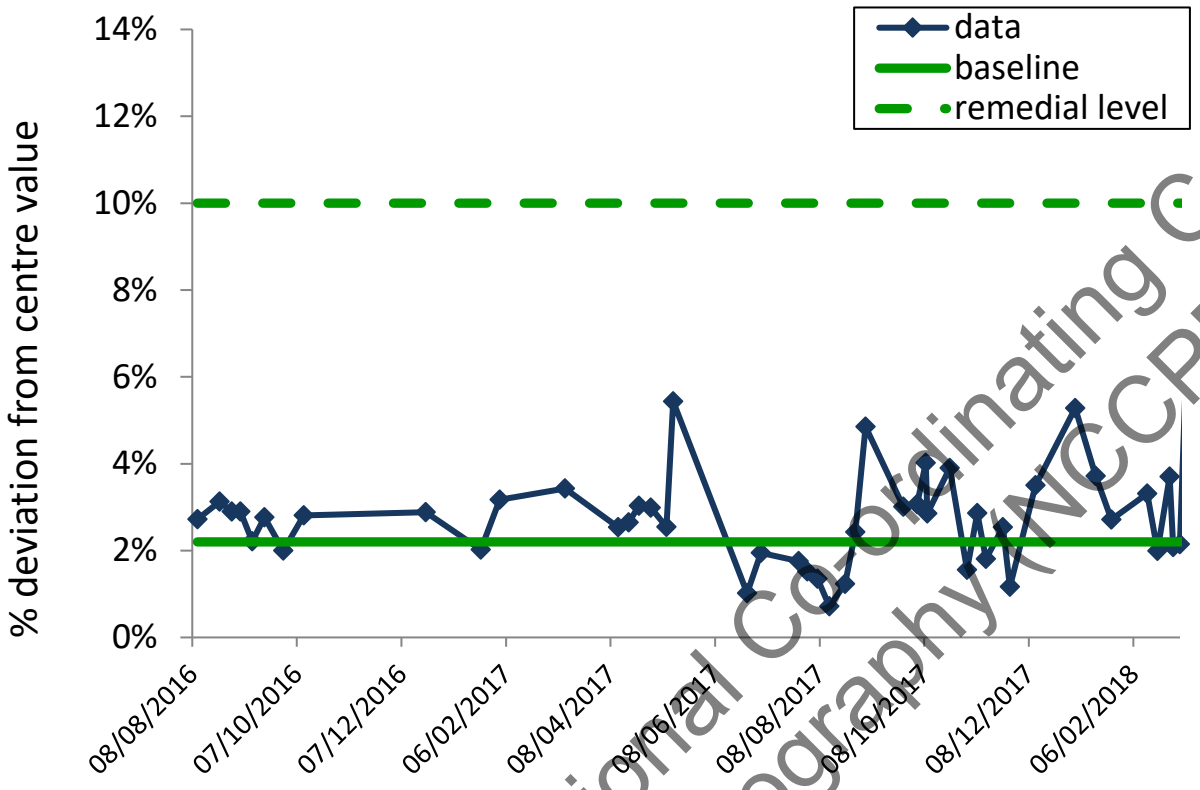


Figure 8. Weekly uniformity test for Tungsten and Rhodium (2D)

3.2.2 Weekly tests – tomosynthesis

The CNR in tomosynthesis mode was also measured in the same way as for 2D. The results are shown in Figure 9, showing good stability with only one result outside the +/- 20% remedial level.

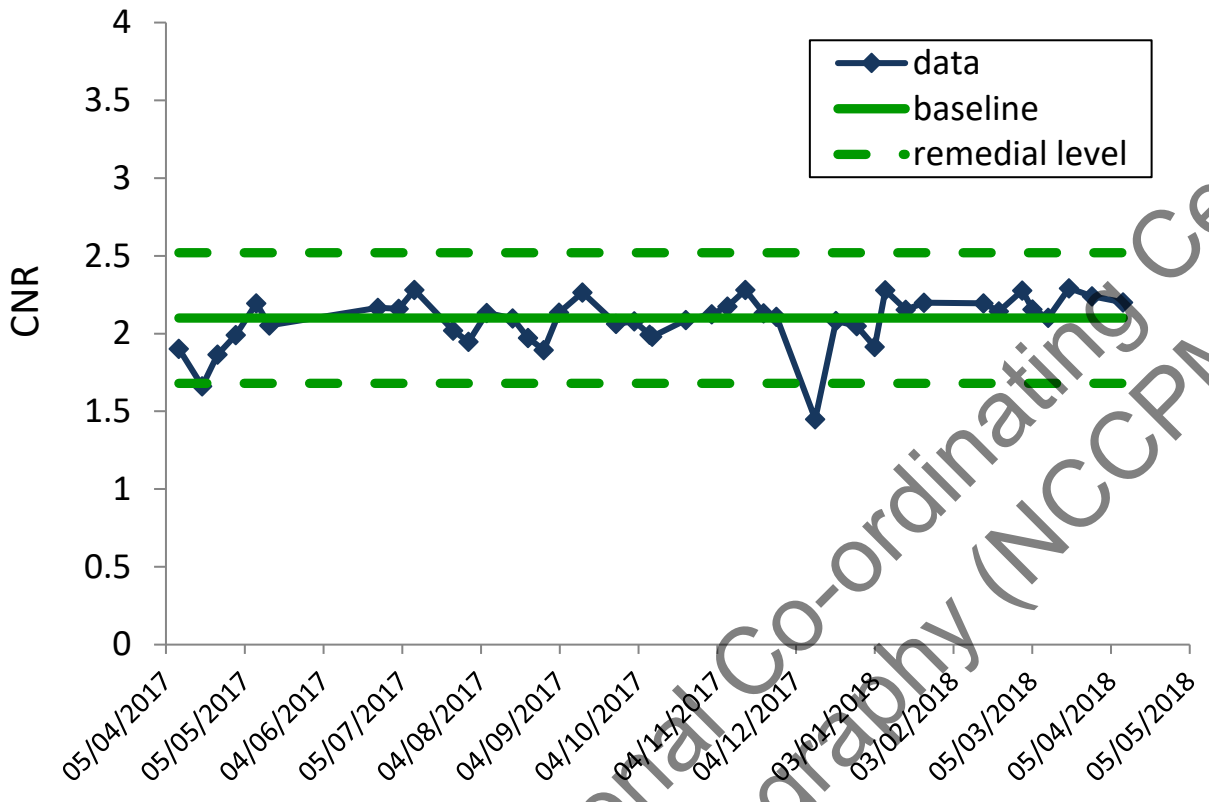


Figure 9. Weekly CNR measurements for 45mm Perspex (tomosynthesis)

3.3 Monthly QC tests

For the monthly test a 2cm thick perspex block and a 7cm thick perspex block were exposed under AEC. For 2D imaging and tomosynthesis the mAs, SNR and CNR were recorded. The results are shown in Figures 10 - 21. The results mostly lie within the remedial levels of +/- 10% for 2D SNR and CNR in 2D modeand +/- 20% for SNR and CNR in tomosynthesis mode. The system occasionally selected a lower kV for both 20mm and 70mm exposures and then the mAs was increased. This may have been because of a combination of a different selection of Perspex Blocks and slightly different compression force applied. The SNR for 7cm Perspex in 2D mode included one different result but was otherwise stable. The CNR was less stable but clearly more consistent in tomosynthesis mode.

3.3.1 Monthly tests – 2D

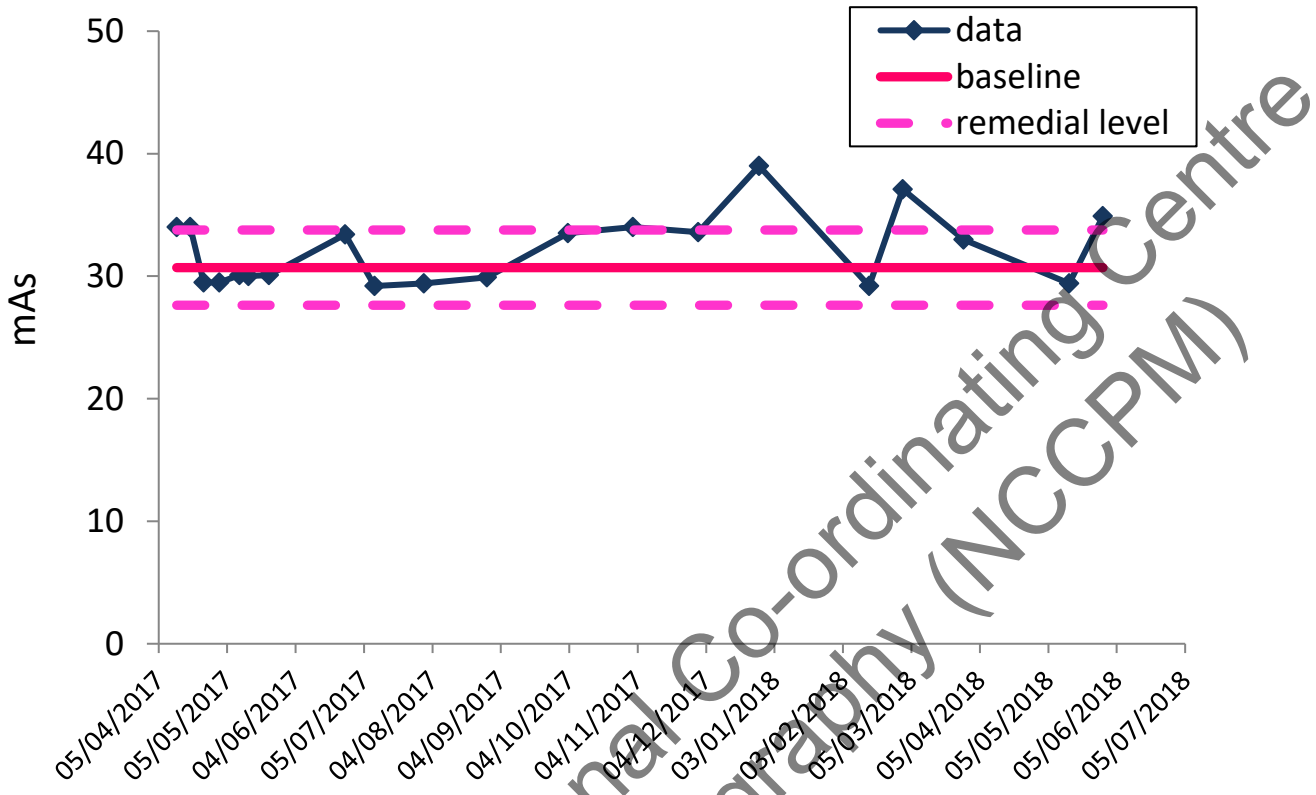


Figure 10. mAs recorded monthly for 20mm Perspex (2D)

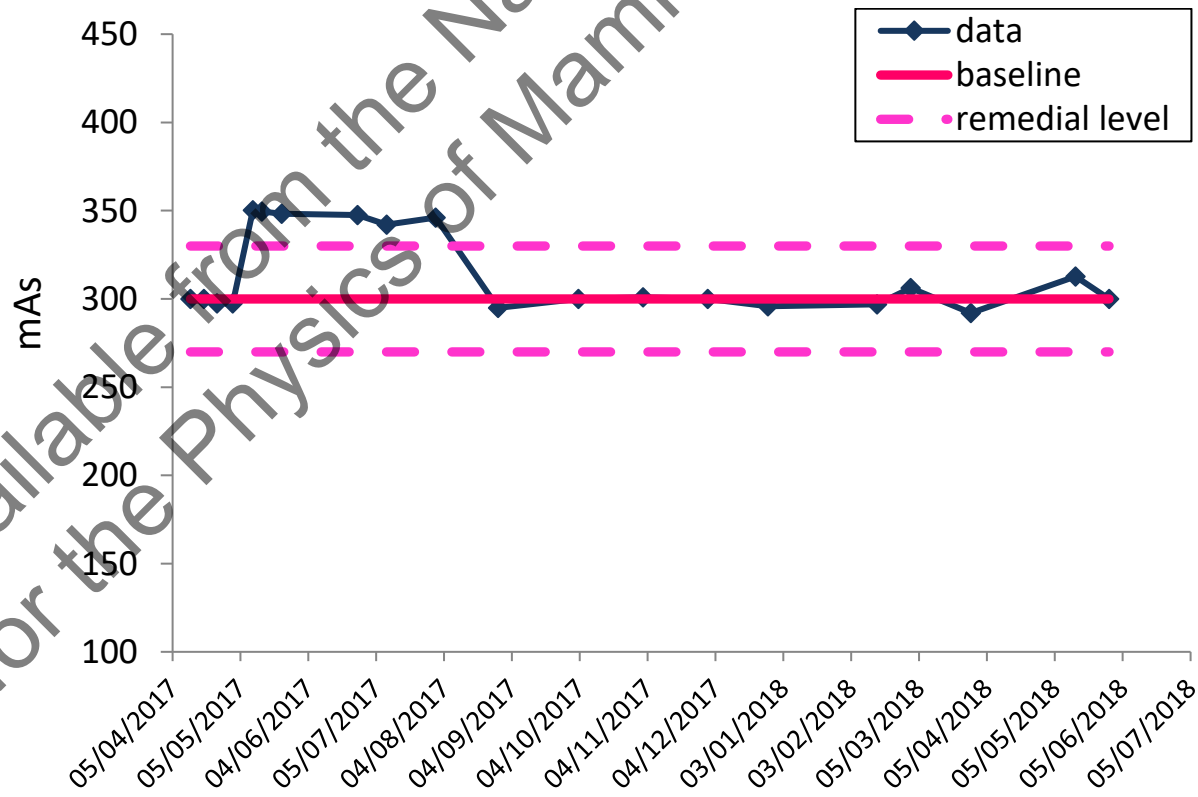


Figure 11. mAs recorded monthly for 70mm perspex (2D)

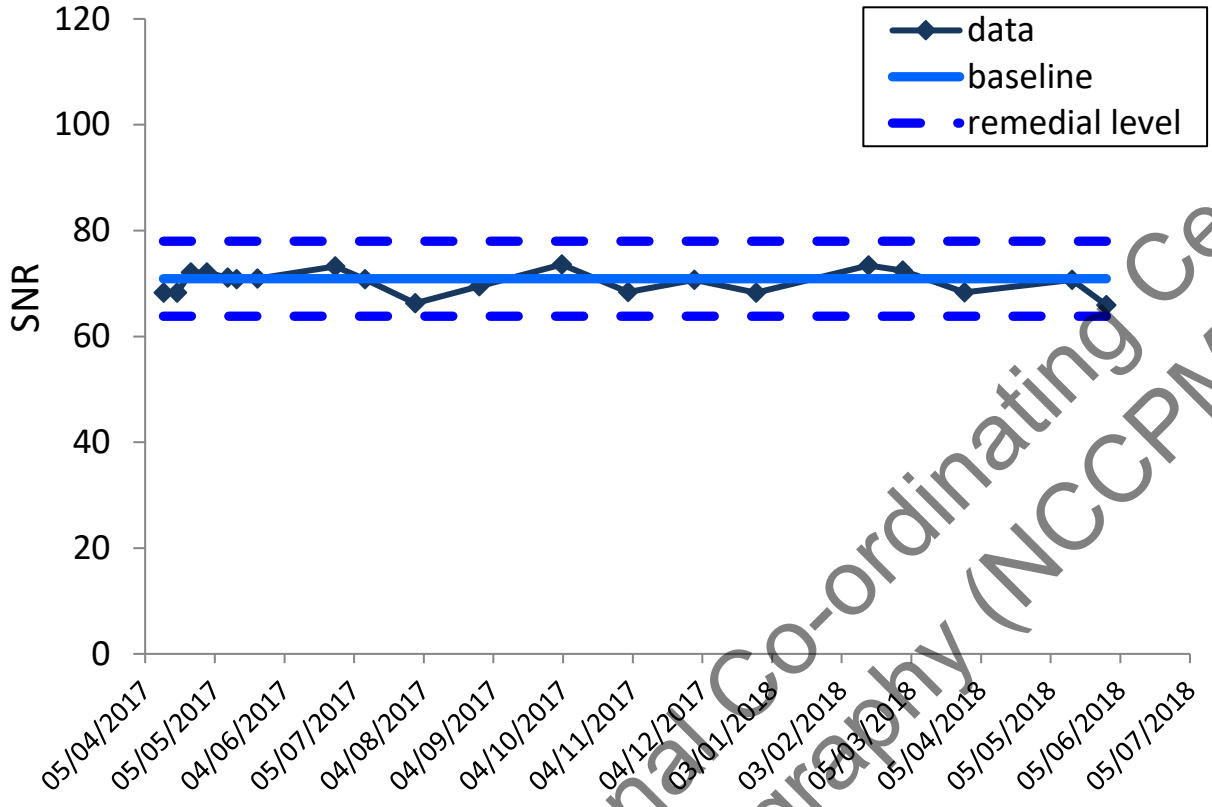


Figure 12. SNR recorded monthly for 20mm Perspex (2D)

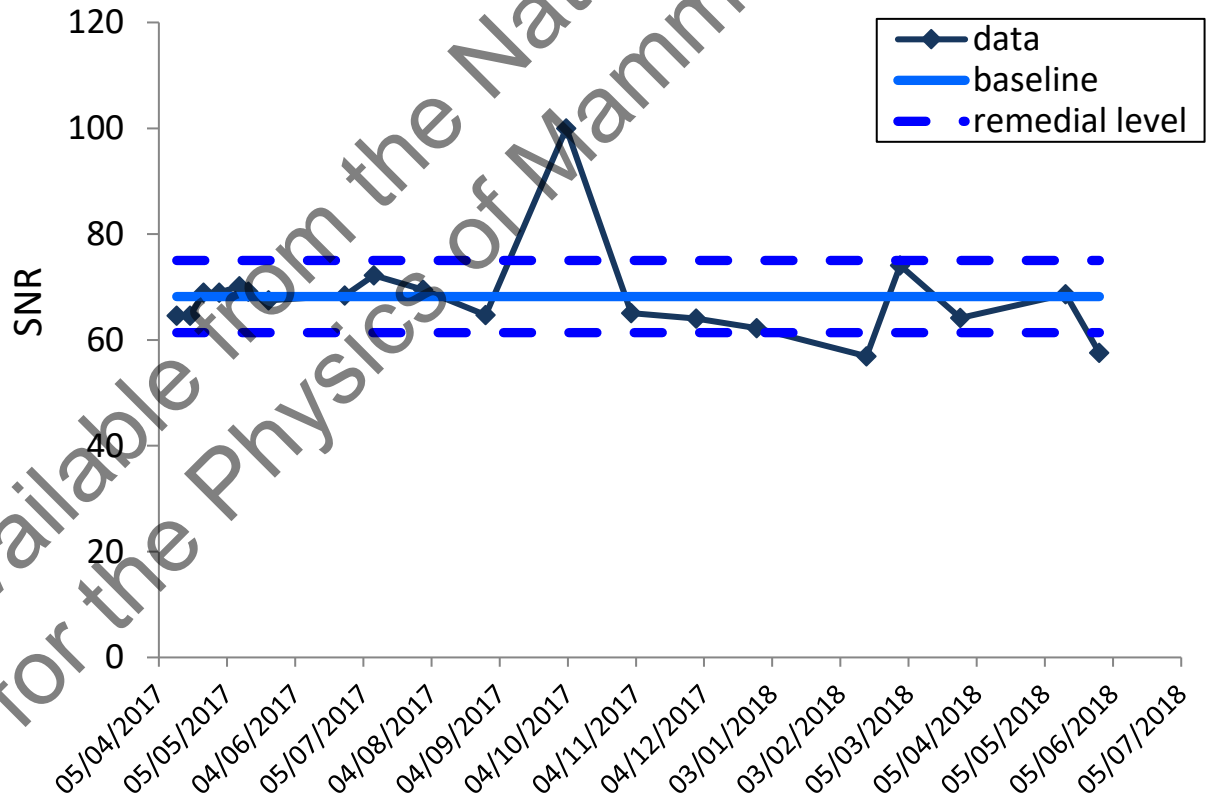


Figure 13. SNR recorded monthly for 70mm Perspex (2D)

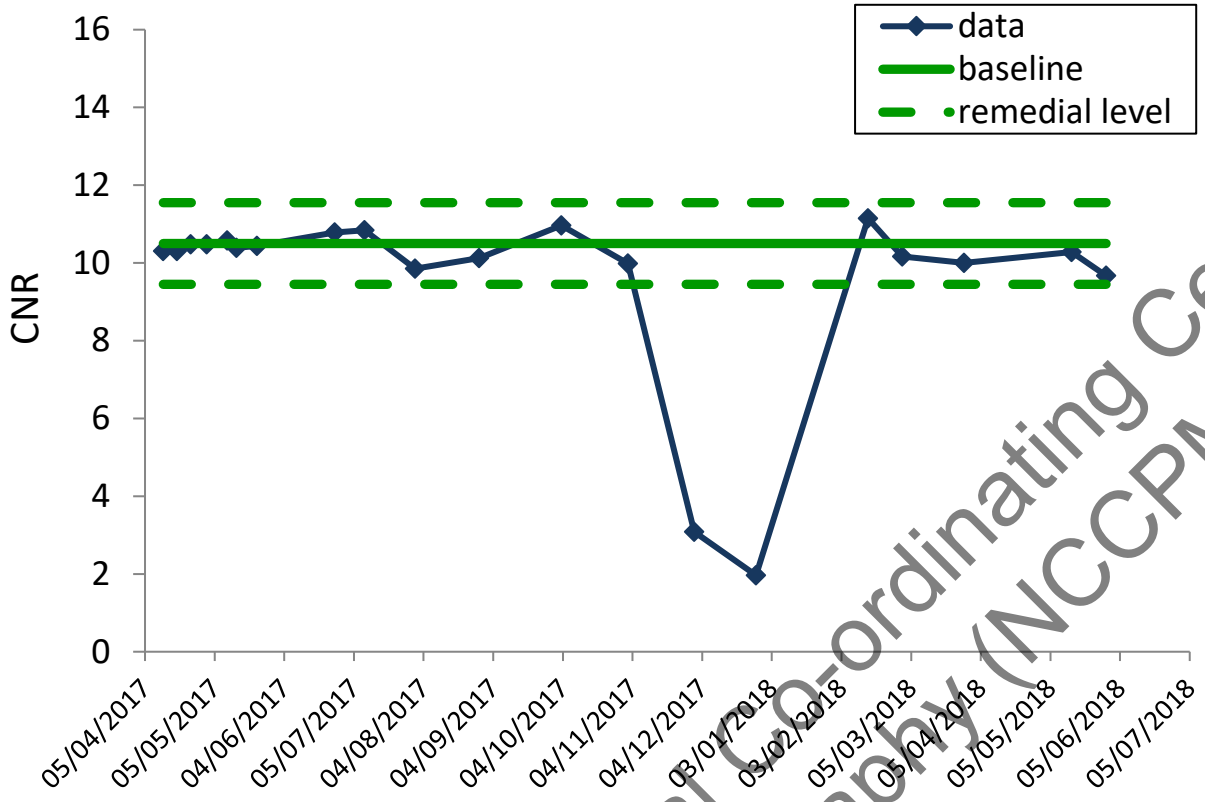


Figure 14. CNR recorded monthly for 20mm Perspex (2D)

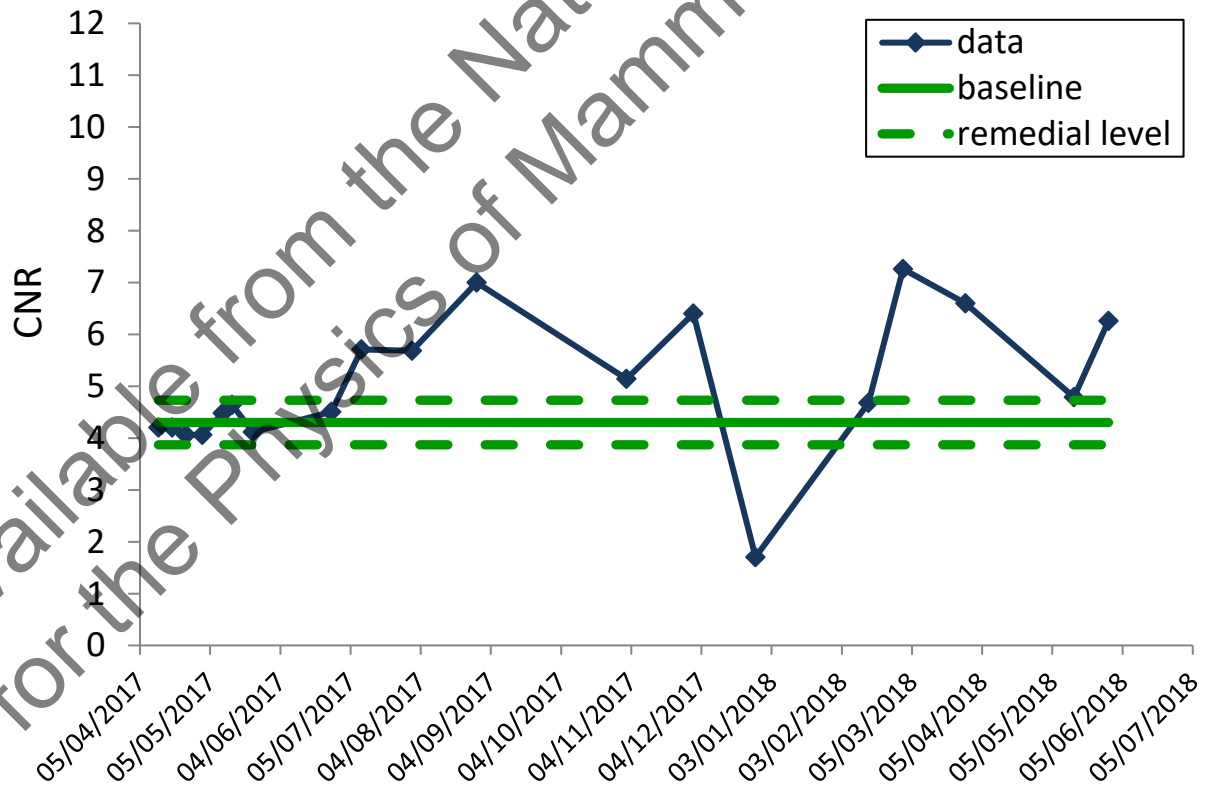


Figure 15. CNR recorded monthly for 70mm Perspex (2D)

3.3.2 Monthly tests – tomosynthesis

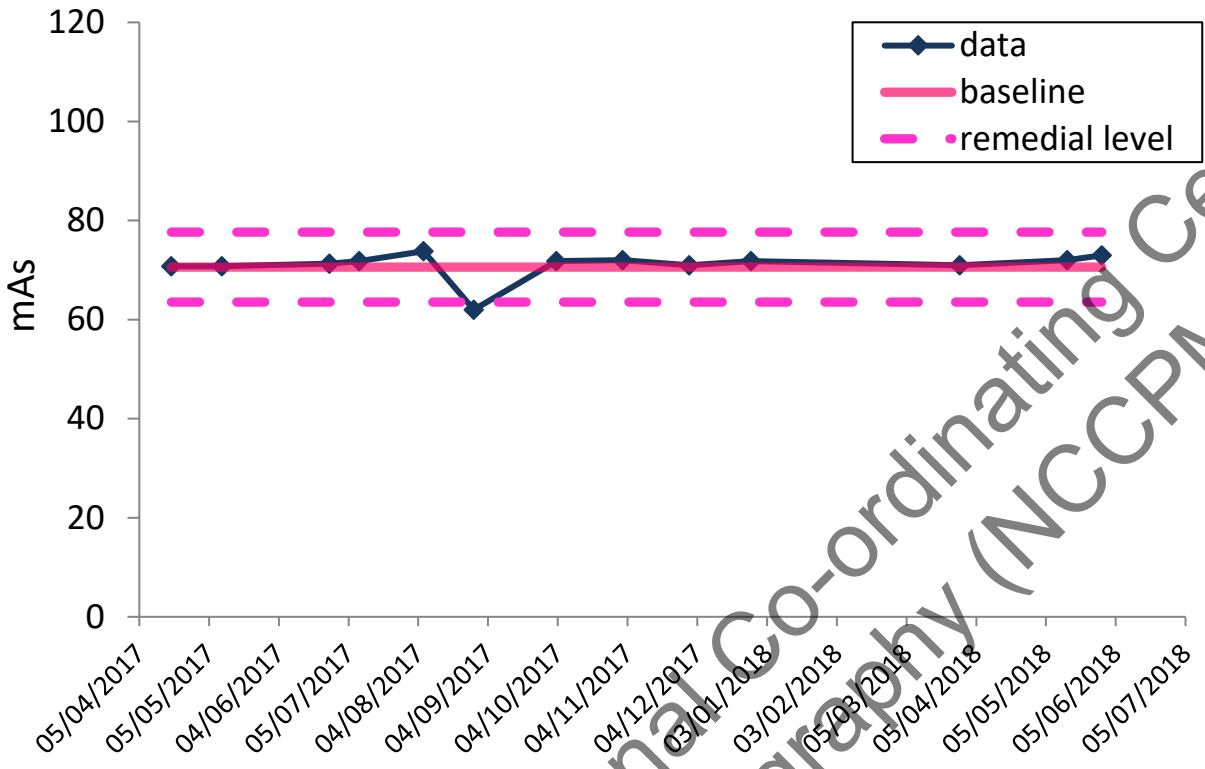


Figure 16. mAs recorded monthly for 20mm Perspex (tomosynthesis)

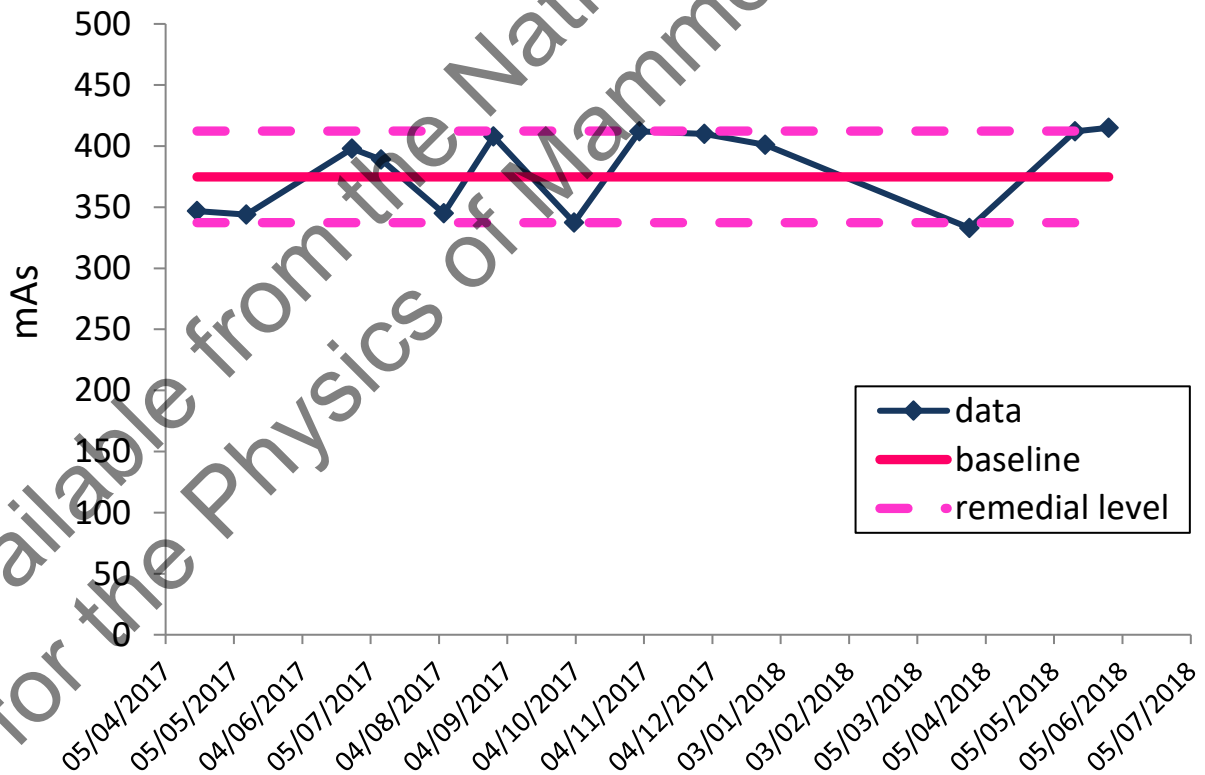


Figure 17. mAs recorded monthly for 70mm Perspex (tomosynthesis)

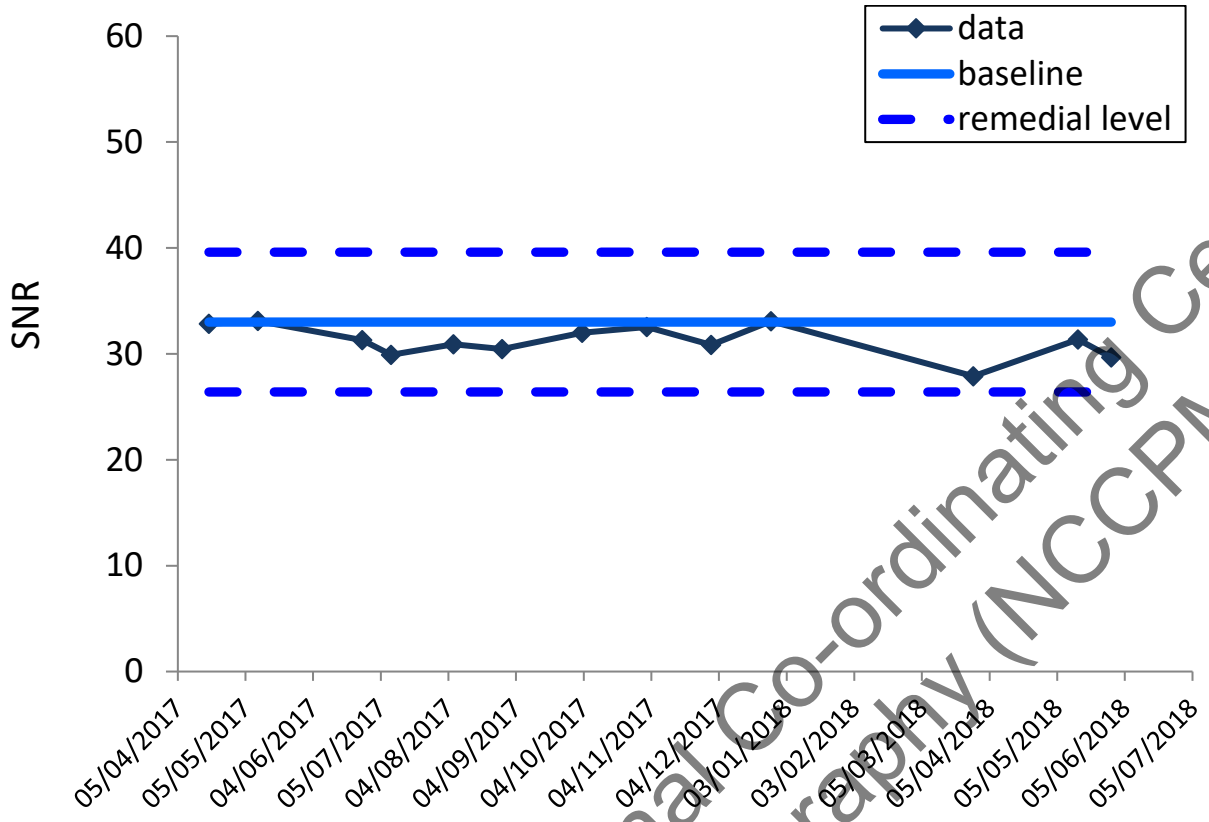


Figure 18. Monthly SNR measurements for 20mm Perspex (tomosynthesis)

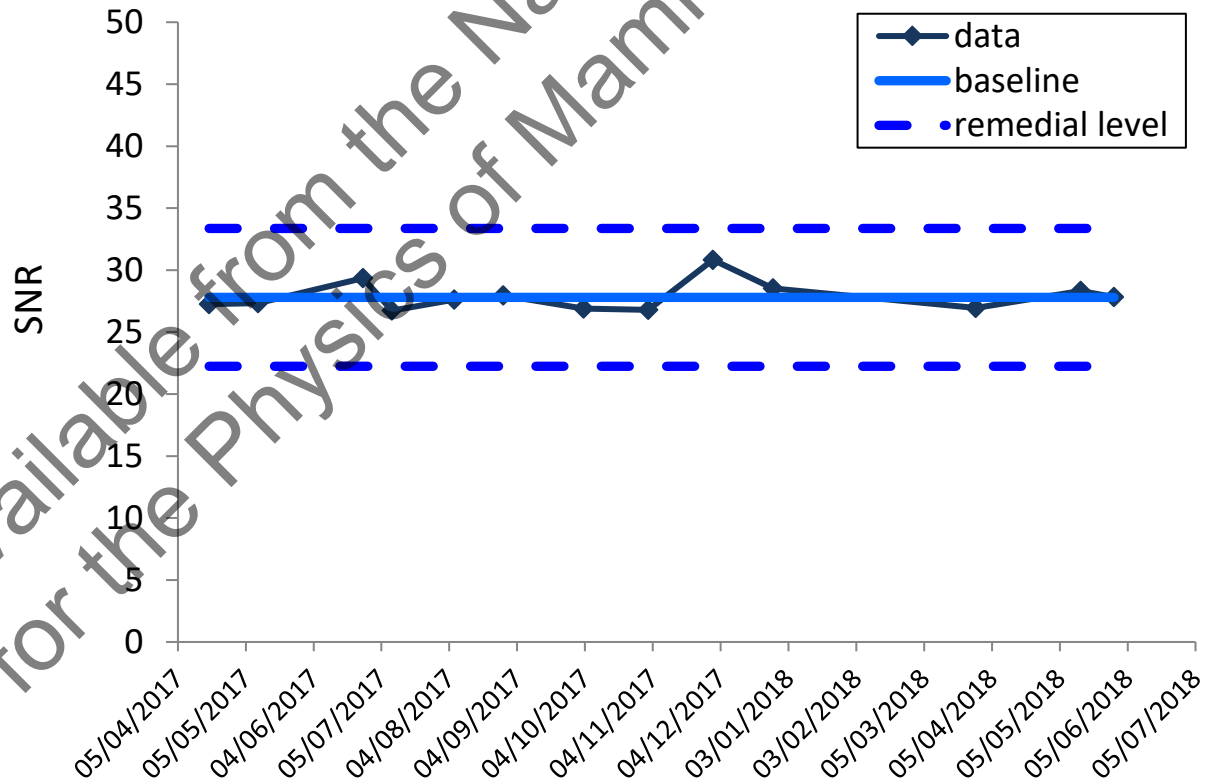


Figure 19. Monthly SNR measurements for 70mm Perspex (tomosynthesis)

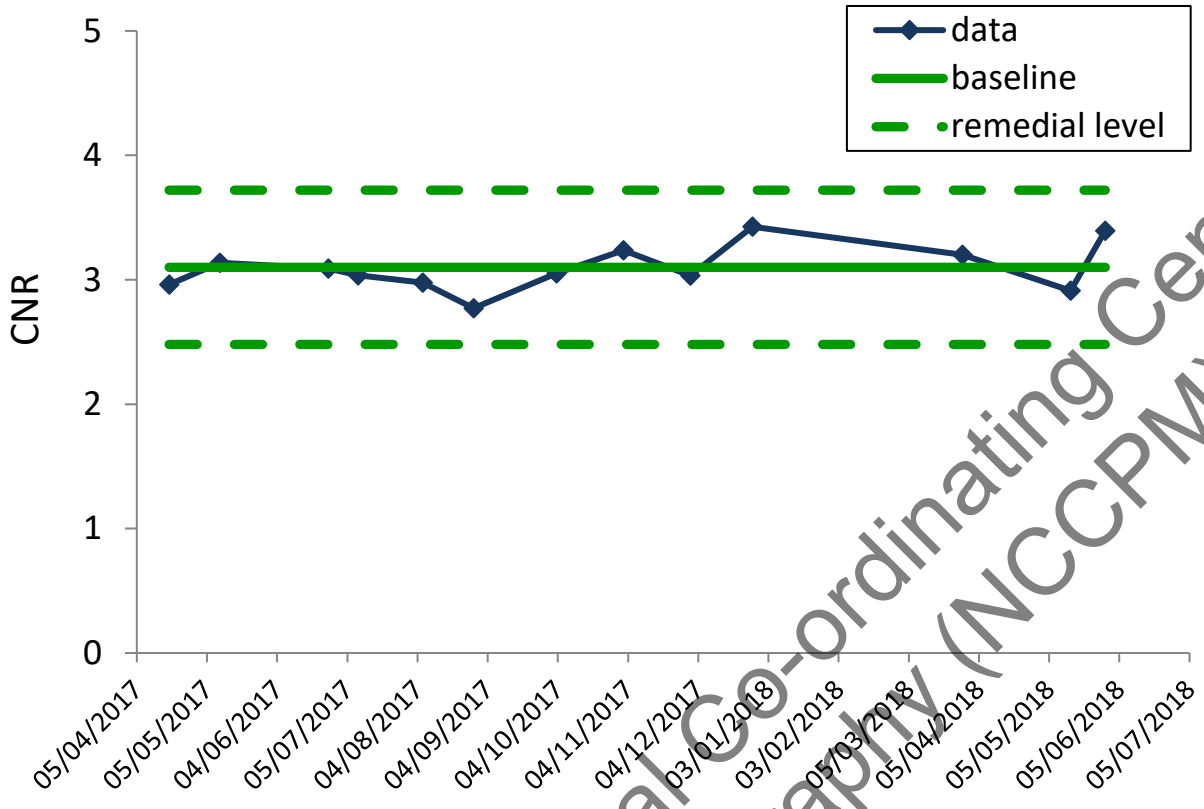


Figure 20. Monthly CNR measurements for 20mm Perspex (tomosynthesis)

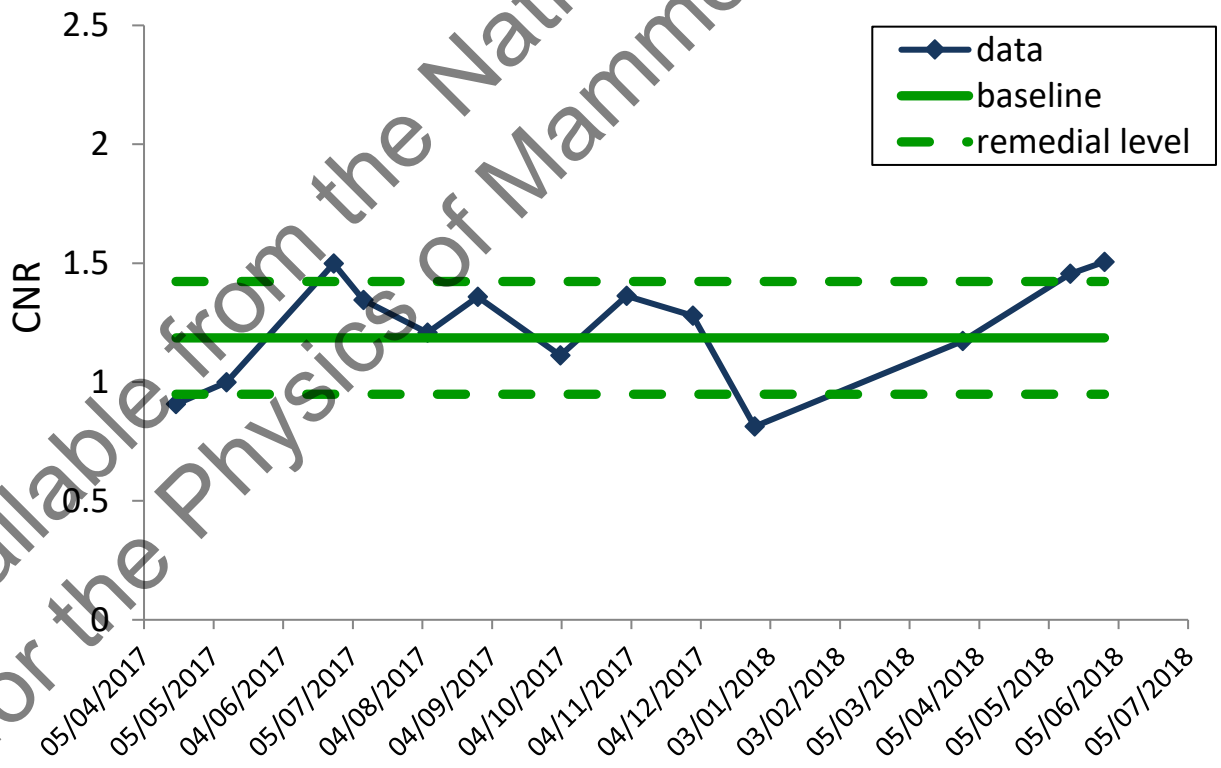


Figure 21. Monthly CNR measurements for 70mm Perspex (tomosynthesis)

4. Data on assessments conducted

4.1 Clinical Dose Audit

For the evaluation, in most cases only the recalled side was imaged with tomosynthesis in both the cranio caudal (CC) and medio-lateral oblique (MLO) views. Lateral views were obtained, instead of MLO, for calcifications. Magnification views were also obtained, if clinically necessary.

The exposure data from a total of 232 women who had been recalled for assessment following their NHSBSP screening examinations were obtained by reviewing their images on PACS. These women had their initial 2D screening mammograms or tomosynthesis for assessment on the Siemens Mammomat Inspiration either before the upgrade (referred to as 'standard') or after the installation of HD Tomo with EMPIRE and Insight 2D/3D technology (referred to as 'post upgrade'). Exposure data figures were entered into the NHSBSP dose calculation software. Doses were analysed from the 2D and tomosynthesis imaging, both for the standard acquisition and post upgrade acquisition. The detailed results of the dose survey are presented in Appendix 2. The average mean glandular doses (MGD) are summarised in Table 1 below.

Table 1. Average MGD for 2D and tomosynthesis images before and after the software upgrade

View	Average MGD (mGy) for 2D		Average MGD (mGy) for tomosynthesis	
	pre upgrade	post upgrade	pre upgrade	post upgrade
CC	1.45	1.46	1.83	1.73
MLO	1.79	1.66	1.92	1.87
MLO (50-60 mm thick breast)	1.48	1.40	1.59	1.63

Table 2: Average compressed breast thickness (CBT) for 2D and tomosynthesis before and after software upgrade

View	Average CBT (mm) for 2D		Average CBT (mmy) for tomosynthesis	
	pre upgrade	post upgrade	pre upgrade	post upgrade
CC	56	55	61	62
MLO	63	60	65	66
MLO (50-60 mm thick breast)	57	55	56	55

The national diagnostic reference level (NDRL) of 2.5mGy for an MLO image of the 50 – 60 mm breast was adopted. This figure was used for comparison in the tomosynthesis images. The dose survey results are below this value in all imaging modes. Pre software upgrade, the average MGD for 50 – 60 mm thick breasts is 1.48 mGy in 2D mode, compared to 1.59 mGy for tomosynthesis. Post upgrade the figures are 1.40 mGy and 1.63 mGy respectively. The tomosynthesis exposure is 7% higher in the standard setting and 16% higher following the upgrade.

4.2 Comparison of displayed dose with calculated MGD

A retrospective dose study was conducted to gather data from the DICOM header for calculating the MGD using the NHSBSP software and compare it with the displayed MGD. The data is shown for 2-D and tomosynthesis in Figures 22 and 23. The gradients are 0.92 and 0.90 respectively which shows that the dose is calculated to be 8%-10% higher than indicated. Although not ideal, this is close enough and the data is consistent enough to allow the displayed dose to serve as a suitable indicator for the purposes of risk estimation, local dose audits and providing information on dose to the patient, the referrer and the practitioners as required by Ionising Radiation Medical Exposure Regulations 2017.

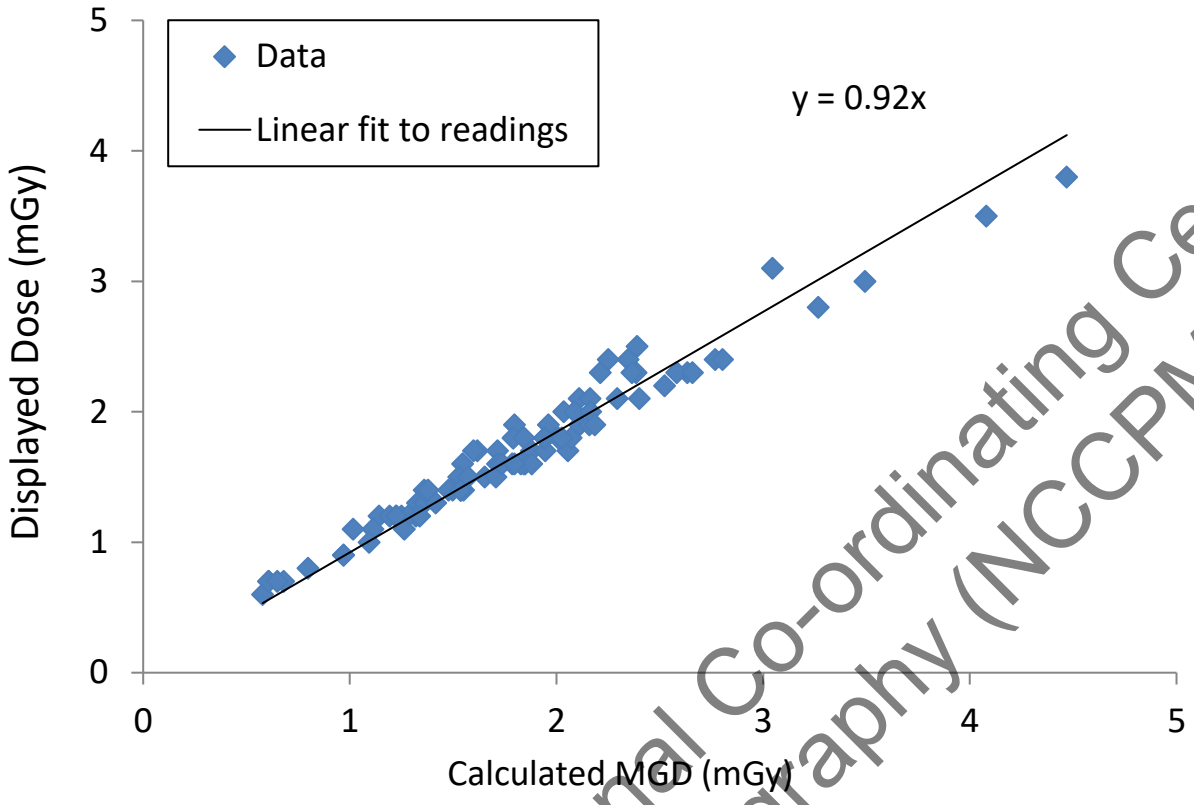


Figure 22. Displayed dose vs calculated MGD for 2D

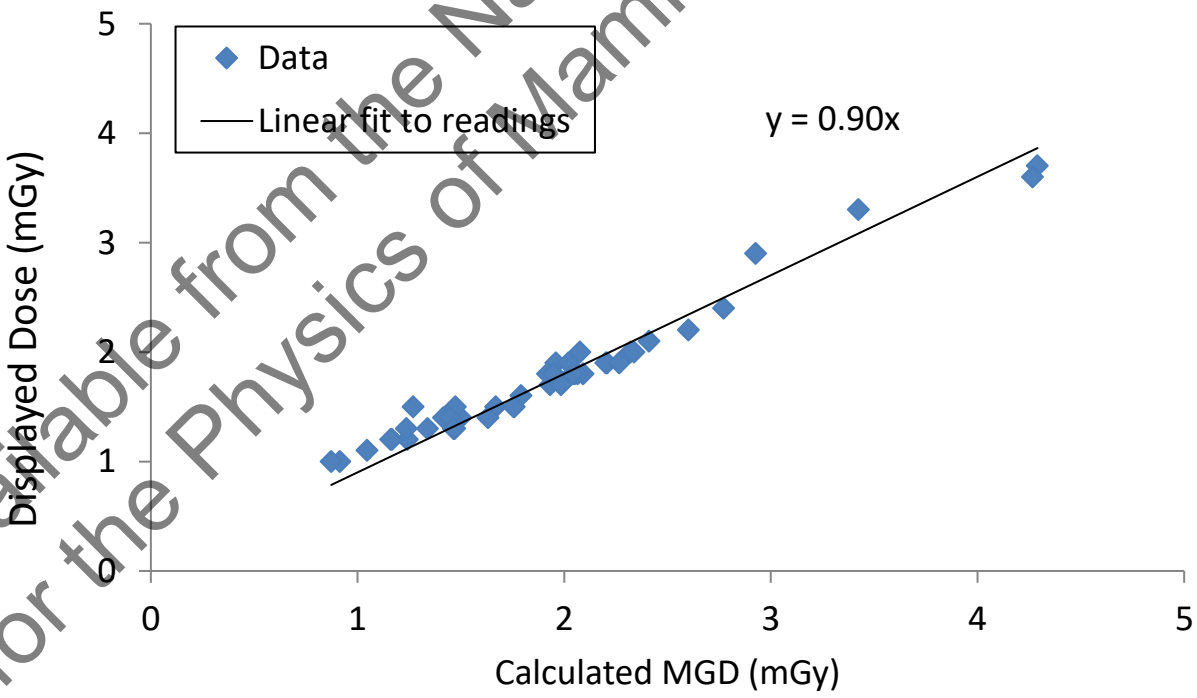


Figure 23. Displayed dose vs calculated MGD for tomosynthesis

4.3 Imaging times

Timings of exposures for a 45mm Perspex block were measured using a stopwatch to determine how long the different steps took, including the time taken for images to appear on the screen and when the next exposure became possible.

All timings are from when the operator pressed the exposure button and are cumulative. The time when the compression is released is indicated by (R).

The test was repeated several times to ensure consistency and the average times are recorded in Table 3.

Table 3. Timings for exposures of a 45mm Perspex phantom

Action	Timings (cumulative, in seconds)
Press foot switch	0
Start of exposure – pre-pulse image	6
Tomosynthesis sequence exposures start	12
Tomosynthesis Sequence exposures end (R)	33 (R)
Reconstruction of tomosynthesis – calculating slices	75
Reconstruction of tomo – storing slices	90
Reconstruction of tomo – calculating Insight 2D/3D	115
Next exposure possible	128

4.4 Timings for image reading by readers

Tomosynthesis images were reported by a total of 9 consultant radiologists, 1 consultant practitioner and 3 advanced practitioners. The images were viewed on Philips mammoPACS workstations; one located centrally within the clinic area as well as one within each of three consulting rooms. Any associated additional mammograms or ultrasound images were also available on PACS.

The screening images, tomosynthesis images and any further magnification views, were reviewed. There were no individualised hanging protocols. Images and display settings were manipulated on an individual case basis.
Timings for arrival of images to PACS and for review of images are addressed in Section 9.1 workflow configuration

4.5 Clinic workflow

The Siemens Mammomat Inspiration with Tomosynthesis equipment was installed in a room which had previously housed a prone stereotactic table. Apart from being used for the evaluation of tomosynthesis, it was also used as the second stereotactic machine in the department.

The clinic workflow during screening assessments maintained the usual routine whereby women arriving for assessment were seen first by the clinical nurse specialists, before having further mammography and/or tomosynthesis, followed by clinical breast examination (CBE) and ultrasound (US) with or without biopsy, as required.
For the first 3 months of the evaluation both 2D magnification views and unilateral tomosynthesis were taken for all cases. Following this period the protocol was changed so that cases were assessed with the relevant tomosynthesis views only. In cases of calcification true lateral tomosynthesis views were also taken. At the discretion of the clinicians involved, 2D plate magnification plate views were undertaken in addition to, or instead of, the tomosynthesis views.

Although formally timed sessions were not conducted during this evaluation, there were multiple instances of clinics overrunning during the initial assessment period and both radiographers and radiologists considered the clinic workflow to be delayed with the introduction of tomosynthesis. Towards the end of the evaluation patient throughput improved and there were fewer instances of delay. As the equipment speed did not change, it is considered likely that the improvement was due to reduction in numbers of 2D plate magnification views accompanying tomosynthesis for each client as well as human factors such as familiarity with equipment.

4.6 Breast Density

Breast density software (Volpara) was available and density values are generated in accordance with the ACR BI-RADS 5th Edition descriptors for breast composition. [8]

Table 4. Breast density descriptors

Category	Description
A	The breasts are almost entirely fatty
B	There are scattered areas of fibroglandular density
C	The breasts are heterogeneously dense, which may obscure small masses
D	The breasts are extremely dense which lowers the sensitivity of mammography

Breast density was similar in those undergoing tomosynthesis in September to October 2016 (Siemens Mammomat Inspiration Tomosynthesis), compared to January and February 2017 (HD Tomosynthesis with EMPIRE and Insight 2D and 3D software installed). In the former group: breast density category A 0%, category B 43%, category C 41% and category D 13% whilst in the latter group, the breast density categories were A 3%, B 42%, C 39% and D 15%.

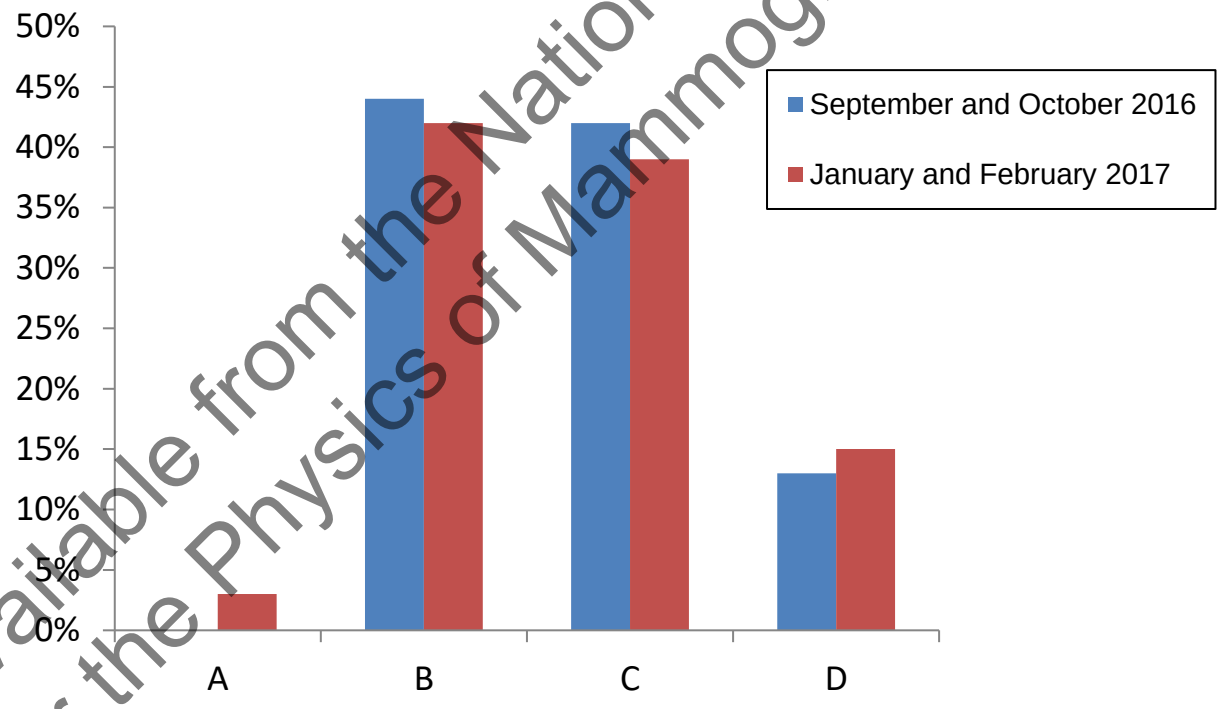


Figure 24. Percentage of women with Volpara breast density A to D, imaged in September and October 2016 (Siemens Mammomat Inspiration Tomosynthesis) and in January and February 2017 (following installation of PRIME, EMPIRE and Insight 2D and 3D)

4.7 Visibility with tomosynthesis

Observer studies were carried out evaluating the visualisation of soft tissue densities and calcifications on 2D vs tomosynthesis images:

Soft tissue

64 cases containing soft tissue lesions were reviewed by 5 experienced consultants and film readers. Readers compared the original screening mammogram with a magnification view (available in 13 cases), tomosynthesis and, where available, the 2D synthetic view (available in 48 cases, following introduction of Insight 2D technology). The 3D reconstructed view was not evaluated. The images were graded M1 (normal), M2 (benign), M3 (indeterminate, probably benign but requires further evaluation), M4 (indeterminate, probably malignant) or M5 (malignant).

A cumulative reader grading was compiled for benign (M1 or M2) vs non benign (M3 to M5) outcomes, against biopsy outcomes of benign (no biopsy or B1or 2) vs atypia/ cancer (B3 to B5) for each of the image categories. Sensitivity and specificity data are shown in Figure 25.

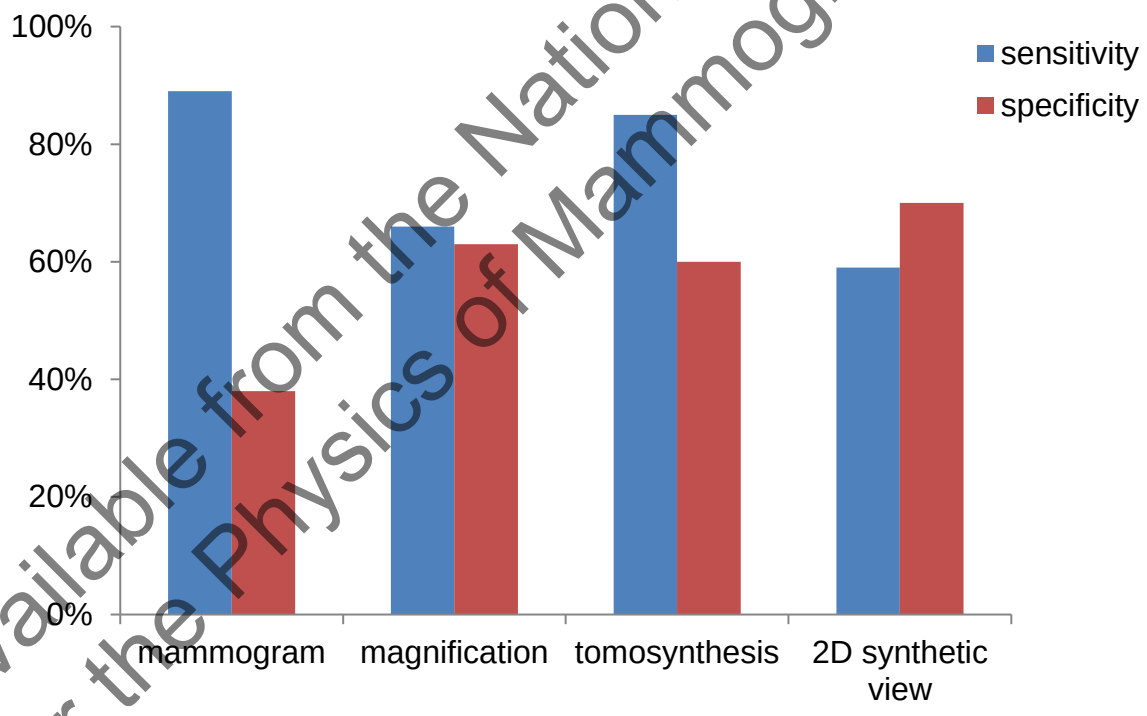


Figure 25. Sensitivity and specificity of screening mammogram, magnification view, tomosynthesis and 2D reconstruction views for soft tissue lesions.

For soft tissue lesions tomosynthesis, magnification and 2D synthetic views demonstrated higher specificity for a biopsy diagnosis of atypia or malignancy

compared to mammograms, which is ideal for a further test to identify true positive malignancies following an initial screening test.

Calcification

During the evaluation period 55 cases recalled for calcification evaluation were also reviewed by the same 5 readers, comparing screening mammograms with plate magnification views (available in 46 cases), tomosynthesis and, where available, the 2D synthetic view (available in 45 cases, following introduction of Insight 2D technology).

As above, M1 to M5 grades were recorded. These were grouped into and benign (M1 and M2) vs non benign (M3 to M5) outcomes and were correlated with benign vs atypia/ cancer biopsy outcomes. Sensitivity and specificity data are in Figure 26.

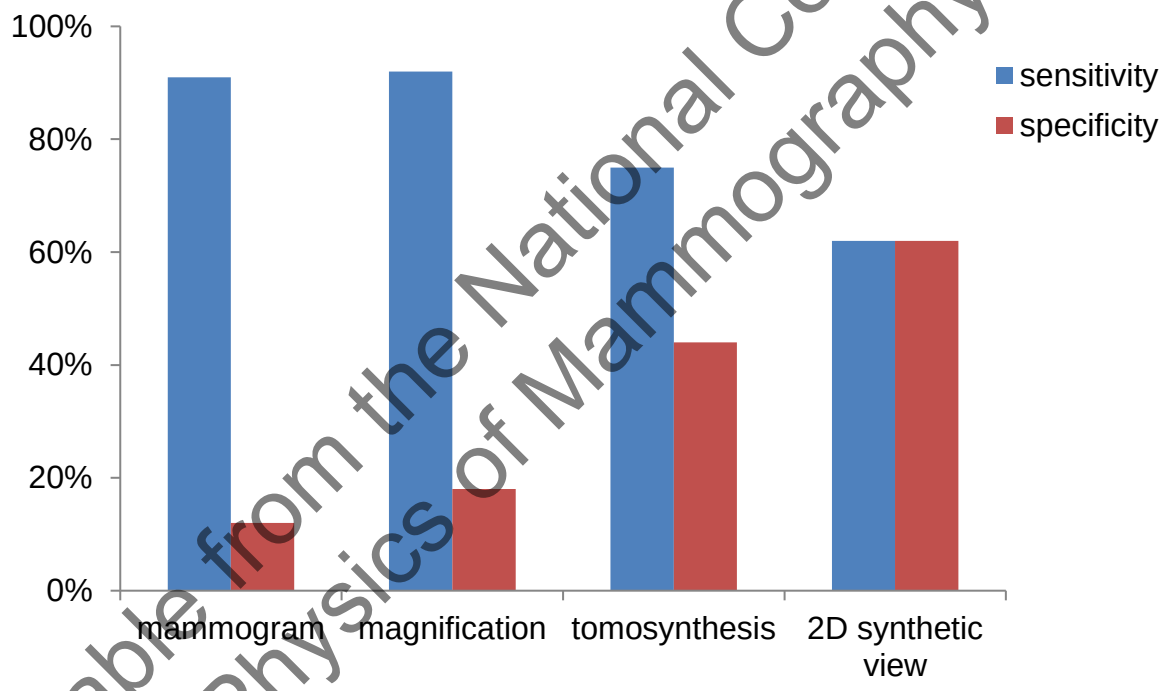


Figure 26. Sensitivity and specificity of mammogram, plate magnification, tomosynthesis and 2D reconstruction views for calcification

In these calcification cases, sensitivity (represented by mammogram graded M3 or higher) of mammograms and plate magnification views was high, consistent with their role in recall to assessment. Tomosynthesis and 2D synthetic views were less sensitive but more specific for a biopsy diagnosis of atypia or malignancy.

4.8 Diagnostic value of tomosynthesis compared to 2D imaging

For soft tissue lesions, the review of 63 cases in section 4.7 shows that the sensitivity of screening mammography and tomosynthesis were both high, consistent with detection of lesions for recall to assessment. Tomosynthesis, magnification and 2D synthetic views were also found to be of high specificity for a biopsy diagnosis of atypia or malignancy, which is ideal for a further test to identify true positive malignancies following an initial screening test.

For calcifications, review of 55 cases in section 4.7 showed screening mammogram and magnification views were of greater sensitivity than tomosynthesis or 2D synthetic views. Specificity of tomosynthesis and 2D synthetic views were however greater for biopsy diagnoses of atypia or malignancy.

5. Equipment reliability

The equipment was generally reliable during the assessment evaluation period. Five faults were recorded on the NHSBSP Equipment Fault Report Forms.

These are recorded at Appendix 4.
Two faults were resolved at a local level or after receiving advice from the Siemens Customer Service Helpdesk. These are identified as:

1. Error message displayed on turning on. Advised by service desk to remove compression and reboot system.
2. Machine frozen – system rebooted

All faults were resolved effectively.

Downtime during the evaluation period was a total of 5.5 days.

6. Electrical and mechanical robustness

There were no safety issues and no electrical nor mechanical problems were encountered during the evaluation period other than the faults reported in section 5.

7. Radiographers' comments and observations

The tomosynthesis equipment evaluation form 11 from the Guidance notes for NHSBSP equipment evaluation [9] was used to collect comments of operators on the Inspiration used in tomosynthesis mode.

The evaluation was split into 2 components – initially during pre-upgrade usage and following upgrade to HD Tomosynthesis with EMPIRE and Insight 2D/3D. For the pre-upgrade period, three questionnaires were completed over twelve-weeks; the first questionnaire covered 19/09/2016 to 14/10/2016, the second 17/10/2016 to 11/11/2016 and the third 14/11/2016 to 09/12/2016. The fourth, post-upgrade questionnaire covered 17/05/2017 to 11/07/2017.

The three pre-upgrade questionnaires were undertaken to address whether there would be any large changes in responses in the pre upgrade stage, with increasing familiarity

with equipment. This was not observed. The results for all four questionnaires are given in Appendix 5. For clarity of presentation, as there were no big changes in responses ove the three pre-upgrade questionnaires, the numbers in the text below refer to pre-upgrade responses from period 3 only (8 responses in total) and post upgrade responses from period 4 (17 responses in total).

Twelve radiography staff (radiographers and 2 assistant practitioners, who had completed the foundation degree course which enables working in all radiographic aspects of NSHBSP assessment) participated in this evaluation. Those trained directly by Siemens specialists were referred to as 'super-users' and they cascaded training to other staff members. Eight completed the first questionnaire, of which 4 were super-users; 7 completed the second questionnaire, of which 3 were super-users and 8 completed the third questionnaire of which 4 were super-users. The post-upgrade evaluation was completed by 17 staff and included the 4 super-users and 12 radiographers and an assistant practitioner.

Features were categorised as either excellent, good, average, satisfactory, poor or not applicable.

7.1 Operator's manual

Siemens provided the following manuals:

Siemens Mammomat Inspiration Operator Manual VB30 and Siemens Mammomat Inspiration Operator Manual VB60 which included Syngo Operator Manual Safety Hints VH22B, Syngo Online Help Security Package VH22B and Syngo Online Help Security Settings VH22B. Also Siemens Mammomat Inspiration Quality Control Manual VB30, Siemens Mammomat Inspiration Tomo Quality Control Manual VB60 and Siemens Mammomat Inspiration Quick Guide.

The majority considered the manual good (1 pre upgrade, 6 post upgrade), average (3 pre, 6 post) or satisfactory (2 pre, 0 post) with 2 pre upgrade not making use of it, either because the applications training was so good that it was not required or because it was a big manual and considered daunting. One respondent commented the manual was comprehensive.

Only few (1 pre, 7 post) compared the manuals to those for 2D mammography and they considered them the same.

A smaller, in-house prepared manual, for the centre's specific needs and for troubleshooting purposes would have been considered a better option by the majority of respondents (7 pre, 15 post).

7.2 Training

The direct training from the applications specialist was rated excellent (1 pre and post), good (1 pre, 4 post), average (2 pre,1 post) and satisfactory (0 pre,1 post). Cascaded training was less well regarded. Respondents did not record any differences between training for the modality and for the workstation.

7.3 Ease of use of the unit

Ratings were excellent (1 pre, 2 post), good (3 pre and 9 post), average (4 pre and 3 post), satisfactory (1 post) and poor (1 post). Super users trained by the applications specialist found the equipment 'very easy to use and straightforward' but other users were more varied in their responses, ranging from 'easy' to 'lots of fiddling'. Some commented that finding patients' details was slow and the time from one tomo exposure to being able to take the next was thought to be long by the user.

7.4 Ease of fitting of the tomosynthesis faceplate

Favourable responses with excellent (3 pre, 4 post), good (2 pre,10 post), average (3 pre, 0 post) and satisfactory (0 pre, 1 post) and comments such as 'easy to attach' and 'straightforward' .

7.5 Quality assurance testing for tomosynthesis

Only a few radiographers had been trained to perform the quality assurance (QA) over the period of the initial 3 questionnaires. This was rated difficult (5 pre, 2 post), average (3 pre, 11 post) and easy (2 pre, 4 post). By the post upgrade questionnaire, the majority (11) rated the process as average.

7.6 Compression times for tomosynthesis

Pre-upgrade, opinion on compression times was divided between acceptable (6) and not acceptable (1). By the final questionnaire the majority (13) found the compression times acceptable. Although the compression was long, it was felt this was expected and reassurance improved client experience. By the final questionnaire, when comparing tomosynthesis with 2D there was an almost even division between the same (5) and worse (5). One recorded tomosynthesis compression to be better than 2D.

7.7 Limit to patient throughput for tomosynthesis

Pre-upgrade the majority (6) found that performance limited throughput and one said it did not. By the final questionnaire, the ratings were more mixed with just over half considering it limited patient troughput (9 limiting and 8 not limiting). One comment was

'It takes much longer to perform tomosynthesis as the exposure time is longer and it takes a while for the slices to process before being able to expose again'.

7.8 Comfort level for the women for tomosynthesis

Most considered the comfort level satisfactory (0 pre, 2 post), average (6 pre, 6 post) or good (2 pre, 4 post). There were 3 who considered it poor on the final questionnaire. Concerns included the possibility of the large face shield catching the woman's face or chin. There were however no reports of women complaining about the face shield and a super-user observed that some women felt it was a more thorough examination.

7.9 Range of controls and indicators for tomosynthesis

All respondents considered the expected controls to be present. There were many comments about the user interface: 'larger icons and message line (font) would be preferable; 'too small and too tiny', 'not user-friendly and not intuitive'. Also, the user interface was considered 'not as user friendly, but after doing a few you get the hang of it'. The lack of touch screen controls was also mentioned as a potential area for development.

7.10 Image appearing at the AWS and image storage for tomosynthesis

Pre upgrade, the time for image to appear at the acquisition workstation was rated at least satisfactory (2) or average (2) and good (3), with only 1 poor response. By the final questionnaire however the response was divided, with time considered satisfactory (3), average (1), good (3) or excellent (1) whilst 7 considered it poor. When compared with 2D, the majority consistently considered it worse than for 2D (5 pre and post). ' Image appears quickly, however it feels like an age before I can do the next acquisition'

Timing for storage was more favourably viewed, with satisfactory (2 pre, 3 post), average (2 pre, 5 post) and good (4 pre and 4 post) outcomes on all questionnaires, and with only 2 poor responses out of 14 on the final questionnaire. It was considered on the initial questionnaires to be the same as 2D (3) or worse (1) and on the final questionnaire 6 indicated the same, 1 better and 3 worse.

7.11 Image handling and image processing facilities at the AWS

With regard to scrolling through the planes, all provided ratings were satisfactory (3 pre and post), average (0 pre, 4 post), good (3 pre, 5 post) or excellent (1 pre and post) and none were poor. When compared with 2D the majority were the same (4 pre, 9 post) and 1 better post upgrade and none were worse. A comment was made that there is more 'clicking' to do but otherwise the handling was similar.

The processing facilities were considered satisfactory or better in the majority of responses - satisfactory (3 pre, 1 post), average (0 pre, 4 post), good (4 pre, 5 post) or excellent (0 pre, 1 post). Only 2 of the final 13 responses indicated poor.

When compared with 2D, the majority were the same (4 pre, 7 post) and 1 was worse post upgrade. Comments varied widely ranging from ‘easy to use’ to ‘not user friendly’.

The query / retrieve function processing facility was not used by many responders, with 4 non responders pre-upgrade and 7 post-upgrade. Ratings were poor (0 pre, 2 post), satisfactory (1pre, 1 post), average (0 pre, 4 post), good (2 pre, 1 post) and excellent (0 pre, 1 post). Comment: ‘too many processes to go through to retrieve images’. When compared with 2D imaging the responders did not note any difference except for 2 reponses in the final questionnaire which were worse.

7.12 Ease of use of the human interface facilities at the AWS

When rating the keyboard, ratings were average (1 pre, 7 post), good (5 pre, 7 post) or excellent (1 pre and 1 post) Most also felt it was the same (6 pre and post) as 2D, with 1 selecting better. Comments include: that it was ‘difficult to pull the keyboard out far enough to use the escape key’, ‘a tracker ball would have been better’ and ‘a touch screen would have been more user friendly’.

There are questions about touchscreen and tracker ball functionality in the questionnaire. These were not part of the evaluated equipment.

The wheel for scrolling through tomosynthesis slices was rated average (1 pre, 7 post), good (3 pre, 4 post) or good (1 pre and post).

7.13 Image quality for tomosynthesis at the AWS and overall

Image quality at the acquisition workstation was rated between satisfactory (1 pre and post), average (2 pre, 1 post), good (4 pre, 14 post) or excellent (1 pre and post) with no poor ratings. Comparison was found to be difficult as there was no prior departmental experience of tomosynthesis.

The overall image quality of the system in tomosynthesis mode was rated identically to the image quality at the acquisition workstation for tomosynthesis, as detailed in the paragraph above.

7.14 Level of confidence in the unit for tomosynthesis

Ratings were poor (0 pre, 1 post), satisfactory (1 pre, 0 post), average (2 pre, 7 post), good (5 pre, 6 post) or excellent (0 pre, 1 post). The majority considered the level of

confidence, when compared with 2D to be the same (3 pre and 8 post) with 1 pre-upgrade considering it worse.

There was a wide range of comments: ‘felt confident with every aspect of the system’ to ‘lost confidence since the upgrade as no further training or explanation’ and ‘not user friendly’.

The level of confidence in the equipment was compromised for women presenting with a breast thickness in excess of 100mm. There was no breast tissue missed at the top or bottom of the reconstructed tomosynthesis images with the exception of greater than 100mm. The maximum compressed breast thickness (CBT) that can be reconstructed in tomosynthesis mode is 100mm. For thicknesses above this, the system will allow the exposure but will display a warning that only the lower 100mm will be reconstructed.

7.15 Hazards

Cumulatively over all the questionnaires 33 responses rated no hazard, whilst 3 raised potential hazards to the radiographer. These included ‘If using push button during the exposure, potential RSI to wrist ie if not using the foot pedal, (should this be included as this is a room planning issue) – risk of accidental exposure’ and comments about the large face shield potentially catching on the woman. Compared to 2D, ratings were the same (4 pre and 6 post) or better (0 pre and 1 post) with a single worse rating post upgrade.

When considering hazards to the woman, this is the only question where there was a trend over the four questionnaires, with increasing numbers of radiographers noted potential hazards as the evaluation progressed. These were mainly the risk of women catching their heads on the large face shield during gantry motion. ‘Face shield may be intrusive, depending on the agility of the patient’ and ‘ the patient must hold head out of the way’.

7.16 General comments

Comments made include:

‘Tomosynthesis easy to use and very user friendly.’

Several comments focused on the acquisition work station with comments including ‘would prefer touch screen, large clear font and less clutter’, ‘patient registration form too long and unable to remove unnecessary fields’, ‘font too small and lacks colour’ and ‘too much clicking to get to items’.

Paddle size - ‘Need more than one paddle for tomosynthesis – clients complain the paddle compresses near their shoulder’

8. Readers' comments and observations

Another evaluation form (based on evaluation form 9 of the evaluation guidelines) was used to collect the views of radiologists and film readers regarding the use of tomosynthesis in assessment. A total of 10 consultant radiologists and 4 advanced practitioners took part in the evaluation.

Initially, three questionnaires were completed over a twelve-week period, during the pre upgrade period. The first questionnaire covered 19/09/2016 to 14/10/2016 and there were 14 respondents, the second 17/10/2016 to 11/11/2016 with 11 respondents and the third 14/11/2016 to 09/12/2016 with 8 respondents. Three questionnaires were conducted pre upgrade to assess any change in scoring with increasing familiarity with the equipment. No trends were found and so the outcomes described below are based on the third pre upgrade questionnaire.

A final, fourth questionnaire was completed post installation of the BTO converter and the software upgrade for EMPIRE and PRIME from 01/01/2017 to 01/05/2017, with 10 respondents who had used the system following the upgrades.

All the results from the four questionnaires are in Appendix 6.

Readers categorised features as either excellent, good, average, satisfactory, poor or not applicable.

Images were reviewed on the Philips PACS, on 12 megapixel BARCO monitors. These were sited in the assessment hub centrally within the Breast screening clinical area and also within the individual clinic rooms used for assessment. Any comments regarding mouse, keyboard, keypad, zoom, cine, hanging patterns and protocols as well as monitor height adjustment refer to the Philips PACS and the related PACS functionality.

Questions relating to the properties of the tomosynthesis images for example contrast, sharpness, quality of images and overall level of satisfaction are a better reflection of the tomosynthesis.

8.1 Operator manual

Readers did not use the official manual.

8.2 Applications training for tomosynthesis

There were some conflicting responses to the questions about applications training, with most readers stating not applicable (11 pre, 6 post). Good applications training was given to an initial small group of superusers, which was cascaded down to the other readers.

8.3 Use of reporting station tools for tomosynthesis

A dedicated Siemens workstation was not used in this evaluation. Images were reviewed on a Philips mammo PACS, within a central clinic hub and also in individual reporting rooms. All comments on the reporting tools are based on the standard Philips PACS workstation reporting tools.

By the final questionnaire the majority of readers rated the mouse, keyboard and keypad controls good (5) or average (3).

8.4 Image handling tools for tomosynthesis

Initially, tomosynthesis images were displayed tiled on PACS and navigation between the planes was by function keys on the keyboard. Following installation of the BTO converter (prior to the final questionnaire) the images were presented stacked and slider and cine functions were available.

8.5 Visibility and usability of on-screen icons for tomosynthesis

There are no dedicated on-screen tomosynthesis icons although a slider bar demonstrates location of images in the stack and image slice number.

8.6 Slab thickness change when viewing tomosynthesis images

It was not possible to alter slab thickness on the PACS workstations used.

8.7 Reading/reporting workflow in tomosynthesis mode

Multiple initial comments were unfavourable and related to images going into an ‘exceptions’ folder and tiled rather than being easily located on the PACS worklists. Following the BTO converter installation, the majority rated the stacked images good (7), with average (1), poor (1) and not applicable (1).

8.8 Time for image to appear on screen in tomosynthesis mode

Prior to the upgrade, for new patient selection, this was rated excellent (2), good (3), satisfactory (1) and average (1). By the final questionnaire, the ratings were excellent (1), good (3), satisfactory (2) and average (3). There was also one rating of poor but the accompanying comment was ‘ very slow initially but much improved’.

8.9 Recording on NBSS for tomosynthesis images

There is no facility on NBSS to record data on tomosynthesis imaging during assessment. Only free text comments can be made.

8.10 Adjustment of reporting monitors to suit the user

The system was set up to integrate to the local Phillips PACS and comments relate to the PACS system. The Siemen’s reporting monitor was not evaluated.

Navigation between tomosynthesis planes

On the local Phillips PACS workstation, the majority of respondents considered it easy to navigate between planes: easy (5 pre, 7 post upgrade), average (2 pre, 1 post upgrade). Post upgrade there was one difficult rating but the comment accompanying this was ‘unstacked initially but better now’.

Hanging protocols for tomosynthesis

There were no specific tomosynthesis hanging protocols on the PACS system. Images could be hung in the same way as standard digital mammograms on the PACS workstation.

8.11 Image quality of tomosynthesis images

Image quality comments were consistently favourable. Initially excellent (1), good (8), average (3) and poor (2) with comments including 'really good spatial details', 'not sharp but good' and 'noisy but good'.

On the final questionnaire, the overall comments on image quality were excellent (1) and good (9). Final comments included: 'Wide angle images. Better than (another manufacturer’s) tomosynthesis acquisitions in terms of contrast and sharpness' and 'Although image quality is flat, the detail in the region of interest is good. Tomosynthesis images have been very helpful in assessment clinics especially in distortion, asymmetry and masses. It has aided confidence in our daily work. Efficiency of image viewing was enhanced after the BTO converter was installed.'

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

Contrast rating improved from good (4), satisfactory (1) and average (1) to a post upgrade rating of excellent (1) and good (9). Comments included ‘noisy but pathology well demonstrated compared with mag views’. Sharpness was also well rated: pre upgrade good (4) and average(3) whilst post upgrade it was rated excellent (1), good (8) and average (1). Overall quality impression ratings were good (4) and average (3) and post upgrade were excellent (1) and good (9)

8.13 Overall satisfaction in use for assessment

Overall satisfaction rose from good (3) and average (3) on the pre upgrade questionnaire to excellent (1) and good (9) on the final questionnaire.

8.14 General Comments

In this evaluation, the tomosynthesis images were integrated into the already established Philips mammo PACS (see section 9.1) and the viewing functionality comments refer to PACS tools. Repeated comments by respondents initially are of images going into a separate ‘exceptions’ folder and not being available on the worklists and images tiled rather than stacked so navigation was cumbersome, by pressing keyboard function (‘F7 and F8’) keys repeatedly to navigate forwards and backwards through the planes. These factors influenced the comments on the initial 3 questionnaires, with multiple similar comments such as, ‘Time consuming when images not stacked or images in PACS exceptions’.

As tomosynthesis was new to the unit, the possibility was raised of some variation over the course of the initial three questionnaires, reflecting increasing experience with the system. There does not however appear to be any significant trend over the initial three surveys. The biggest change is seen on the final, fourth questionnaire, following the BTO converter installation, as the more streamlined display of the images led to increased ease of usage with improved workflow scores and comments.

Opinions on the quality of the tomosynthesis images were generally positive. There were some comments on the initial questionnaire such as ‘both contrast, especially for calc, and sharpness for stellate lesions and distortions can be improved’. However by the final questionnaire ratings of good or excellent for contrast and sharpness were noted. Comments include: 'Wide angle images. Better than (another manufacturer’s) tomo acquisitions in terms of contrast and sharpness' and 'Although image quality is flat, the detail in the region of interest is good. Tomosynthesis images have been very helpful in assessment clinics especially in distortion, asymmetry and masses. It has aided confidence in our daily work. Efficiency of image viewing was enhanced after BTO converter.'

9. Information Systems

9.1 Workflow configuration

Tomosynthesis was evaluated on the dedicated breast imaging PACS. At the start of the evaluation this was a Philips iSite v4.4 with Barco 5 megapixel monitors. This was upgraded to Intellispace PACS v4.4.542.0 with Barco Coronis Colour 12 megapixel monitors, 3 months into the evaluation. The upgraded PACS system had tomosynthesis viewing software and the storage capacity was specified to include tomosynthesis data acquired at assessment. The reader evaluation studies were carried out on the updated PACS system.

The use of existing PACS hardware ensured that all readers could see all tomosynthesis examinations on any workstation at any time and the cases could be assimilated into teaching and MDM (multidisciplinary team meeting) processes.

9.1.1 Workflow

Image storage and review in the department is designed to support optimal workflow. Screening images are imported directly or indirectly (using a hard drive) into PACS and presented for reading alongside digital and scanned analogue priors which may have been acquired in the local screening or symptomatic service, or imported from local hospitals. Dedicated mammography PACS workstations are present in the film reading room, the assessment clinic hub and in each of three assessment/ultrasound rooms. In addition the images are visible on a web browser version of PACS in all mammography rooms, and in the MDM seminar room.

All mammograms for women attending a screening assessment clinic are added to an assessment clinic PACS folder. The assessment team review all cases prior to clinic and specify which further tests are appropriate (for example additional views, ultrasound, stereotactic biopsy). Initially during the evaluation, tomosynthesis was performed in addition to magnification views. After one month, tomosynthesis alone replaced magnification views, in most cases, for soft tissue lesions. Lateral magnification views were obtained for microcalcifications.

The images obtained on the Inspiration were sent directly to PACS. There were issues regarding both NBSS and the DICOM labelling of the tomosynthesis data set that required resolving, as detailed below:

1. NBSS issues

The Philips PACS system provided a DICOM worklist to the modality (ie the ultrasound, mammogram or tomosynthesis machine) for all planned examinations. This specified the accession number and attributed the exam code for each unique examination which was then presented as an episode on the PACS timeline. NBSS however only specified a single accession number for mammography at assessment, which was used for a variety of further imaging including magnification views, stereotactic examinations and tomosynthesis.

Local preference was to allocate separate exam codes to stereotactic procedures so that they were distinct from additional imaging such as magnification views. This was achieved by amending the accession number of the stereotactic examination at the time the images were obtained. The examination then went to a separate 'exceptions' folder on PACS until it was resolved manually on PACS, with a new exam code added. Examinations were resolved within a few hours of the examination taking place and the examination was then visible on the client timeline.

Initially this process of amending the accession number was also adopted for the tomosynthesis examinations. However the delay until they were added to the client timeline was problematic within the assessment clinic setting. Although they could be viewed in the exceptions folder, this added an extra search into the image review workflow during clinic. To avoid this delay, it was decided to retain tomosynthesis images on same timeline as the magnification views.

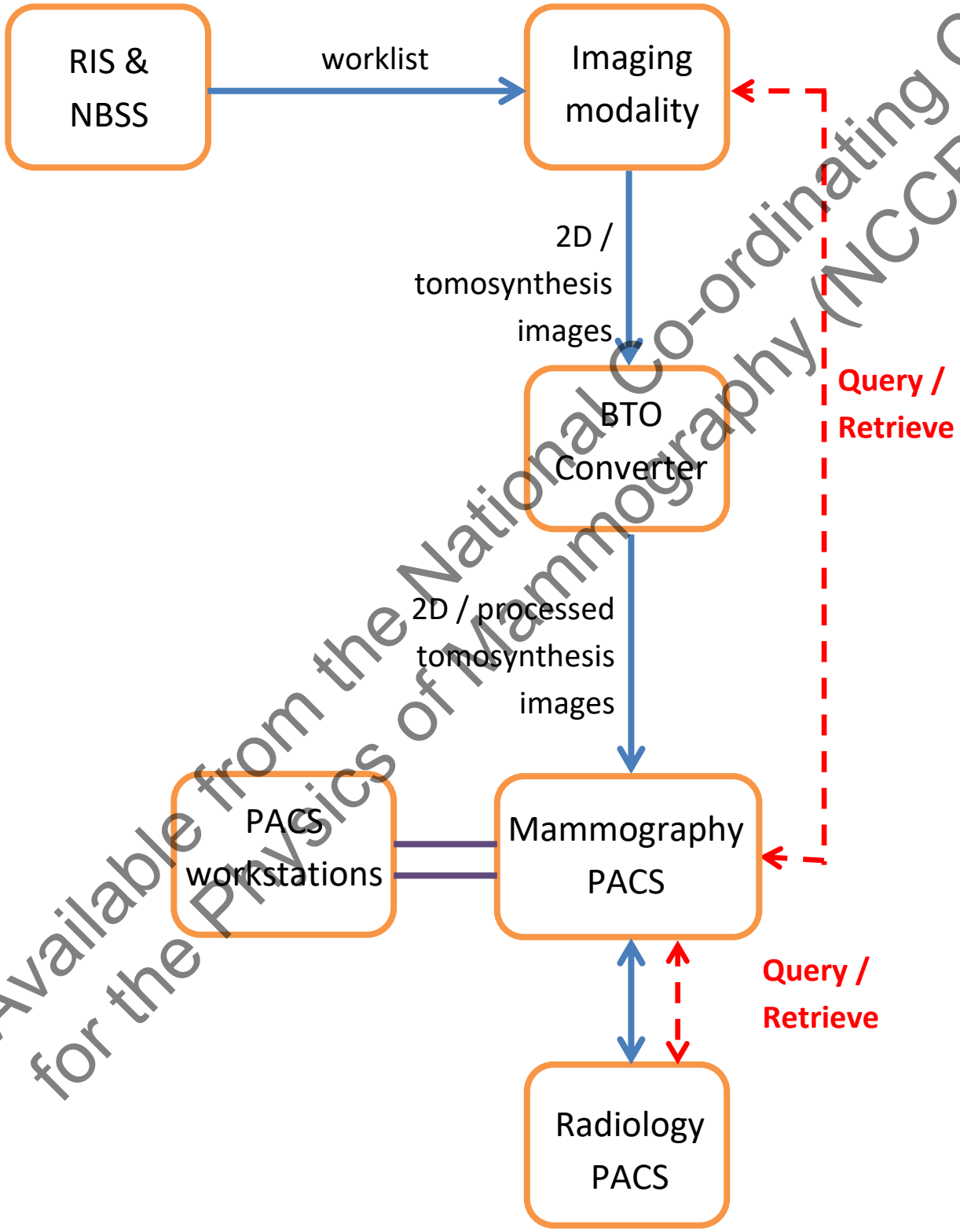
2. DICOM labelling.

Initially the Siemens tomosynthesis images were labelled as CT images in the DICOM header. This meant that the examination was presented as a set of multiple consecutive images, which could be stacked to mimic a formal tomosynthesis image set. The user navigated forwards and backwards through the tomosynthesis planes using keyboard function keys. No dedicated tomosynthesis viewing functions, such as a tomosynthesis localiser nor variable slab thickness, were available. Image loading to PACS was slow for the consecutive images.

This problem was resolved by the installation of a dedicated software package to modify the label in the DICOM header. The software (BTO convertor) was provided by Siemens. Images were sent from the Inspiration to the BTO converter, and thence on to the PACS system as formal tomosynthesis images. The tomosynthesis examination became available without delay on the PACS workstation and was compatible with the PACS tomosynthesis viewing software.

We evaluated the time taken for the images to be acquired, made available on the workstation and reviewed as follows. 10 random cases were used to estimate the time taken.

Figure 27. Image workflow diagram for 2D and tomosynthesis images



9.2 Image sizes

Table 6. 2D and tomosynthesis image file sizes, obtained from the NHSBSP technical evaluation of Siemens Mammomat Inspiration.[3]

Image type	Pixels per frame	Frame size (mm)	File size per frame (MB)	Frames per image	Total image file size (MB)
2D large format	2800 x 3518	238 x 299	19.2	1	19.2
Tomosynthesis projections	2816 x 3584	239 x 305	19.7	26 for processing +26 for presentation (including pre pulse)	1024
Tomosynthesis reconstructed focal planes	2728 x 3480	232 x 296	18.5*	61 for 60mm thickness	1129*

* Number of pixels and file size for local planes is variable. This represents the upper end during testing.

10. Confidentiality and security issues

The evaluation complied fully with NHS Cancer Screening Programmes' Confidentiality and Disclosure Policy.[10]

All electronic patient data was stored on NBSS and images were stored on the Philips MammoPACS system. Secure access to the reporting stations was limited to authorised users with an individual login.

Clinical information was recorded on standard, local breast screening assessment paper proformas. These were modified to incorporate a section to record location and description of abnormalities seen on tomosynthesis as well as a tomosynthesis rating; this is a 1 to 5 scale, comparable to that used for mammography, where 1 represents normal, 2 benign, 3 indeterminate probably benign, 4 indeterminate probably malignant and 5 malignant. The paperwork was kept in a secure storage facility.

11. Training

11.1 Radiographer training

The applications training for tomosynthesis use was delivered by a Siemens applications specialist over a 2.5 day period to three radiographers, one assistant practitioner and one specialist practitioner, known as superusers. The training was cascaded to other radiography staff over the same period covered by the first pre-upgrade part of the evaluation and was done on the job during the routine clinical work. The Siemens applications specialist provided electronic quick guides to support cascading training to the rest of the staff.

11.2 Reader training

All the Radiologists underwent tomosynthesis training. Most attended training at King's College Hospital, London, whilst others underwent training locally using an archive of validated cases. The content from both included: the principles of tomosynthesis, tomosynthesis appearances of normal, benign and malignant cases, 2-D vs. tomosynthesis imaging comparison and hands-on reading of test cases with practical self-assessment and feedback.

Radiologists and advanced practitioners had some applications training at the time of installation and user tips were also cascaded from superusers. There were many changes to the system and image display in the initial stages as outlined earlier, so users had to be adaptable to new ways of working to manage the changes as they arose.

Siemens application specialists delivered training to a group of radiographer and trainer superusers and the training was cascaded to all radiographers who worked with the equipment. As the Siemens tomosynthesis system was new to the unit, radiographers did not use tomosynthesis until they had completed training.

12. Discussion

12.1 Equipment and practical considerations

At the start of the evaluation, the user interface at the Inspiration workstation was not considered intuitive to use, with comments also about display font size and small icons.

As staff became more familiar with the system, these user interface issues were overcome.

The Inspiration comes supplied with different sized face shields. The larger face shield is for tomosynthesis and special care had to be taken to ensure the client's face was not resting on this large shield, to prevent moving with the arc of the tube. The smaller face shield is not designed for use with tomosynthesis as the client's face might catch on the shield as it moves with the arc of the tube.

The Inspiration provides tomosynthesis images for up to 100mm of compressed breast tissue. This level of breast thickness was not encountered during the Inspiration evaluation. The Inspiration was being used within the assessment setting to evaluate specific lesions, rather than for screening. If required, it would have been possible at the time of assessment to ensure that the area of interest was included in the tomosynthesis images.

Reliability of the Inspiration was good during the evaluation period. Helpdesk support was available if required.

12.2 Physics testing and routine QC tests

Physics commissioning found the Siemens Mammomat Inspiration performance to be satisfactory. A dose survey found the average mean glandular dose for MLO exposures of 50 to 60 mm thick breasts to be 1.48mGy pre upgrade and 1.40 mGy post software upgrade, well below the NDRL of 2.5mGy. Tomosynthesis average MGD for MLO views of 50 to 60 mm thick breasts were 1.59mGy pre upgrade and 1.63 post upgrade.

Quality control tests carried out during the evaluation, as presented in section 3, showed general stability of performance. Occcasional outlying measurements were not reproducible and were likely to be operator related rather than the equipment under evaluation. The test results, taken as a whole, demonstrated consistent performance within NHSBSP limits.

12.3 Clinical Assessment

The quality of imaging from this system is very good, with good sharpness and contrast and excellent overall image quality. Small observer studies have shown the tomosynthesis views to be of higher specificity than 2D mammography for both calcification and masses, as would be appropriate for an assessment tool. The tomography images were considered a useful tool by radiologists and film readers.

Initially, there were delays in throughput for clinics. Multiple factors included those related to acquiring the images, transfer of images to PACS and issues with viewing of images, which will be discussed in section 12.5. Following the installation of the BTO converter software, clinic throughput improved and overall reader satisfaction levels also improved. Reading images was easy and quick by the end of the evaluation with timings given in section 9.

12.4 Radiographers and Radiologists views

Radiographers trained by the applications specialist considered the training good, but cascaded training was less well regarded. This was the first Siemens system in the unit and radiographer comments described the user interface as not intuitive. This, combined with waiting times for the system to be ready and length of exposure compared to 2D led to increased time taken per woman and initial delays to assessment clinic workflow. This became less noticeable with increasing experience with the equipment.

Radiologists found the quality of the images to be very good.

12.5 Image acquisition, transfer and storage

Image acquisition – there was increased time required to explain the procedure to clients and longer time required to perform the tomosynthesis examination, compared with 2D magnification views.
Transfer and viewing of images – initially, transfer of images from the Inspiration to PACS was slow, taking up to 5 minutes. Images were tiled rather than stacked, resulting in a long row of multiple thumbnail images on the client timeline on PACS. This slowed reading of the tomosynthesis images, as navigation through the image planes was via keyboard function keys. With installation of the BTO converter software, the image transfer time issues were resolved to an average transfer time of 112 seconds. The images were now presented on PACS stacked rather than tiled and tomosynthesis viewing functions could be used.
The tomosynthesis images are comparable in size to other manufacturers. The large size (over 1,000MB) of tomosynthesis images has an impact on PACS storage, and consideration should be given to adequate provision of capacity. It is possible to store data as raw images for subsequent reconstruction, provided the relevant reconstruction technology remains available.

13. Conclusion

Overall, the Siemens Mammomat Inspiration tomosynthesis was found to be a useful tool in assessment. The quality of images was considered very good by the radiologists. Other than comments about the user interface, radiographers found the equipment straightforward to use although more dedicated training time with the apps specialist would have been beneficial. The equipment was very reliable during the evaluation period.

There were extensive issues with NBSS and PACS integration at the start of the evaluation but the subsequent installation of a BTO converter facilitated the smooth transfer of images from the modality to the PACS.

Radiation doses were within the reference dose for tomosynthesis, both initially with the standard system and also post HD Tomosythesis with EMPIRE, and Insight 2D and 3D upgrades.

The Siemens Mammomat Inspiration tomosynthesis system was found to be suitable for use in assessment in the NHS Breast Screening programme.

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Appendix 1: Physics survey report

RPC

MAMMOGRAPHY X-RAY SURVEY:
COMMISSIONING CHECKS

SWLBSS, ROSE CENTRE, ST. GEORGE'S HOSPITAL
ROOM 1
SIEMENS MAMMOMAT INSPIRATION

Report No. SGH-BSP-MMC-R1-15-mb

Report Date: 25/07/2016

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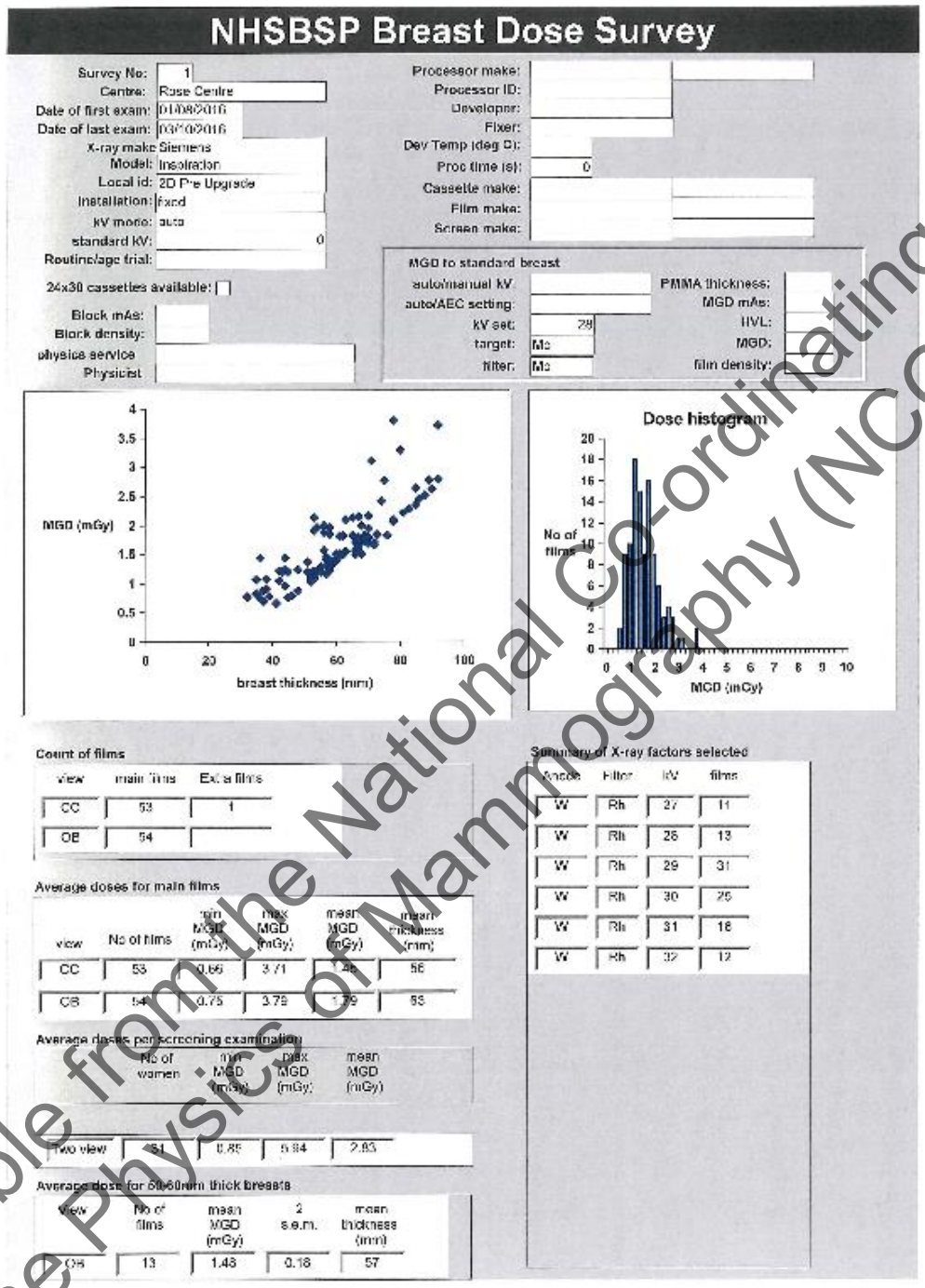
BUREAU VERITAS

St George's University Hospitals NHS
NHS Foundation Trust

Appendix 2: Dose surveys



NHSBSP Breast Dose Survey

Survey No: 1
Centre: Rose Centre
Date of first exam: 01/08/2016
Date of last exam: 03/08/2016
X-ray make Siemens
Model: Inspiration
Local id: 2D Pre Upgrade
Installation: fixed
kV mode: auto
standard kV: 0
Routine/age trial:
24x30 cassettes available:
Block mAs:
Block density:
physics service
Physicist

Processor make:
Processor ID:
Developer:
Fixer:
Dev Temp (deg C):
Proc time (s): 0
Cassette make:
Film make:
Screen make:

MGD to standard breast
auto/manual kV:
auto/AEC setting:
kV set: 28
target: Mo
filter: Mo
PMMA thickness:
MGD mAs:
HVL:
MGD:
film density:

Count of films

view	main films	Extra films
CC	53	1
OB	54	

Summary of X-ray factors selected

Anode	Filter	kV	films
W	Rh	27	11
W	Rh	28	13
W	Rh	29	31
W	Rh	30	25
W	Rh	31	18
W	Rh	32	12

Average doses for main films

view	No of films	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	53	0.66	3.71	1.46	56
OB	54	0.75	3.79	1.79	58

Average doses per screening examination

	No of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
Two view	51	0.85	5.84	2.83

Average dose for 50-60mm thick breasts

view	No of films	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
OB	13	1.48	0.18	57

Figure 28. Breast dose Survey 2D 'standard'.

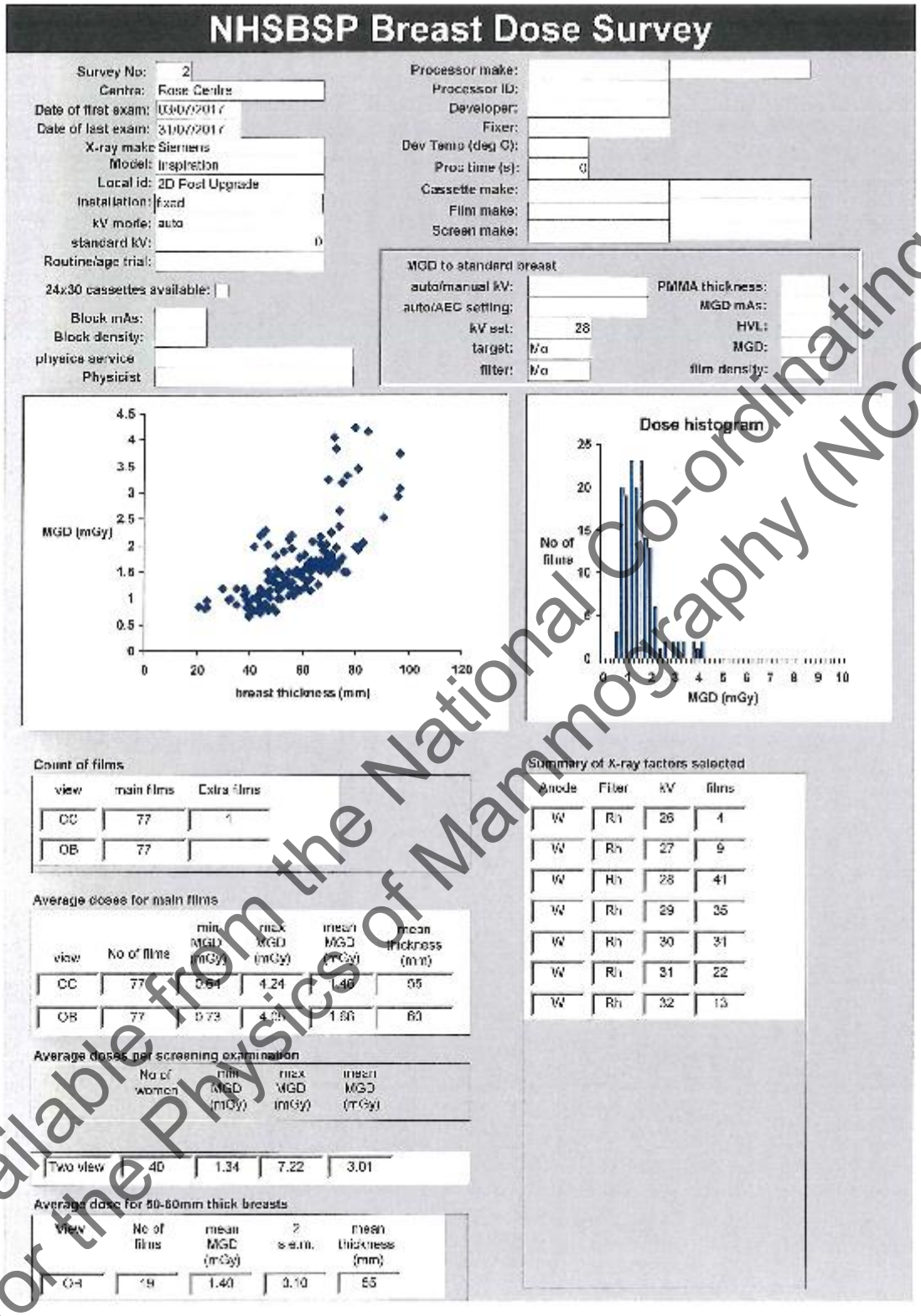


Figure 29.

Breast dose Survey - 2D ‘post upgrade’.

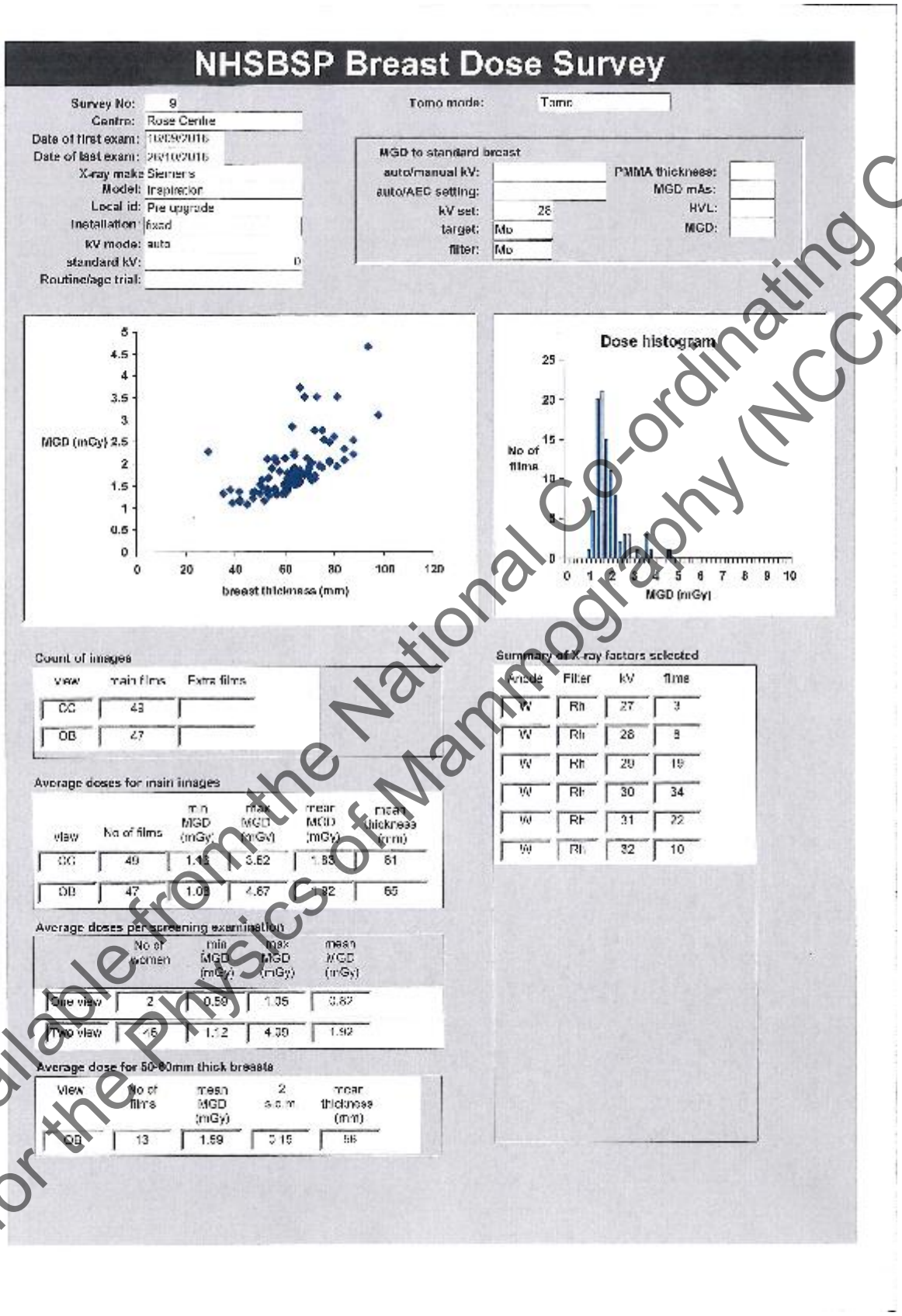


Figure 30. Breast Dose Survey Tomo ‘standard’

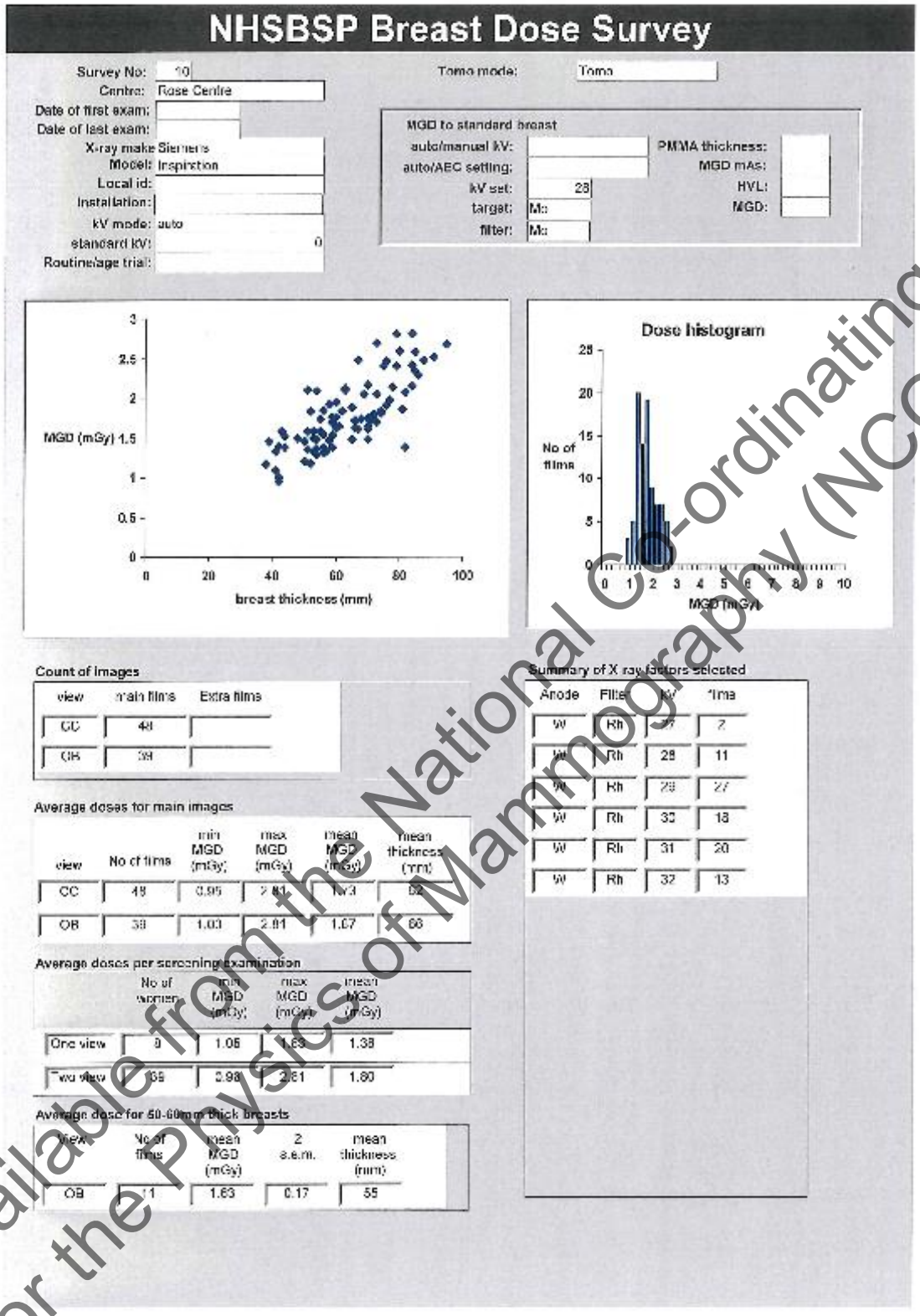


Figure 31. Breast Dose Survey Tomo 'post upgrade'

Appendix 3: Manufacturer specific QC tests

The the daily NHSBSP required QC tests were undertaken as there were no specific QC tests required by the manufacturer.

Appendix 4: Fault reports requiring engineer visits

Date	Fault	Solution
18 October 2016	White line artefacts on magnification images	Factory calibration files restored. Detector calibrated.
26 January 2017	Digital Detector failure error	Unable to replicate fault. Saved logs collected.
8 March 2017	Issues with tomo imge transfer	Syngo configuration changed to send through BTO converter
13 April 2017	Error code 7 displayed	Attempted to resolve remotely initially, Customer service engineer attended. Carried out reference in web based service screen. Biopsy run completed
21 July 2017	Biopsy comnnection loose and exposed from protective covers.	Reseated and secured stereo connector. Test stereo exposure performed.

The total machine down-time during the evaluation was 5.5 days.

Appendix 5: Radiographers' answers to questionnaire

		Questionnaire number				Comments
		1	2	3	4	
How do you rate the supplier's operator manual (if used)?	Excellent	-	-	-	-	Majority considered the manual good, average or satisfactory. Those that did not use it commented that they did not need to, as the applications training was so good it was not necessary or it was too big and considered daunting. The manual was considered the same for 2D and tomo.
	Good	3	3	1	6	
	Average	-	-	3	6	
	Satisfactory	2	2	2	-	
	Poor					
	Not used	4	1	2	-	
	No response	-	1	-	5	
	Compared with 2D:					
	Better	-	-	-	-	
	Same	-	2	1	7	
	Worse	-	-	-	-	
How good was the clinical applications training for tomosynthesis provided by the supplier for modality	Excellent	1	1	1	1	Majority considered the training excellent, good, average or satisfactory. The training from the applications specialist was well rated. Cascaded training was less well regarded. The results for the workstation were identical to those for the modality
	Good	2	3	1	4	
	Average	1	1	2	1	
	Satisfactory	-	1	-	1	
	Poor	1	1	-	-	
	Not used	3	-	3	8	
	No response	-	-	1	1	
	Compared with 2D:					
	Better	-	1	-	2	
	Same	1	2	3	3	
	Worse	1	1	-	2	

		Questionnaire number				Comments
		1	2	3	4	
How good was the clinical applications training for tomosynthesis provided by the supplier for workstation	Excellent	1	1	1	1	
	Good	2	3	1	4	
	Average	-	1	2	-	
	Satisfactory	1	1	-	1	
	Poor	1	1	-	-	
	Not used	3	-	3	8	
	No response	1	-	-	2	
	Compared with 2D:					
	Better	-	1	-	2	
	Same	1	2	3	3	
	Worse	1	1	-	2	
How do you rate the unit's ease of use for tomosynthesis ?	Excellent	-	2	1	2	The super-users who had been trained by the applications specialist found the equipment 'very easy to use and straightforward' but other users were more varied in their responses, ranging from 'easy' to 'lots of fiddling'.
	Good	6	3	3	9	
	Average	1	1	4	3	
	Satisfactory	-	1	-	3	
	Poor	1	-	-	1	
	Not applicable	-	-	-	-	
	No response	-	-	-	-	
How easy was it to attach/remove any special tomosynthesis devise used with the X-Ray equipment e.g. faceplate, bucky?	Excellent	2	3	3	4	Favourable responses with comments such as 'easy to attach' and 'straightforward'
	Good	5	3	2	10	
	Average	1	1	3	-	
	Satisfactory	-	-	-	1	
	Poor	-	-	-	1	
	Not applicable	-	-	-	-	
	No response	-	-	-	1	
How do you find carrying out the special QA tests for tomosynthesis ?	Difficult	-	1	1	2	Only a few radiographers had been trained to perform the QA over the period of the initial 3 questionnaires. This number rose by the time of the fourth questionnaire, with the
	Average	5	3	3	11	
	Easy	2	2	2	4	
	Not performed	1	1	2	-	
	No response	-	-	-	-	

		Questionnaire number				Comments
		1	2	3	4	
How do you find carrying out the calibration tests for tomosynthesis?	Difficult	1	1	2	2	majority, at that stage, rating the process as average.
	Average	2	1	1	10	
	Easy	2	2	1	2	
	Not performed	3	3	4	1	
	No response	-	-	-	2	
How do you find carrying out the reporting workstation QA?	Difficult	1	1	1	2	
	Average	1	1	2	8	
	Easy	-	2	2	2	
	Not performed	6	3	3	3	
	No response	-	-	-	2	
Were the compression times acceptable for each exposure?	Acceptable	2	5	6	13	Initially opinion on compression times was divided between acceptable and not acceptable but by the final questionnaire the majority found the compression times acceptable. Although the compression was long, radiographers felt this was expected and prior explanation and reassurance improved client experience. Compared with 2D, opinions were divided relatively evenly between the same or worse, with 2 responses for better.
	Not acceptable	3	1	1	1	
	Not applicable	-	-	-	-	
	No response	1	1	1	3	
	Compared with 2D:					
	Better	-	1	-	1	
	Same	1	2	1	5	
	Worse	2	1	-	5	

		Questionnaire number				Comments
		1	2	3	4	
Did the performance limit patient throughput?	Limited	7	4	6	9	Initially the majority found that performance limited throughput. By the final questionnaire, the responses were more mixed with just over half considering it limited.
	Not limited	1	3	1	8	
	Not applicable	-	-	-	-	
	No response	-	-	-	-	
	Compared with 2D:					
	Better	-	-	-	2	'It takes much longer to perform tomosynthesis as the exposure time is longer and it takes a while for the slices to process before being able to expose again'
	Same	-	2	-	3	
	Worse	4	2	5	5	
How do you rate the comfort of women during tomosynthesis exposures, including acceptability of gantry motion?	Excellent	-	1	-	-	Most considered the comfort level satisfactory average, or good. There were 3 who considered it poor and concerns included the possibility of the large face plate catching the woman's face or chin. There were however no reports of women complaining and a super-user observed that some women felt it was a more thorough examination.
	Good	3	1	2	4	
	Average	2	4	6	6	
	Satisfactory	3	1	-	2	
	Poor	-	-	-	3	
	Not applicable	-	-	-	-	
	No response	-	-	-	-	
Range of controls and indicators (on –screen icons)for tomosynthesis: were all the expected controls present?	Yes	8	6	7	17	All respondents felt the expected controls were present.
	No	-	-	-	-	

		Questionnaire number				Comments
		1	2	3	4	
Range of controls and indicators (on –screen icons)for tomosynthesis: were they easy to find?	Yes	6	6	7	11	Comments: 'larger icons and message line (font)' would be preferable; 'too small and too tiny', 'not user-friendly and not intuitive'.
	No	2	-	-	6	
Range of controls and indicators (on –screen icons)for tomosynthesis: were the icons easy to use?	Yes	8	6	7	11	The user interface was considered 'not as user friendly, but after doing a few you get the hang of it'. The lack of touch screen controls was also commented on. Also see comments in the row above.
	No	-	-	-	6	
How do you rate the time for an image to appear at the acquisition workstation?	Excellent	-	1	-	1	Although the initial three questionnaires considered the time for image to appear at the acquisition workstation to be at least satisfactory with only 1 poor response, by the final questionnaire the response was divided, as 8 considered the time satisfactory or better whilst 7 considered it poor. When compared with 2D, apart from the first questionnaire, the majority consistently considered it worse than for 2D. ' Image appears quickly, however it feels like an age before I can do the next acquisition'
	Good	4	1	3	3	
	Average	3	4	2	1	
	Satisfactory	-	-	2	3	
	Poor	1	1	1	7	
	Not applicable	-	-	-	-	
	No response	-	-	-	2	
	Compared with 2D:					
	Better	3	1	-	2	
	Same	-	1	2	2	
	Worse	2	4	5	5	

		Questionnaire number				Comments
		1	2	3	4	
How do you rate the time for storage of the image?	Excellent	-	-	-	-	Timing for storage was satisfactory or better with only 2 poor responses out of 14 on the final questionnaire. When compared with 2D the majority considered it to be the same with, on the final questionnaire, 6 the same, 1 better and 2 worse.
	Good	3	4	4	4	
	Average	2	2	2	5	
	Satisfactory	1	1	2	3	
	Poor	-	-	-	2	
	Not applicable	-	-	-	-	
	No response	2	-	-	3	
	Compared with 2D:					
	Better	-	-	-	1	
	Same	3	4	3	6	
	Worse	-	-	1	3	
How do you rate the time for auto-deleting an image?	Excellent	-	-	-	1	This question was included in the survey but the auto delete function was not an active feature on the equipment being evaluated. Many commented that auto – delete was not done.
	Good	1	1	2	1	
	Average	1	1	-	3	
	Satisfactory	1	2	-	3	
	Poor	-	-	-	-	
	Not applicable	1	3	1	-	
	No response	4	0	5	6	
	Compared with 2D:					
	Better	-	-	-	1	
	Same	3	2	1	2	
	Worse	-	-	-	-	
How do you rate image handling at the acquisition workstation: scrolling through the image slices?	Excellent	1	2	1	1	All provided responses were satisfactory or better and none were poor. When compared with 2D only 1 of the total of 21 responses over the 4 surveys was poor with 18 the same and 2 better. In the first questionnaire a comment was made that there is more ‘clicking’ to do but otherwise the handling was similar.
	Good	2	2	3	5	
	Average	2	3	-	4	
	Satisfactory	3	-	3	3	
	Poor	-	-	-	-	
	Not applicable	-	-	-	-	
	No response	-	-	1	4	
	Compared with 2D:					
	Better	-	-	-	2	
	Same	2	3	4	9	
	Worse	1	-	-	-	

		Questionnaire number				Comments
		1	2	3	4	
How do you rate image handling at the acquisition workstation: the processing facilities?	Excellent	1	2	-	1	Majority considered the processing facilities satisfactory or better, with only 2 of the final 13 responses indicating poor. When compared with 2D, majority were the same (15 of the total 19 responses over 4 surveys) and 2 were better and 2 were worse. Comments were varied including 'easy to use' and 'not user friendly'.
	Good	2	2	4	5	
	Average	1	1	-	4	
	Satisfactory	3	2	3	1	
	Poor	-	-	-	2	
	Not applicable	-	-	-	-	
	No response	1	-	1	7	
	Compared with 2D:					
	Better	-	1	-	1	
	Same	2	2	4	7	
	Worse	1	-	-	1	
How do you rate image handling at the acquisition workstation: use of query/retrieve?	Excellent	-	-	-	1	Many non responders, as many were not using the query / retrieve function. Comments were that there were 'too many processes to go through to retrieve images'. When compared with 2D all responses were the same except 2 of the 8 responses in the last questionnaire which were worse.
	Good	1	2	2	1	
	Average	1	2	-	4	
	Satisfactory	2	1	1	1	
	Poor	-	-	-	2	
	Not applicable	-	-	1	1	
	No response	4	2	4	7	
	Compared with 2D:					
	Better	-	-	-	-	
	Same	3	3	2	6	
	Worse	-	-	-	2	
How easy was it to use, for tomosynthesis, the following (complete any applicable): keyboard?	Excellent	-	1	1	1	Responses were all satisfactory or above, with the majority average or good. Most also felt it was the same as 2D. Comments include: that it was difficult to pull the keyboard out far enough to use the escape key, a tracker ball would have been better and a touch screen would have been more user friendly.
	Good	3	1	5	7	
	Average	3	3	1	7	
	Satisfactory	-	1	-	-	
	Poor	-	-	-	-	
	Not applicable	-	-	-	-	
	No response	2	1	1	2	
	Compared with 2D:					
	Better	-	-	-	1	
	Same	2	4	6	6	
	Worse	1	-	-	-	

		Questionnaire number				Comments
		1	2	3	4	
How easy was it to use, for tomosynthesis, the following (complete any applicable): touchscreen?	Excellent	-	-	-	-	This question was included in the survey but there was no touch screen on the equipment being evaluated.
	Good	-	-	-	3	
	Average	-	-	-	4	
	Satisfactory	-	-	-	-	
	Poor	-	-	-	-	
	Not applicable	-	-	-	9	
	No response	-	-	-	1	
	Compared with 2D:					
	Better	-	-	-	1	
	Same	-	-	-	3	
	Worse	-	-	-	-	
How easy was it to use, for tomosynthesis, the following (complete any applicable): tracker ball?	Excellent	-	2	-	1	This question was included in the survey but there was no tracker ball on the equipment being evaluated. It is thought that ratings here reflect the use of the mouse which was included with the system.
	Good	3	-	3	3	
	Average	3	2	-	7	
	Satisfactory	-	1	1	-	
	Poor	-	-	-	-	
	Not applicable	1	2	3	6	
	No response	1	-	1	-	
	Compared with 2D:					
	Better		1	-	1	
	Same	1	2	3	3	
	Worse	1	-	-	-	
How easy was it to use, for tomosynthesis, the following (complete any applicable): wheel for scrolling through the tomosynthesis slices?	Excellent	-	1	1	1	Responses were in the majority average or better.
	Good	3	-	3	4	
	Average	3	4	1	7	
	Satisfactory	-	-	-	-	
	Poor	-	-	-	-	
	Not applicable	1	1	-	4	
	No response	1	1	3	1	
	Compared with 2D:					
	Better	-	-	-	-	
	Same	1	-	-	-	
	Worse	-	-	-	-	

		Questionnaire number				Comments
		1	2	3	4	
How do you rate the following? image quality at the AWS for tomosynthesis images?	Excellent	-	1	1	1	Comparison was found to be difficult as there was no previous departmental experience of tomosynthesis.
	Good	1	3	4	14	
	Average	4	2	2	1	
	Satisfactory	2	1	1	1	
	Poor	-	-	-	-	
	Not applicable	-	-	-	-	
	No response	-	-	-	-	
How do you rate the following? overall image quality of this system in tomosynthesis mode?	Excellent	-	1	1	1	Overall image quality in tomosynthesis was rated identically to that for image quality at the AWS for tomosynthesis.
	Good	1	3	4	14	
	Average	4	2	2	1	
	Satisfactory	2	1	1	1	
	Poor	-	-	-	-	
	Not applicable	-	-	-	-	
	No response	-	-	-	-	
What was your level of confidence in the unit?	Excellent	1	1	-	1	Wide range of comments: 'Felt confident with every aspect of the system' to 'Lost confidence since the upgrade as no further training or explanation', ' not user friendly'
	Good	4	4	5	6	
	Average	2	1	2	7	
	Satisfactory	-	-	1	-	
	Poor	1	1	-	1	
	Not applicable	-	-	-	-	
	No response	-	-	-	2	
	Compared with 2D:					
	Better	-	1	-	-	
	Same	2	2	3	8	
	Worse	2	-	1	-	
Were there any potential hazards with use in tomosynthesis mode to: you	Hazards	2	-	-	1	Repetitive strain injury from long exposure times if not using the foot pedal and possibility of accidental radiation exposure to operator due to limited space behind the control panel.
	No hazards	6	6	6	15	
	Not applicable	-	-	-	-	
	No response	-	1	2	1	
	Compared with 2D:					
	Better	-	1	-	1	
	Same	-	3	4	6	
	Worse	-	-	-	1	

		Questionnaire number				Comments
		1	2	3	4	
Were there any potential hazards with use in tomosynthesis mode to: the woman	Hazards	1	4	5	9	Over the course of the questionnaires, larger numbers of radiographers noted potential hazards, mainly risk of clients catching their head on the face plate during gantry motion. 'Faceguard may be intrusive depending on the agility of the patient' and 'patient must hold head out of the way'
	No hazards	4	2	3	7	
	Not applicable	-	-	-	-	
	No response	3	1	-	1	
	Compared with 2D:					
	Better	-	1	-	1	
	Same	-	1	3	3	
	Worse	1	2	2	4	

Appendix 6: Readers' answers to questionnaire

Comments and observations

	Questionnaire 1	Questionnaire 2	Questionnaire 3	Questionnaire 4
How good were the operator manual instructions for tomosynthesis? (State N/A if not applicable/not used)	N/A	N/A	N/A	N/A
How good was the application training for tomosynthesis provided by the supplier?	12 N/A; 1 average; 1 poor	12 N/A; 1 good	11 N/A; 1 average; 2 poor	6 N/A; 1 good; 2 satisfactory; 1 average

Comments and observations

	Questionnaire 1	Questionnaire 2	Questionnaire 3	Questionnaire 4
Did you attend any external training course for tomosynthesis?	11 yes (9 external, 2 local training)			9 yes (7 external, 2 local training),
How do you rate the use of the reporting workstation controls for tomosynthesis?				
Mouse/trackerball	5 N/A; 6 good; 2 average	1 N/A; 5 good; 1 satisfactory; 4 average	1 N/A; 5 good; 2 average	1 N/A, 5 good; 3 average
Keyboard	8 N/A; 4 good; 2 average	3 N/A; 2 good ; 1 satisfactory; 4 average	1 N/A; 5 good; 2 average	2 N/A; 5 good; 3 average
Keypad	9 N/A; 4 good; 1 satisfactory	2 N/A; 3 good; 1 satisfactory; 4 average	3 N/A; 3 good; 2 average	2 N/A; 5 good; 3 average
How do you rate the image handling tools (zoom, etc.) for tomosynthesis?	11 N/A; 3 good	3 N/A, 3 good; 1 satisfactory; 3 average	1 N/A; 3 good; 2 satisfactory; 2 average	1 N/A; 4 good; 1 satisfactory; 4 average

Comments and observations

	Questionnaire 1	Questionnaire 2	Questionnaire 3	Questionnaire 4
How do you rate the special tomosynthesis image handling tools such as slider or ciné etc.)?	11 N/A; 3 good	7 N/A; 1 good; 1 satisfactory; 1 average	1 N/A; 5 good; 1 satisfactory; 1 average	1 N/A; 5 good; 1 satisfactory; 2 average; 1 poor
How do you rate the visibility and usability of on-screen icons for tomosynthesis?	12 N/A; 2 average	3 N/A; 4 good; 2 average; 1 poor	4 N/A; 3 good; 1 average	8 N/A; 1 satisfactory; 2 average
Did you sometimes change the slab thickness when reviewing the tomosynthesis images?	N/A	N/A	N/A	1 N/A; 8 no; 1 yes
How do you rate the reading/reporting flow pattern in tomosynthesis?	4 N/A; 2 good; 5 average; 1 poor 'had to view on temporary workstation as no PACS integration; images go into 'exceptions'	3 good; 3 average; 3 poor 'images go into exceptions (three comments), better when stacked'	2 good; 2 poor 'difficult when tiled, better when stacked' (3 similar comments)	1 N/A; 7 good; 1 average; 1 poor 'BTO converter installed, appropriately much improved'. The poor rating comment was 'images unstacked on PACS but improved'
How do you rate the time for an image to appear on the screen in tomosynthesis mode?				

Comments and observations

	Questionnaire 1	Questionnaire 2	Questionnaire 3	Questionnaire 4
New patient selection	3 N/A; 1 excellent; 2 good; 2 average; 1 satisfactory; 1 poor	3 N/A; 1 excellent; 4 good; 2 satisfactory; 2 average	3 N/A; 2 excellent; 3 good; 1 satisfactory; 1 average	1 Excellent; 3 good; 2 satisfactory; 3 average; 1 poor Poor comment was 'very slow intially but much improved'
In-examination change	3 N/A; 2 excellent; 2 good; 3 satisfactory; 2 average	1 N/A; 3 excellent; 3 good; 1 satisfactory; 2 average	3 N/A; 2 excellent; 3 good; 1 satisfactory; 1 average	1 N/A; 1 excellent; 3 good ; 2 satisfactory; 2 average; 1 poor Poor comment was 'very slow intially but much improved'
How easy was it to record findings for tomosynthesis on NBSS?	N/A	N/A	N/A	N/A
How easy is it to adjust the height and angle of the reporting monitors to suit the user?	4 easy; 2 difficult	N/A	2 easy; 2 average	4 N/A; 5 easy; 1 average

Comments and observations

	Questionnaire 1	Questionnaire 2	Questionnaire 3	Questionnaire 4
How easy was it to navigate between the tomosynthesis slices?	1 N/A; 11 easy; 1 satisfactory	6 easy; 5 average	5 easy; 2 average	7 easy; 2 average; 1 difficult Comment for difficult was ' unstacked intially but better now'
How easy was it to set up different hanging protocols in tomosynthesis?	N/A	N/A	N/A	N/A
How easy was it to change from one hanging protocol to another in tomosynthesis?	N/A	N/A	N/A	N/A
How do you rate the following properties of the tomosynthesis images? Contrast	1 excellent; 8 good; 3 average; 2 poor 'Noisy but pathology well demonstrated compared with mag views', 'both contrast especially for calc and sharpness for stellate lesion+distortions can be improved'	1 excellent; 3 good; 5 average; 1 poor	4 good; 1 satisfactory; 1 average	11 excellent; 9 good

Comments and observations

	Questionnaire 1	Questionnaire 2	Questionnaire 3	Questionnaire 4
Sharpness	2 excellent; 8 good; 2 average; 2 poor	2 excellent; 4 good; 2 satisfactory; 3 average	4 good; 3 average	1 excellent; 8 good; 1 average
What is your impression of the quality of images provided by the tomosynthesis system?	3 excellent; 6 good; 2 satisfactory; 3 average 'really good spatial details', 'not sharp but good', 'noisy but good'	1 excellent; 5 good; 2 satisfactory ; 2 average; 1 poor 'Need better functionality/slice, Cannot see where in breast you are in medial/lat,superior/inferior, no slide bar on pacs of dedicated work station, time consuming if in exceptions'	4 good; 3 average	1 excellent; 9 good
What is your overall level of satisfaction with using this tomosynthesis system for assessments?	2 excellent; 5 good; 3 satisfactory; 4 average	1 excellent; 5 good; 2 satisfactory; 2 average	3 good; 3 average	1 excellent; 9 good Comments 'Good for images, huge difficulty with getting images stacked (in initial stages) onto PACS' (5 similar comments)

Comments and observations

	Questionnaire 1	Questionnaire 2	Questionnaire 3	Questionnaire 4
Any additional comments on general or imaging performance of the system for tomosynthesis	‘Overall useful in asymmetric density and distortion, implants' and ‘helpful in asymmetric densities' and 'bit slow'.	‘Time consuming to view as imaging goes to exceptions folder'; 'huge improvement to have images on PACS and stacked, limited functionality, cannot tell where in breast-no slider bar, Cannot slab, distortions sometimes less clearly seen than expected of mag views, good for round mass etc, cases go to exeptions-need extra time to view'; 'image contrast quality could be improved'; 'useful for real density vs composite'	Tomosynthesis images are good. There are problems with PACS integration' and 'Contrast could have been better, dedicated monitor could have enhanced reporting'	Wide angle images. Better than (another manufacturer) tomo acquisitions in terms of contrast and sharpness'; 'Although image quality is flat, the detail of region of interest is good. Tomosynthesis images have been very helpful in assessment clinics especially in distortion, asymmetry and mass. It has aided confidence in our daily work. Efficiency of image viewing has been enhanced after BTO converter.'

Appendix 7: Manufacturer's comments

On the Mammomat Revelation, we have a wide range of paddles suitable for Tomosynthesis for all breast sizes.

We have reviewed our Applications Training policy and the number of days per system has now been increased.

The DICOM BTO converter box in no longer needed on the Mammomat Revelation as this is now incorporated into the system and the customer can now choose between CTO or BTO format.