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NHS Breast Screening Programme equipment report

Practical evaluation of GE Healthcare Senographe Pristina: digital breast tomosynthesis system

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Executive summary

The purpose of this evaluation was to assess the practical function of the GE Healthcare Senographe Pristina mammography machine, in 3-D mode, for use within a breast screening assessment clinic within the NHS Breast Screening Programme. The dedicated modality workstation running SenoIris mammography reporting software, known as the “SenoIris workstation”, was also evaluated for its effectiveness with reviewing tomosynthesis images.

The evaluation took place between February and June 2017 and the system was fully integrated with NBSS, CRIS and GE PACS without issue. The Senographe Pristina was well received overall and generally performed well with downtime of less than 1 day due to mechanical problems.

The mammographers found the system easy quick and easy to use commenting positively on the integrated 2-D / 3-D bucky and the tube head auto start function which were considered by the team to decrease overall examination times. The omission of the foot pedal as per the previous model was also a welcomed improvement along with the static universal face shield. Examination times averaged at 107 seconds with the unit being ready for the next exposure 18 seconds after the start of the first exposure. As with the 2-D mode some difficulties were experienced with the tube park function and the sensitivity of the touch-screen console and some improvements in these areas would be welcomed.

A dose survey was carried out for both the 2-D and the tomosynthesis components of the examination. Average mean glandular dose for 50-60 mm breasts was found to be 1.46 for each component. Each of these dose components is below the National Diagnostic Reference Level of 3.5 mGy.

The SenoIris reporting workstation was considered easy to use by the radiology team with hanging protocols being easy to tailor to individual preferences. The image quality was considered excellent and a retrospective review of the cases imaged as part of this assessment demonstrated 75% of lesions to be considered better demonstrated with tomosynthesis than with the standard 2-D mammogram and 85% of cases where tomosynthesis was considered to have been a significant or useful aid to diagnosis. An increased confidence in decision making when using tomosynthesis was reported.

1. Introduction

1.1 Evaluation centre and timeline

The evaluation took place at the Nottingham Breast Institute which is part of the Nottingham University Hospitals NHS Trust. This NHSBSP invites approximately 40,000 women for breast screening per year, of which approximately 30,600 attend. Approximately 800 are recalled for further assessment. The Nottingham Breast Institute meets relevant national quality standards for breast screening and meets the criteria for evaluation centres outlined in the Guidance Notes for Equipment Evaluation[1]

The GE Healthcare Senographe Pristina was installed in February 2017 for the purpose of the evaluation which was completed between February 2017 and June 2017.

Figure 1 GE Pristina Gantry

1.2 Equipment evaluated

1.2.1 X-ray set and acquisition workstation

The Senographe Pristina is a full-field digital mammography unit with a 3-D option which enables the machine to generate both 2-D and 3-D images. Software MGA-1.2.0-2 and Operating system MG Helios-6.6.2-1.3 has been used throughout the evaluation.

The Senographe Pristina is powered by a high frequency single phase generator which is integrated into the gantry. It uses a 24cm x 29cm caesium iodide detector with 100 micron resolution. It uses Molybdenum (Mo) and Rhodium (Rh) anode tracks with Molybdenum and Silver (Ag) filters. They can be used in Mo/Mo or Rh/Ag combinations with 2 kV points available. There is a single Automatic Optimisation of Parameters mode (AOP) for 3-D imaging, Standard. This is to ensure the best balance between image contrast and breast dose. Manual selection is also available. A universal grid which is compatible with both 2-D and 3-D imaging is also used.

The unit uses a touch screen console with additional buttons for power, preparation and x-ray exposure and emergency stop. The protective lead shield is integrated within the console unit. The acquisition monitor is available in both 1MP LCD and 3MP options for immediate image display. In contrast to the console it uses the traditional keyboard and mouse configuration. The 3MP monitor was used for this evaluation and was mounted on a swing arm.

Figure 1:Console/monitor

1.2.2 Paddles

Standard paddles in 2 sizes were available for use with tomosynthesis imaging: 24cm x 29cm and 19cm x 23cm. The smaller paddle can be offset against the centre of the breast support plate to optimise positioning and the field-of-view is automatically selected based on the compression paddle size. Each paddle is recognised automatically when inserted into the machine.

Figure 3: Paddles

1.2.3 Face shield

A universal face shield is provided for use with 3-D imaging in place of the standard face shield. It is attached directly to the gantry and remains stationary throughout the exposure to improve patient comfort.

Figure 4: Universal face shield

1.2.4 Operation

In tomosynthesis mode the Senographe Pristina takes 9 evenly spaced projections using a “step and shoot” tube motion which avoids image blur. The sweep angle of the unit is 25° and the machine is able to complete the 3-D examination at any angle between -160° / +160°. No additional devices need to be connected to the machine for 3-D use as the tomosynthesis capabilities are fully integrated and no foot pedal is required as with the previous model.

The Senographe Pristina has a remote angulation function which enables the tube head to automatically rotate to the first image position on the depression of the Preparation button, prior to the exposure.

The 9 processed images are sent immediately to the acquisition monitor for quality review. The raw images are sent immediately to the Reconstruction Station, which is integrated within the Control station, where they are reconstructed into planes and slabs. Planes are reconstructed at 0.5 or 1mm intervals. Slabs are overlapping 10mm thickness slices. The overlap enables recognition of 3-D features and a more accurate identification of lesion distribution. The reconstructed images are automatically transferred to the SenoIris workstation and Trust PACS on closure of the examination when defaulted to do so.

The maximum compressed breast thickness for complete volume reconstruction is 130mm. Breast thicknesses of between 130mm and 160mm may not be reconstructed fully and it is not possible to reconstruct images for a breast thickness over 160mm. Projections are displayed on the acquisition work station with eContrast3 for image processing.

1.2.5 Integration with NBSS and PACS

The Senographe Pristina was fully integrated into the existing Trust PACS (GE Healthcare) enabling the images to be reported alongside images taken from other machines.

The Trust radiology system (CRIS) was already well established in the unit with the mammography worklist being transferred directly to the machine. Clients were selected from the worklist and images were transferred directly to the Trust PACS and the workstation. There were no set-up or operational issues. DBT volumes (tomographic planes) are displayed on SenoIris with a distinct processing.

1.3 Practical Considerations

The Senographe Pristina was on loan for the duration of the evaluation. The Nottingham Breast Institute has 2 main areas for breast imaging: screening and symptomatic, which are separated by a single processing area. In order to maintain an acceptable workflow during a busy assessment clinic it was agreed to locate the machine in the symptomatic side of the imaging department.

For the duration of the evaluation the tomosynthesis images were taken during the screening assessment clinic held once a week on a Wednesday morning. Between 3 and 4 members of radiography staff were available for imaging during the clinic along with 2 radiologists.

The recall to assessment cases were reviewed prior to the clinic so the patients could be imaged on arrival. The SenoIris workstation was situated in the reporting room directly opposite the room housing the Senographe Pristina. No delays relating to the use of the Senographe Pristina in 3-D mode or the SenoIris modality workstation were reported.

1.4 Objectives of the evaluation

The primary objective of this evaluation was to assess the 3-D suitability of the Senographe Pristina within breast screening assessment clinics included to:

- assess the funtionality and reliability of the Senographe Pristina within a busy screening assessment clinic
- assess the practical aspects of its use and to report on the mammographers experiences and observations
- report on the radiation dose to the breast for women imaged during the evaluation
- report on the film reader’s views of image quality and of their experiences operating the SenoIris workstation.
- report on how the Senographe Pristina interfaces with other systems

2. Acceptance testing, commissioning and performance testing

2.1 Acceptance testing and commissioning

The Senographe Pristina was installed in February 2017 over a 3-week period alongside the installation of the SenoIris workstation. The system installation remained on schedule. As the machine was a temporary replacement for an existing machine the network connections were already in place resulting with no problems with integration of the system to PACS, NBSS or CRIS.

Acceptance testing and commissioning was completed by the Northampton Medical Physics department in early March 2017 in accordance the NHSBSP protocols[2]. The machine was tested in relation to image quality and dose in the Standard and Standard + AOP modes and was found to be in acceptable ranges.

The SenoIris workstation was also commissioned in March 2017 in accordance to the NHSBSP protocols[2] and was found to be acceptable. The full reports can be found in Appendix A.[3]

3. Routine quality control

The quality control tests were completed daily, weekly and monthly during the evaluation period accordance to NHSBSP guidelines [3,4,5.] The tests were completed by different mammographers each day.

3.1 Daily QC tests

A 4.5 cm thick block of Perspex was imaged using Standard setting daily. The mAs and SNR(signal to noise ratio) were recorded and shown in figures 5 to 7. The mAs and SNR for tomosynthesis exposures were recorded and shown in figures 8 to 10.

All results remained within the recommended limits.

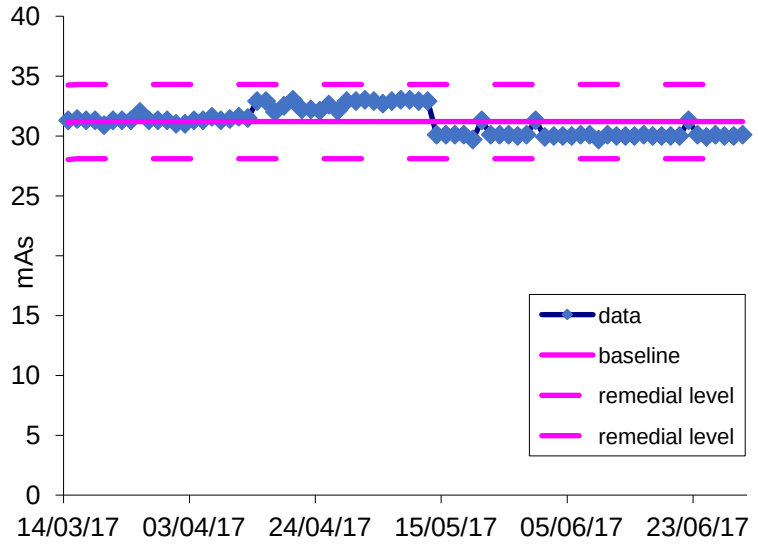

Figure 5: mAs recorded daily for 45mm of Perspex (2D)

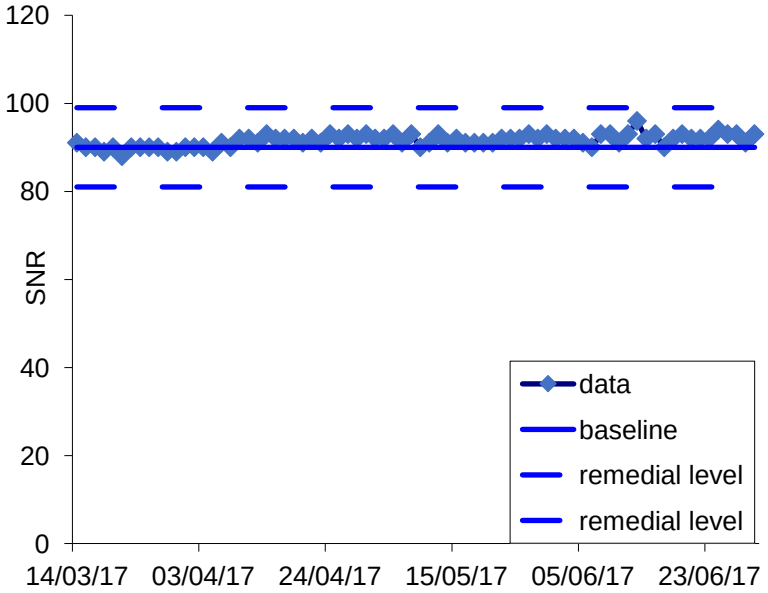

Figure 6: SNR recorded daily for 45mm of Perspex (2D)

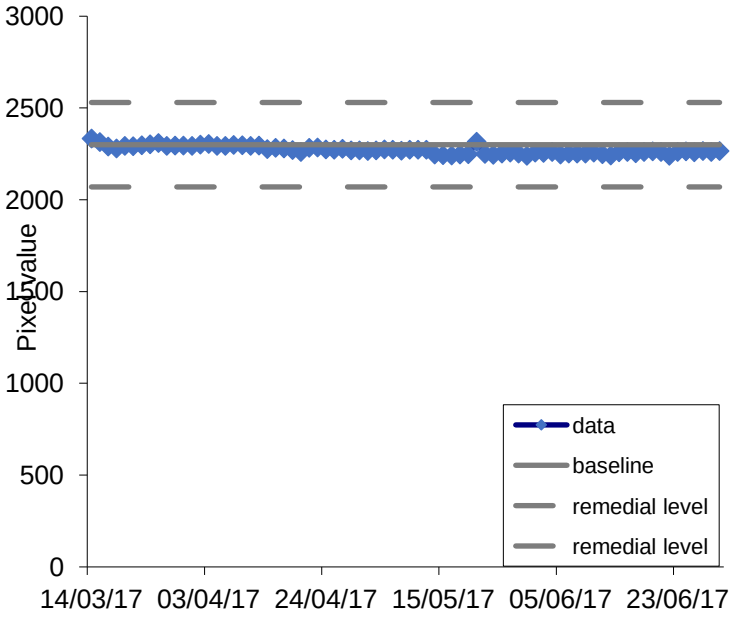

Figure 7: Pixel value recorded daily for 45mm of Perspex (2D)

3.2.2 Daily tests – tomosynthesis exposure and artefacts

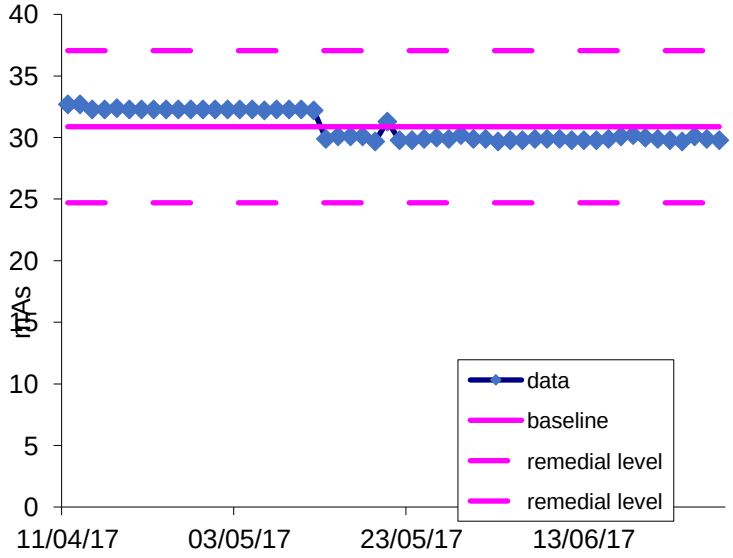

Figure 8: mAs recorded daily for 45 mm of Perspex (tomosynthesis)

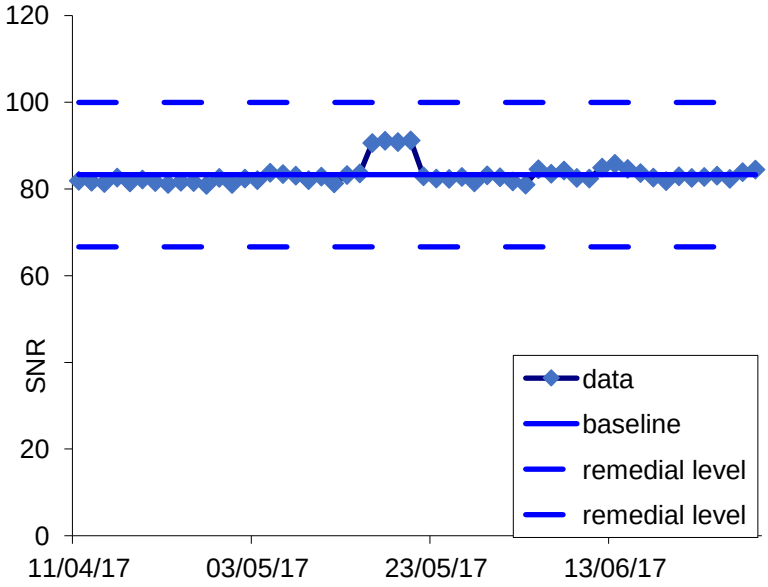

Figure 9: SNR recorded daily for 45mm of Perspex (tomosynthesis)

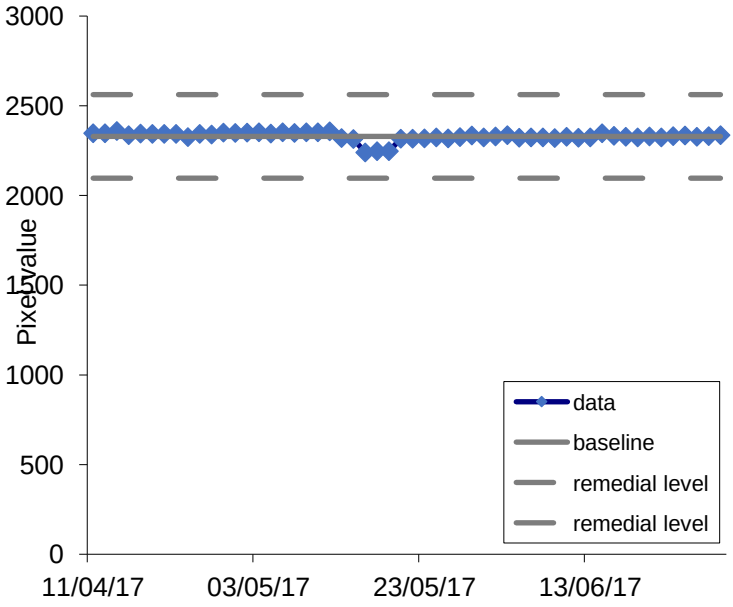

Figure 10. Pixel value recorded daily for 45mm of Perspex (tomosynthesis)

3.2 Weekly QC tests

Weekly CNR (contrast to noise) ratio testing was completed and the results can be seen in figures 8 and 13. The results were within recommended limits. TOR(MAM) images were also scored figures 12,14 &15

3.2.1 Weekly tests – 2D

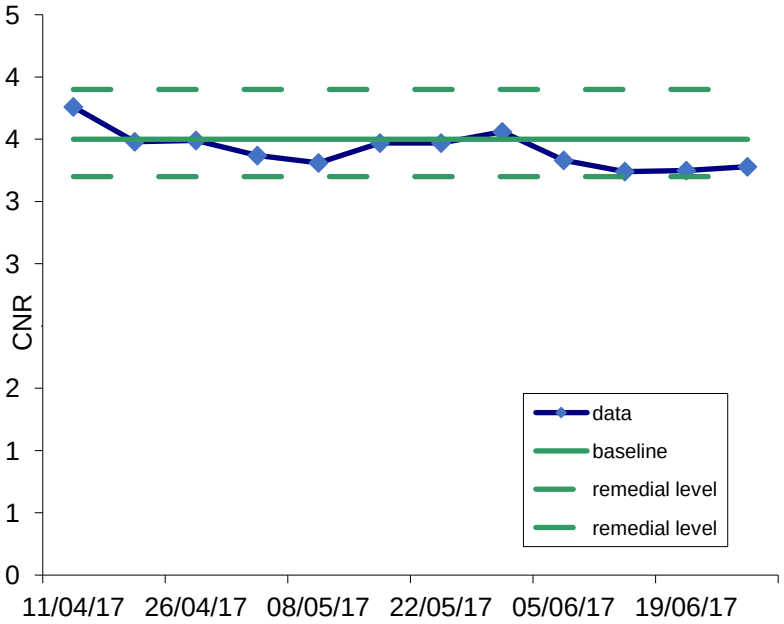

Figure 11: Weekly CNR measurements for 45mm Perspex (2D)

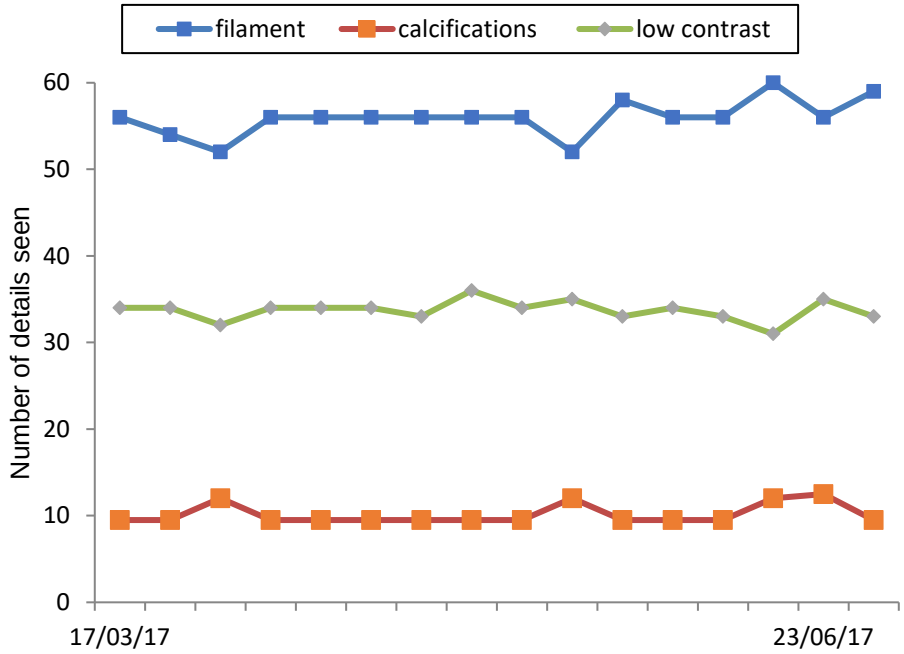

Figure 12: Weekly tests of image quality measured with TORMAM test object (2D)

3.2.1 Weekly tests – tomosynthesis

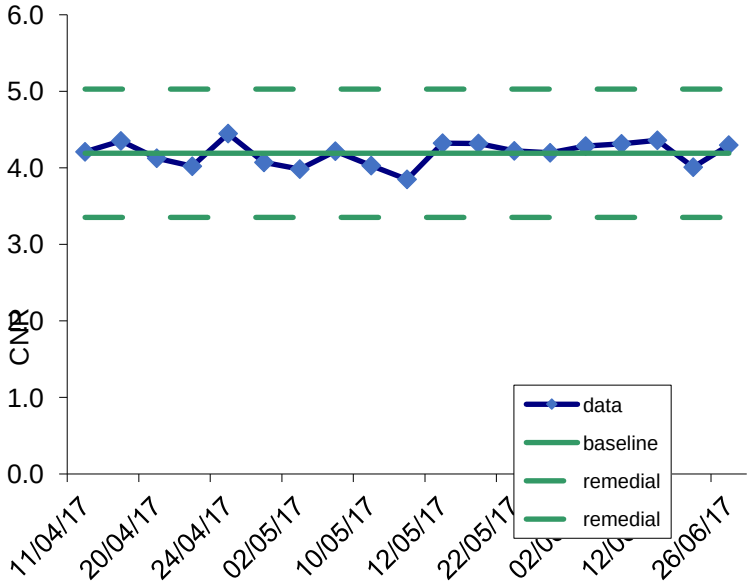

Figure 13: Weekly CNR measurements for 45mm Perspex (tomosynthesis)

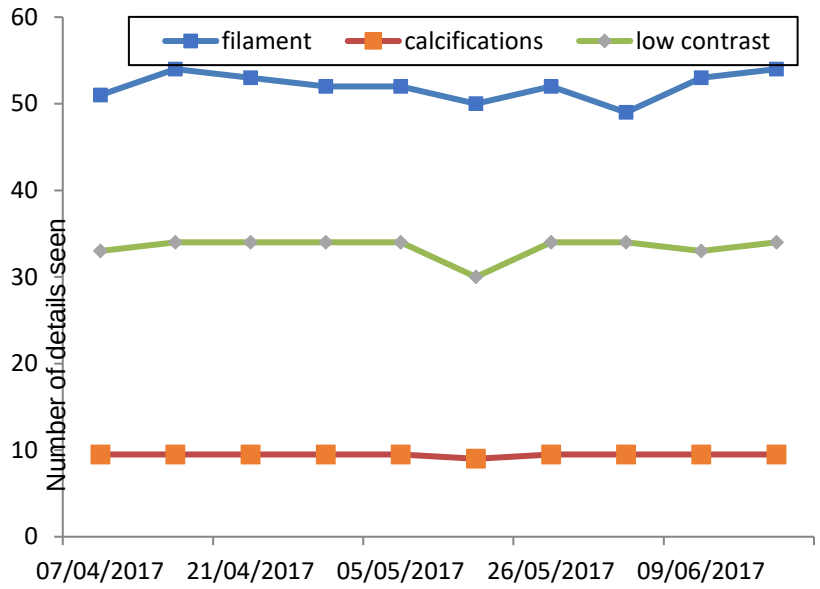

Figure 14: Weekly tests of image quality measured with TORMAM test object (tomosynthesis) planes displayed

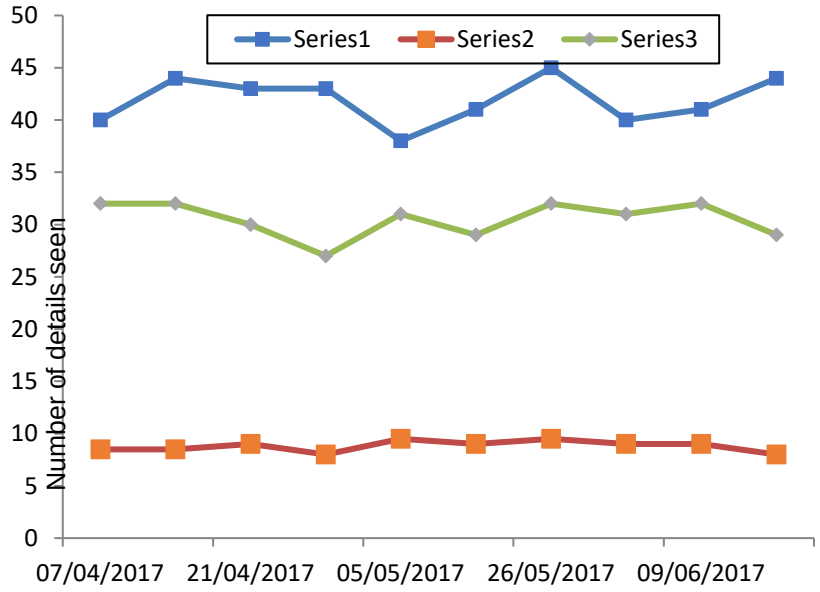

Figure 15: Weekly tests of image quality measured with TORMAM test object (tomosynthesis) slabs displayed

3.4 Monthly QC tests

The GE QC routine was followed for the monthly test. The test now only comprises of 2 thicknesses of 30 mm and 50mm which covers the range of beam qualities used by the machine clinically.

The results are presented in Figure 16 to 21. All results remained within the recommended values throughout the evaluation.

There were no reported artefacts in any of the QC images.

3.4.1 Monthly tests – 2D

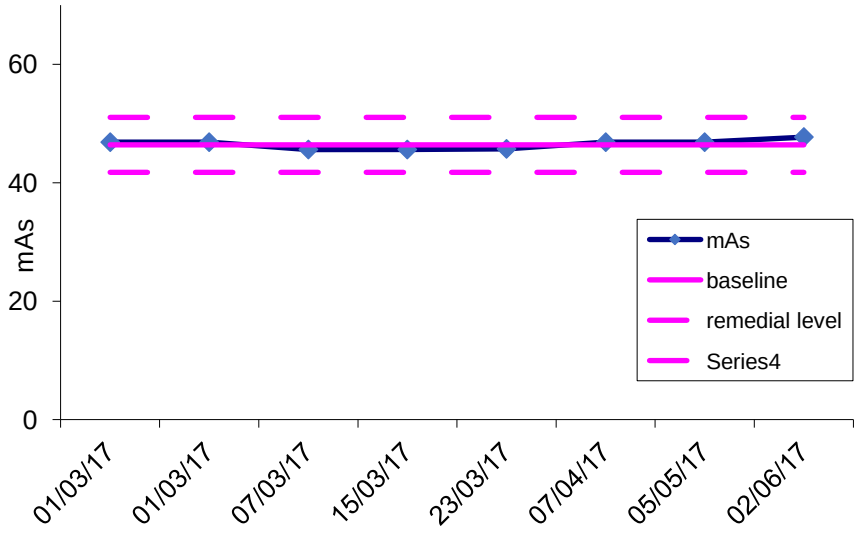

Figure 16: mAs recorded monthly for 30mm Perspex (2D)

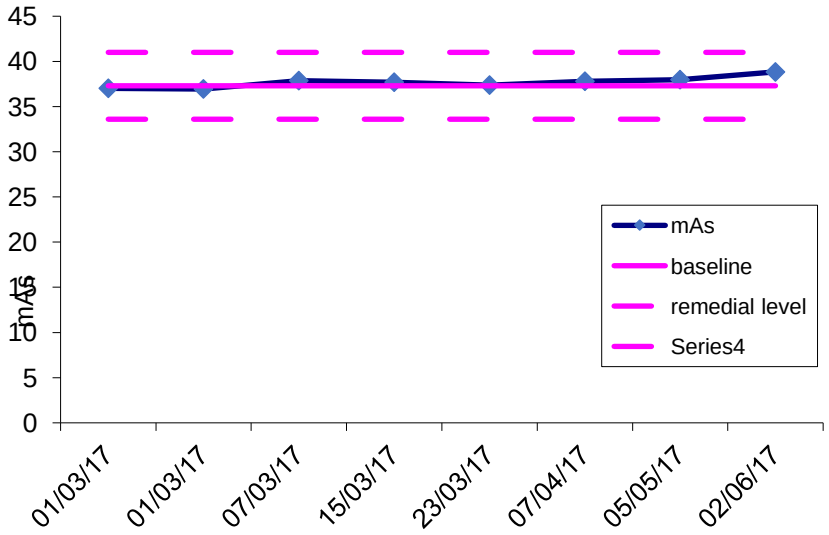

Figure 17: mAs recorded monthly for 50mm Perspex (2D)

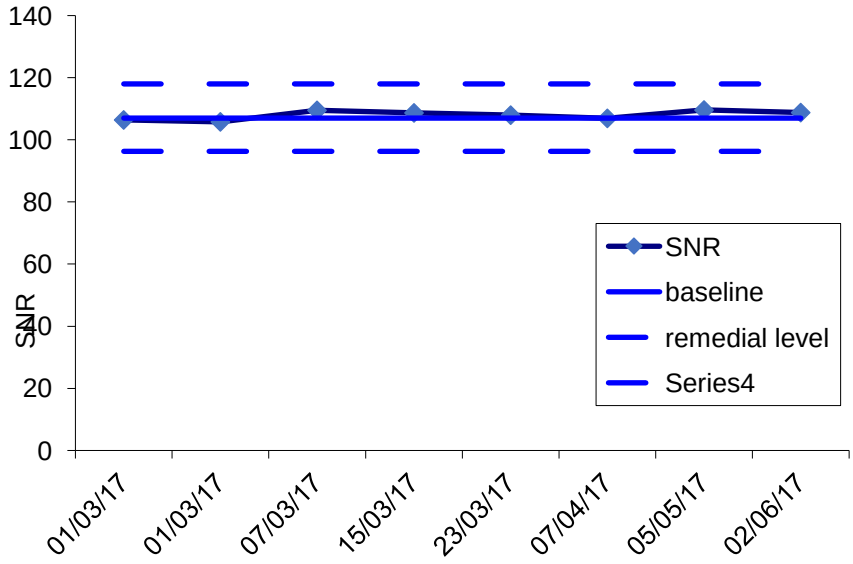

Figure 18: Monthly SNR measurements for 30mm Perspex (2D)

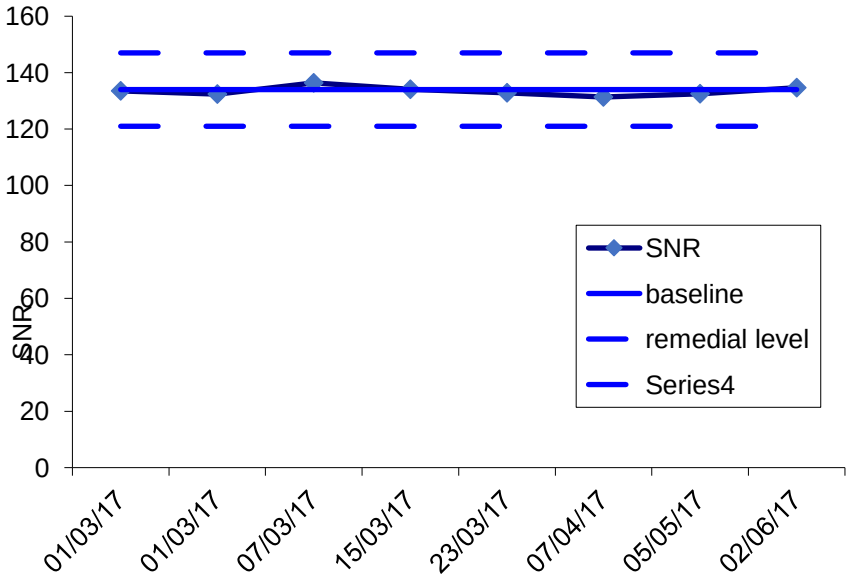

Figure 19: Monthly SNR measurements for 50mm Perspex (2D)

3.4.2 Monthly tests - tomosynthesis

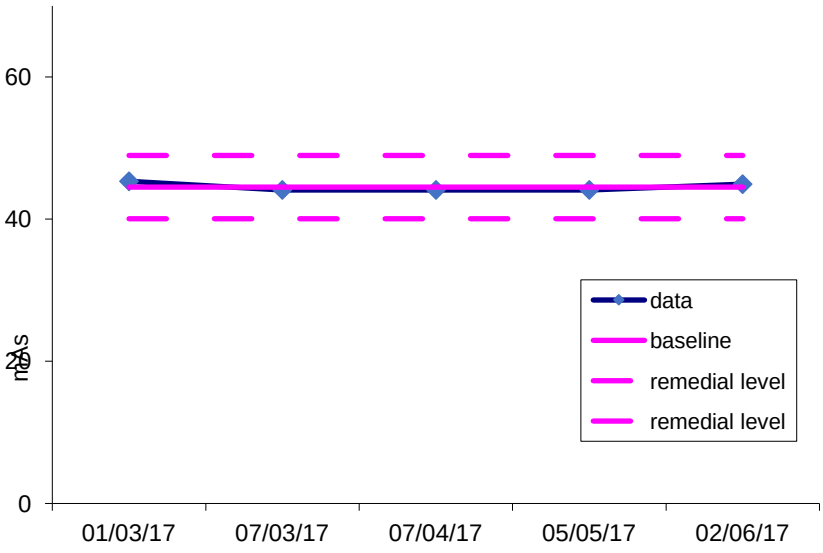

Figure 20: mAs recorded monthly for 30mm Perspex (tomosynthesis)

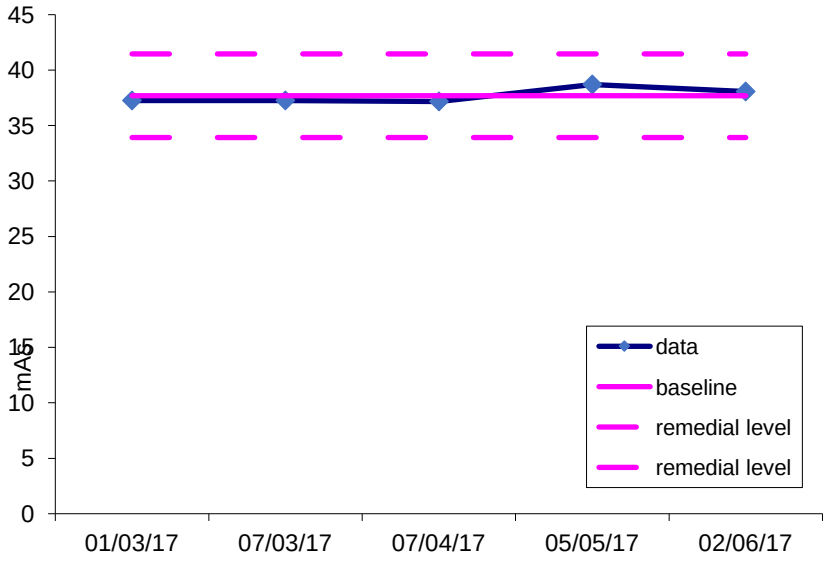

Figure 21: mAs recorded monthly for 50mm Perspex (tomosynthesis)

4. Data on assessments conducted

4.1 Clinical Dose Audit

The exposure data from each woman was recorded following the exposure. This data was entered into the NHSBSP dose calculation database.

The detailed dose surveys are presented in Appendix 2. The average mean glandular dose (MGD) and compressed breast thickness (CBT) are summarised in Table 1.

Table 1: Average values of MGD and CBT for different components of exposure

View	Group of women	Average MGD (mGy)	Average CBT (mm)	Average MGD (mGy) for tomosynthesis	Average CBT (mm)
CC	all	1.63	59	1.63	60
MLO	all	1.70	62	1.70	61
MLO	CBT 50-60mm	1.46	56	1.46	57

The average MGD for an MLO of 50 to 60 mm breast was 1.46mGy for the 2D exposure which is well below the NDRL of 2.5 mGy. The tomosynthesis dose for a 50 to 60 mm breast was also 1.46 mGy.

4.2 Comparison of displayed dose with calculated MGD

A comparison of the calculated MGDs with the doses displayed on the acquisition workstation, which are stored in the DICOM headers. The calculated MGDs are obtained by calculation using data published by Dance et al.[6,7]. The displayed dose is plotted against the calculated MGD with the trend line going through the origin as shown in Figure 27.

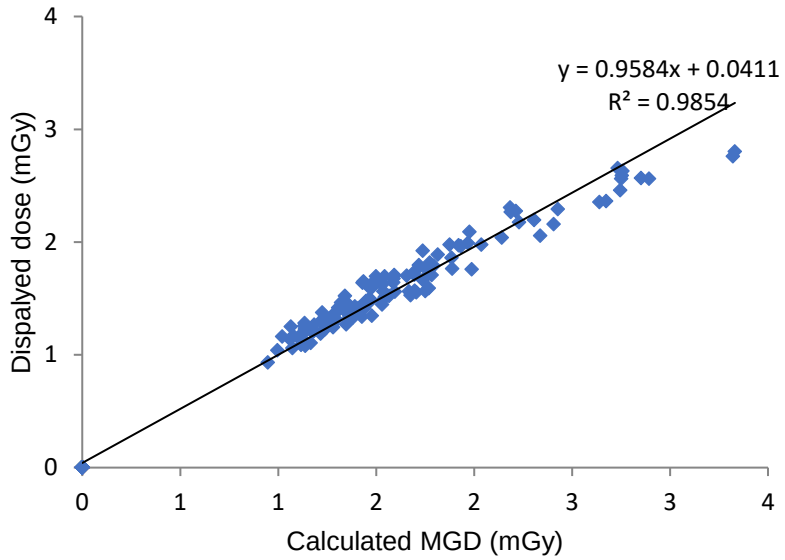

Figure 22: Displayed dose against calculated MGD

4.3 Imaging times

The timings for image acquisition in both 2-D and 3-D modes were taken using a phantom and a stopwatch to identify how long each step of the process took. This included the time taken for the first image to appear, the length of the exposure, the time taken for the final image to appear and the complete cycle time.

All the timings are cumulative and can be seen in Table 2 below.

Table 2. Stopwatch timings in seconds for exposures of a 45mm Perspex phantom

Exposure stage	Time for tomosynthesis mode in seconds	Time for 2D mode in seconds
Start of exposure	0	0
First image appears on screen	7	5
End of exposure (release of compression)	14	9
Last tomosynthesis image appears on screen	16	-
Unit ready for next exposure (cycle time)	18	10

The acquisition time for a 2-view tomosynthesis examination for a single breast was also assessed. As all the images for this assessment were acquired by radiographers during a screening assessment clinic there were no cases where a standard 2-D mammogram and tomosynthesis were taken. There were also no cases where both breasts were imaged.

The time at which the first and last images were displayed were taken from the DICOM headers and the difference calculated. The time taken ranged from 74 seconds to 153 seconds with an average the time taken being 107 seconds. This time includes re-positioning the client between images and the automatic movement of the tube head to the start position when the exposure button is depressed.

As the unit is ready for the next exposure 18 seconds after the start of the first exposure it can be accepted that the range in times is due to the time taken to position the client for the subsequent view.

4.4 Timings for image reading by readers

All the tomosynthesis images for this assessment were acquired in patients undergoing further assessment for potential abnormalities identified on their 2-D screening mammogram. The images were acquired as part of the patient's work-up in the screening assessment clinic. This weekly clinic is led by 2 (of 6) consultant breast radiologists, who are accredited to work in the National Health Service Breast Screening Programme (NHSBSP).

All the cases were interpreted by 2 radiologists who reviewed the images in consensus during the assessment clinic as they became available. Following acquisition the images were sent to both Trust PACS and the dedicated modality workstation supplied with the Pristina system which runs SenoIris mammography reporting software. All the radiologists were already familiar with the SenoIris software at the time of the practical evaluation so the preference was to interpret the studies on the modality workstation. The patient's 2-D screening mammograms were imported from the PACS onto the SenoIris workstation together with any relevant priors before the tomosynthesis images were reviewed so that appropriate comparisons could be made.

The tomosynthesis images were read utilising a hanging protocol tailored to the preferences of the radiologists, who were all experienced tomosynthesis readers. The hanging protocols are relatively easy to tailor to individual users requirements, but in practice all readers used the same hanging protocol throughout the evaluation period. Standard image manipulation tools are also available – pan, zoom, windowing, measurement etc. The image navigator enables quick and efficient review of the tomosynthesis and 2-D studies side by side. It was also easy to switch between thick and thin slices (Slabs and Planes) as well as view the synthetic 2-D images generated from the tomosynthesis data set. A specialist keypad was supplied with the workstation but, due to the reader's familiarity with the reporting software, all choose to manipulate the images using the computer mouse.

The time taken to review each case varied according to the complexity and the number of available prior mammograms. Informal discussions with the radiology team revealed a total reading time including the consensus read of around 5 minutes per case.

4.5 Clinic workflow

The Senographe Pristina system was sited in a mammography room situated in the normal clinic working area where screening assessment and symptomatic clinics take place. The SenoIris workstation was located in the reading room which also houses the mammography PACS workstations and is the clinic hub where all the radiologists complete breast imaging reporting. Consequently there was no impact on workflow.

4.6 Breast Density

A breast density assessment was undertaken for each of the women imaged as part of the evaluation. One radiologist assigned a percentage breast density for each case using the following classification – Fatty (0% to 33%), Mixed (34% to 66%) and Dense (67% to 100%). The results from the 100 cases are:

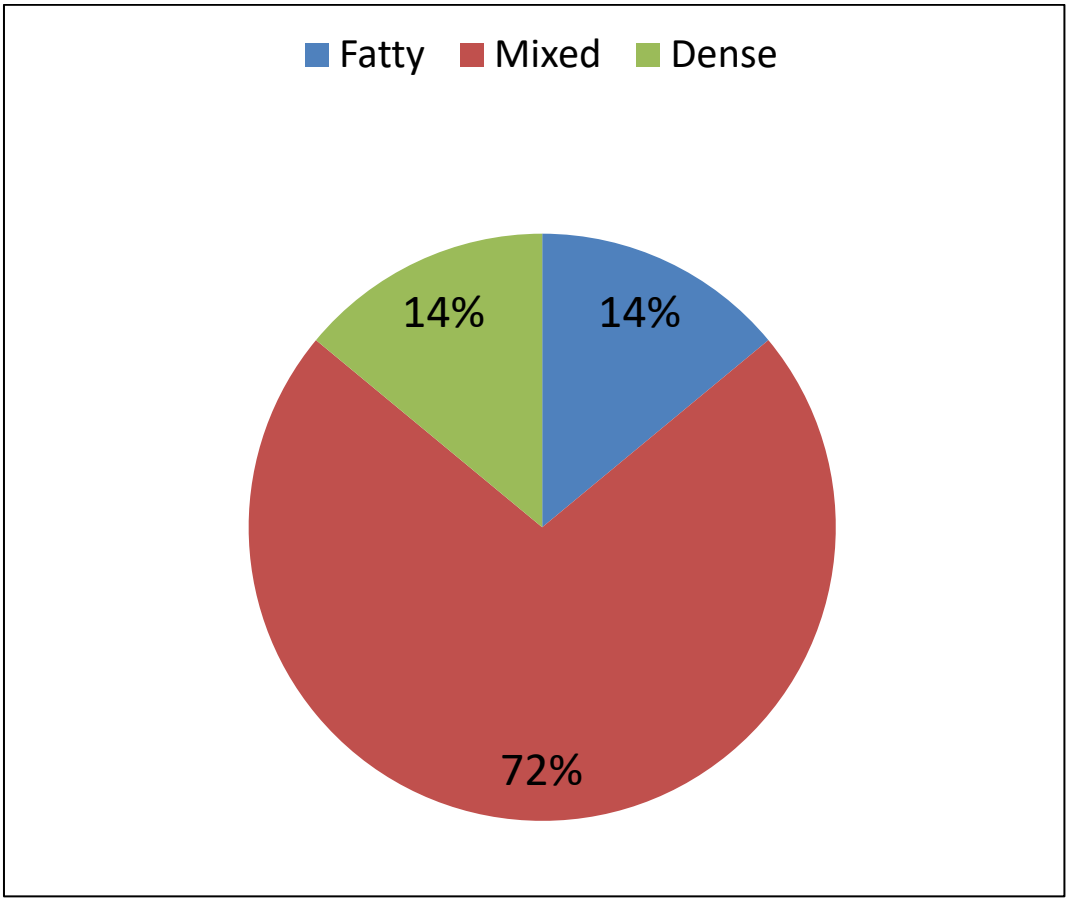

Figure 23: Assessment of Breast Density

4.7 Visibility with tomosynthesis

Each of the 100 cases imaged as part of this evaluation was retrospectively reviewed by an experienced breast radiologist with 17 years of experience in mammographic image interpretation. The data collection sheet can be found in Appendix 4. Thirty-five cases had a malignant diagnosis, 29 benign and 36 cases were judged normal after assessment.

64 cases had a definite visible lesion; these consisted of 50 masses, 8 parenchymal distortions and 6 asymmetric densities. For each of these an assessment was made as to whether the lesion was better seen, equally visible or more poorly demonstrated on the tomosynthesis images in comparison with the standard 2-D screening mammogram. The results are summarised in Figure 24. Overall 48 lesions (75%) were better demonstrated with tomosynthesis than 2-D with the other 16 (25%) equally well demonstrated on both modalities. In no cases was a lesion less well demonstrated on tomosynthesis than on the standard 2-D screening mammogram.

In the 36 cases with a normal outcome, the patient was recalled for a possible abnormality seen on the 2-D screening mammogram. The tomosynthesis studies were interpreted as normal at the time of the original assessment and reviewed again as part of this evaluation. No significant abnormality was demonstrated on the tomosynthesis study in any of these patients. In all cases, the potential abnormality on the 2-D image was seen to be the result of tissue overlap or a summation effect with no lesion visible on scrolling through the 3-D data set.

Tomosynthesis was not used in the assessment of any cases where microcalcifications were the predominant mammographic feature, so it is not possible to make any formal assessment of the visibility of microcalcifications with the system.

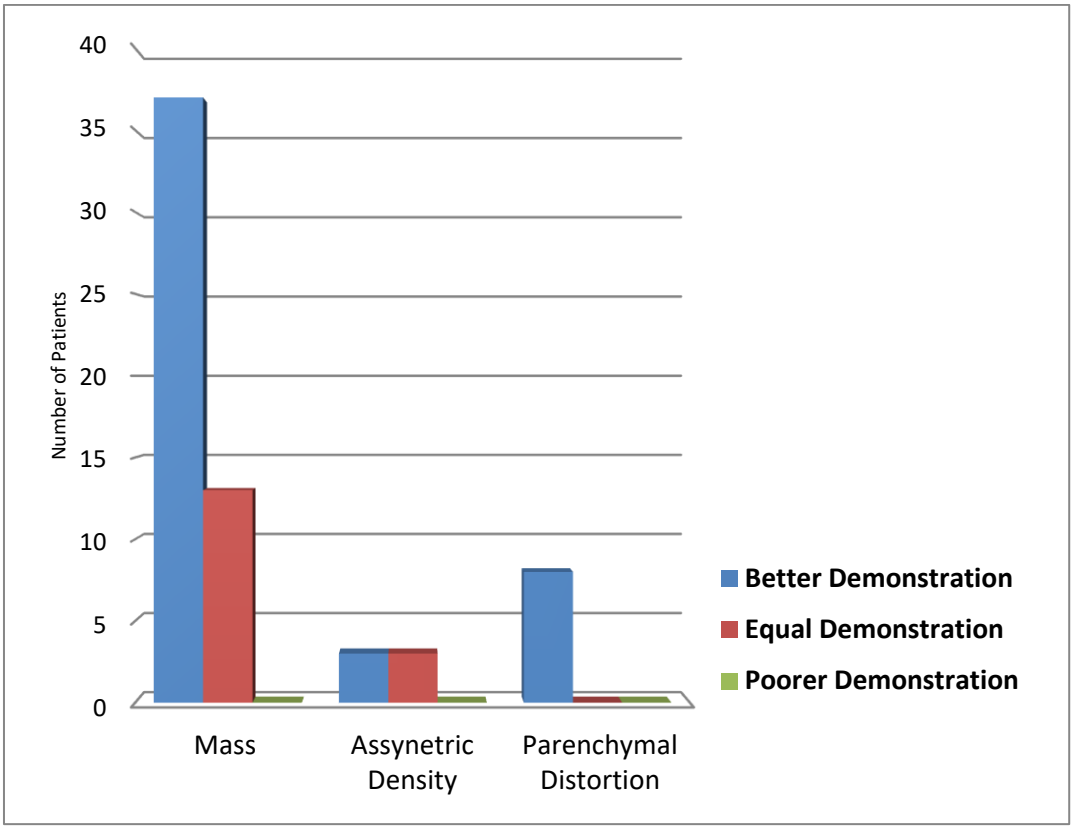

Figure 24: Breast lesion visibility with tomosynthesis compared with 2-D mammography

4.8 Diagnostic value of tomosynthesis compared to 2-D imaging

For each of the 100 cases, a judgement was made as to the contribution tomosynthesis made to the assessment of the screen detected abnormality. The reader rated whether the images were a significant aid to diagnosis, a useful aid to diagnosis or whether they had made no contribution at all. Overall the tomosynthesis images were judged to have a made a significant or useful contribution to diagnosis in 85 cases (85%). In only 15 cases (15%) did tomosynthesis make no additional contribution to the assessment process. Figure 24 shows the contribution made to cases with a malignant, benign or normal outcome after assessment.

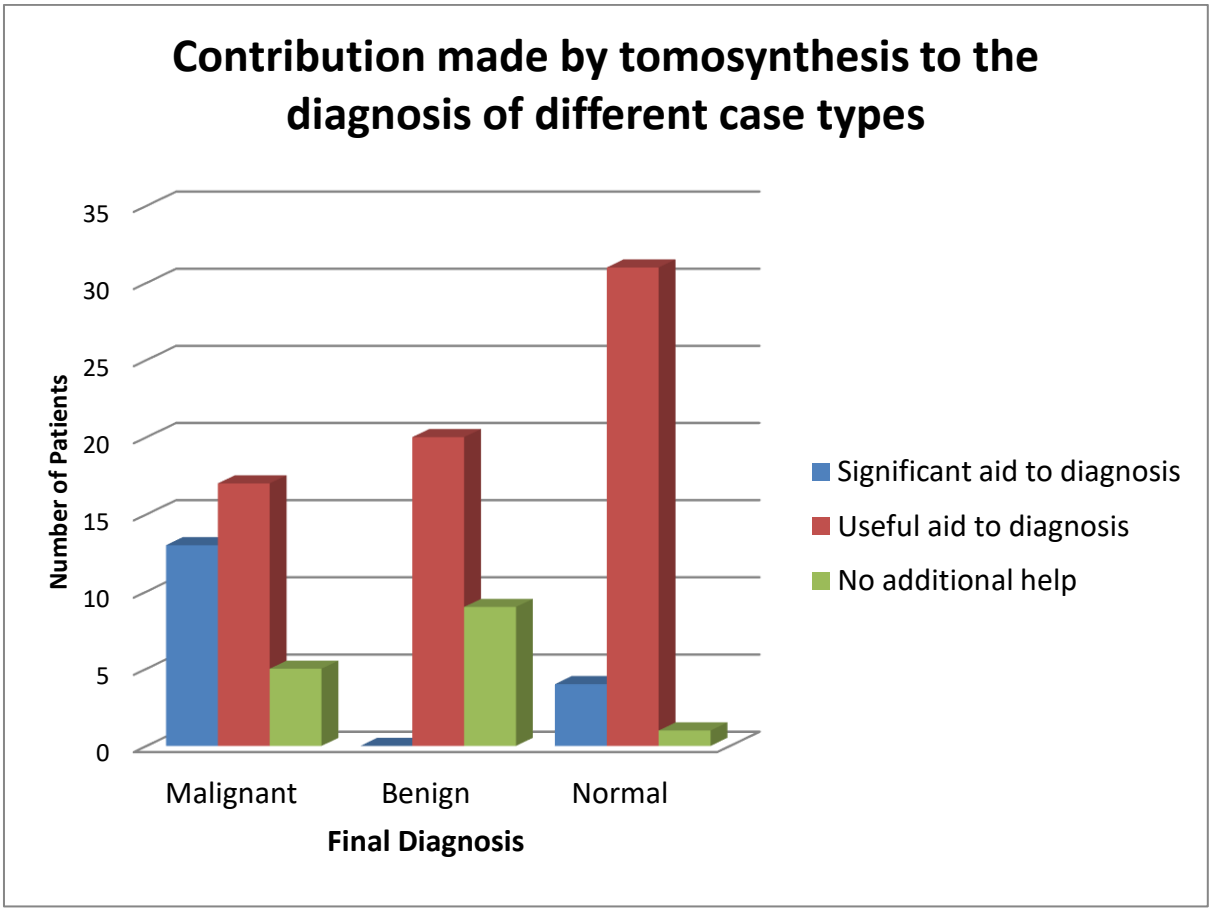

Figure 25: Contribution made by tomosynthesis to the diagnosis of different case types

In the 85 cases where tomosynthesis made a significant or useful aid to diagnosis, margin characterisation was the most commonly stated reason why tomosynthesis was helpful (58%). In 9 cases (11%) tomosynthesis made a contribution to assessing lesion extent and in 2 cases (2%) tomosynthesis found unsuspected multifocal disease.

5. Equipment reliability

Four errors have been logged with GE during the evaluation period with a total downtime of less than 1 day. All faults were recorded on the NHSBSP Equipment Fault Report form and sent to NCCPM.

The first error was image acquisition failure whilst in 2-D mode and resulted with the examination being completed on a different machine. The machine was accessed both remotely and in person on the same day with the error log indicating a grid sync error. The error was not able to be produced and has not re-occurred. The machine was temporarily out of use, but for less than half a day.

The second and fourth errors were due to the button to remove the paddle becoming jammed in a halfway down position and the paddle not being able to be removed. On the second occasion the paddle lock mechanism was replaced. There have been no reported incidents since.

The third error was due to the system not switching on correctly. The fault was investigated on-site and after a force shut-down and re-boot of the Axis computer the system operated correctly. The machine was temporarily out of use for half a day.
No faults were solely related to the 3-D function.

Details of faults reported are summarized in Appendix 5.

6. Electrical and mechanical robustness

There have been no safety issues or electrical or mechanical problems throughout the duration of the evaluation.

7. Radiographers' comments and observations

The radiographer's comments and observations were collected using the NHSBSP Equipment Evaluation form 11. Eleven questionnaires were returned. The full details of their observations can be found in Appendix 6.

7.1 Operator's manual

Soft-copy versions of the operator manual were available on the acquisition workj station and on the SenoIris workstation. Additional hard-copy versions of the operator manual were requested at the start of the evaluation but they were not supplied until after its completion.
The majority of staff commented that they had not seen a manual or that they had not needed to use one. It was considered to be Good (3) and Average (5) by those who did see it. 6 went onto indicate that they preferred a simplified in-house version and one radiographer suggested that a simplified version is good for a new user. 1 commented that they preferred the full version and 1 did not have a preference.

7.2 Training

9 radiographers received tomosynthesis and acquisition workstation training directly from the GE application's specialist. This was a mix of band 6 and band 7 staff. This training was cascaded to the remainder of the team.

The training for both was rated as Excellent (3) and as Good (6) by those who were trained by GE and all indicated that it was comparable to the 2-D training received.

7.3 Ease of use for tomosynthesis

All 11 respondent's indicated that the ease of use for tomosynthesis as Excellent. One commented that it is very quick to use and another commented that it is much easier than the previous GE tomosynthesis system as the tube head positions automatically and no foot pedal is required.

7.4 Ease to attach/remove any special tomosynthesis devises

The respondent's rated this as: Excellent (2), Good (7), Average (1) and Satisfactory (1). One radiographer commented that the tomosynthesis faceplate can be stiff to remove and 2 others commented that the paddle could be stiff to remove.

7.5 QA tests for tomosynthesis

The radiographer's rated the ease of the QA tests as Average (5) and Easy (6). One commented that they felt that there were too many tests and that the requirement to use the SenoIris workstation for analysis was time-consuming.

The calibration tests were rated as Average (4) and Easy (3). 4 respondents had not completed this test and were unable to comment.

The radiographers found the QA testing for the reporting monitor to be Difficult (1), Average (3) and Easy (3). 4 had not completed this test. One commented that there was no formal training for QA testing for the SenoIris workstation but that advice was sought from the medical physics team. Another commented that the testing was time-consuming due to the number of images.

7.6 Compression times

All 11 respondents commented that the compression times were acceptable for each exposure. One commented that they were short.

When compared to 2-D imaging 2 indicated that they thought the compression times were better and 9 indicated that they felt they were the same.

7.7 Patient throughput

All 11 respondents said that the unit's performance did not limit patient throughput. Two commented that this unit takes less time to complete a tomosynthesis examination than with the previous model as the 3-D is integrated and the tube aligns automatically.

4 commented that the patient throughput was better than 2-D and 7 commented that it was the same.

7.8 Patient comfort

The comfort for the patient was considered to be Excellent (7) and Good (4) by the radiographers. Two commented that the short examination time contributed to this along with the static face-guard which improved patient comfort.

However one radiographer commented that the gantry motion is still not smooth as it is a stop-start motion.

7.9 Range of controls and indicators for tomosynthesis

All 11 respondents commented that all the expected controls were present and that they were both easy to find and easy to use. 1 said that it was better than 2-D and the

remaining 10 said that it was the same as 2-D. One commented that they thought that the controls were well laid out.

7.10 Image appearing on the AWS and image storage

The time taken for an image to appear on the AWS was rated as Excellent (3) and Good (8) and was considered to be comparable to the time taken for the 2-D image to display. One radiographer commented that it took a while for the examination to appear on the SenoIris workstation.

Image storage was rated as Excellent (1), Good (7) and Average (1) with 2 indicating that they felt unable to comment. The 9 who responded said that this was comparable to 2-D image storage.

The auto-delete function was rated as Good by 4 of the respondents and deemed comparable to 2-D. The remaining 7 did not comment.

7.11 Image handling at the AWS

Although the majority of the image handling and processing was completed by the radiologists at the SenoIris workstation the radiographers indicated that they found scrolling through the image levels at the AWS to be Excellent (2), Good (6) and Average (2). One respondent indicated that they did not use the scroll function at the AWS but used the SenoIris workstation.

2 radiographers rated the processing facilities at the AWS as Excellent. 9 rated them as Good and 1 as Average. 10 of the respondents used the query/retrieve function and considered this Excellent (1), Good (8) and Average (1).

7.12 Ease of controls at the AWS

The image handling and processing facilities could be operated in 3 ways; keyboard, tracker ball and wheel scrolling via the mouse. The majority of the team used the keyboard and the mouse wheel. The ease of use of the keyboard for this function was rated as Excellent (2) and Good (8), and the wheel scrolling method was also deemed to be Excellent (1) and Good (8). One commented that the wheel scrolling was very quick and easy to use.

The tracker ball was only used by 4 of the radiographers, but was recorded as being Excellent (3) and Good (1).

The touchscreen received mixed reviews due to the issues surrounding the intermittent responsiveness to touch. This was rated as Excellent (2), Good (4), Average (2) and Poor (1).

7.13 Image quality

Overall the image quality at the AWS was well received. 3 respondents recorded it as Excellent, 7 as Good and 1 as Average. One radiographer commented that the images were too high contrast but this comment related to the default eContrast setting.

The overall image quality of the system in tomosynthesis mode was considered Excellent by 4 respondents and Good by 6. One commented that they were unsure and another said that they liked the level of contrast.

7.14 Level of confidence in the unit in tomosynthesis mode

A high confidence level was reported for the unit in tomosynthesis mode with 5 radiographers indicating their confidence level to be Excellent and the remaining 6 indicating it to be Good. 3 radiographers judged it better than in 2-D mode and 8 judged it as being the same.

7.15 Hazards

Whilst the majority of respondents (10) said that there were no potential hazards to the mammographer 1 commented that the glare from the light beam diaphragm when the tube is parked is uncomfortable on the eyes.

One hazard to the woman was indicated. It was commented that if the standard face shield is not swapped for the universal face shield prior to 3-D imaging that it will move and may shock the lady if they haven’t been warned. No other hazards were identified.

7.16 Additional comments

7.16.1 Tube park position

The Senographe Pristina has the added function of being able to angle the tube head up to 33° independently to the breast support table to allow for additional space for improved ergonomic positioning.

Many of the team have commented positively that they find this to be a useful feature and that they can see the ergonomic benefits when positioning for medio-lateral oblique and lateral images whilst standing.

However, it has been reported that when the tube head is angled the reflection from the light beam shining onto the compression paddle creates a “glare” that prevents the breast from being seen and makes positioning difficult. One radiographer also reported that when the tube head is angled more steeply that there is a shadow displaced onto the field-of-view which is distracting.

The respondents who have highlighted these issues have said that they would use the tube park position routinely if these issues were resolved.

7.16.2 Console

The touch screen console has been positively received by the team as has been reported as easy to use.

Some of the team commented that the touch screen is sometimes unresponsive to touch when selecting laterality which delayed the exposure. On advice from GE the console has been cleaned twice a day which improved the responsiveness. However, this routine is not specifically indicated within the 2-D operator manual (Revision 2).

7.16.3 Tomosynthesis

Many positive comments were received relating specifically to the tomosynthesis function of the Senographe Pristina. No longer needing to change the bucky for a 3-D examination was positively received by the team along with the remote tube angulation function as it was felt that examinations times as a whole were decreased.

One respondent commented encouragingly that the universal face shield made positioning easier due to its increased width and improved patient comfort during the exposure. One radiographer said that the Senographe Pristina is “A high quality piece of kit which is especially efficient for tomosynthesis”.

7.16.3 General comments

A variety of general comments were also received. These included:

- “It is quicker and easier to use”
- “Women have commented on how impressed they are with the machine”
- “A lovely piece of equipment”
- “Looks good”

8. Readers’ comments and observations

The readers’ comments and observations were collected using the NHSBSP Equipment Evaluation form 12. The full details of their observations can be found in Appendix 7.

8.1 Operator’s manual

A soft copy version of the manual was available on the SenoIris workstation. Only one of the respondents accessed the manual and reported it as Good. A hard-copy manual was provided after the evaluation period.

As the radiologists were already familiar with using other GE workstation’s they did not find it necessary to consult with a manual.

8.2 Application’s training

Application’s training for the SenoIris workstation was by request. 3 radiologists accessed this training and considered it Excellent (2) and Good (1).

8.3 External training courses

3 of the radiologists commented that they had attended external training courses for tomosynthesis. These were held at King’s College Hospital (2) and GE Headquarters, France (1). 1 did not attend any external training courses.

8.4 Ease of use of the workstation controls

Keypad, keyboard and mouse/tracker ball controls were available for use with the SenoIris workstation. The radiologists used a combination of the 3 options depending on personal preference. One commented that they only used the mouse/tracker ball and another commented that they do not use this option but regularly use the keypad and keyboard. The remaining respondents used all 3 options. No option was used by all 4 radiologists.

The keypad and keyboard were both considered Excellent by 2 radiologists and Good by 1. The mouse/tracker ball was also considered as Excellent (1) and Good (2).

8.5 Image handling tools

The image handling tools included image zoom, distance, angle and area measurements and image inversion. They were rated as Excellent (3) and Good (1).

8.6 Special tomosynthesis image handling tools

Dedicated image handing tools for tomosynthesis review included cine-loop, bookmarks, breast localizer and breast height ruler. These tools were rated as Excellent (3) and Good (1) with one comment that the cine-loop is a little quick.

8.7 On-screen icons

The on-screen icons were rated as Excellent (3) and Good (1) for both visibility and usability

8.8 Slab thickness changes when viewing tomosynthesis images

No change in slab thickness is possible.

8.9 Reading/reporting workflow pattern in tomosynthesis mode

The flow patterned was considered to be Excellent (2) and Good with one commenting that they did not use the reporting function.

8.10 Time taken for an image to appear in tomosynthesis mode

The time taken for the image to appear from a new patient and from an in-examination change was rated as Excellent (2) and Good (2). It was commented that the data transfer from the Senographe Pristina can be slow, taking a couple of minutes, but that once the images were in the cache that viewing different images or patients is very quick.

8.11 Recording findings for tomosynthesis on NBSS

This is not routinely done.

8.12 Monitor adjustment to suit the user

The ability to be able to adjust the height and angle of the monitor was considered Easy (2) and Average (1). One radiologist did not make any adjustments.

8.13 Navigation between tomosynthesis slices

All 4 respondents commented that this was Easy.

8.14 Hanging protocol set-up for tomosynthesis

1 respondent set-up the hanging protocols for the team and deemed the ease of this process to be Average. It was commented that it is a time-consuming process to set up individual hanging protocols for each user and that it takes some practice. However, it was also noted that all user preferences could be configured.

Changing between hanging protocols once they had been set-up was considered Easy (2).

8.15 Image quality of tomosynthesis images

Both the contrast and sharpness were considered Excellent by all 4 radiologists. The overall image quality of tomosynthesis images was also indicated as being Excellent (4).

8.16 Overall level of satisfaction of this tomosynthesis system

All 4 radiologists indicated their satisfaction level to be Excellent. One went on to comment that they have much more confidence in decision making during screening

assessment clinics when viewing tomosynthesis images compared to traditional spot compression images.

8.17 Additional comments

None made.

9. Information Systems

9.1 Workflow configuration

The Senographe Pristina was connected directly to the hospital radiology system (CRIS), the Breast Screening system (NBSS), the Trust PACS (GE Healthcare) and the SenoIris workstation. This enabled both breast screening and symptomatic worklists to be transferred directly to the machine and for images to be automatically transferred for radiology review. The SenoIris workstation received both the raw and processed tomosynthesis images, and the PACS system received the raw images for long-term storage purposes. The tomosynthesis images were reviewed by the radiologists on the SenoIris workstation.

Previous mammography examinations could be reviewed alongside the 3-D images via the query/retrieve functionality from both Trust PACS and the Senographe Pristina.

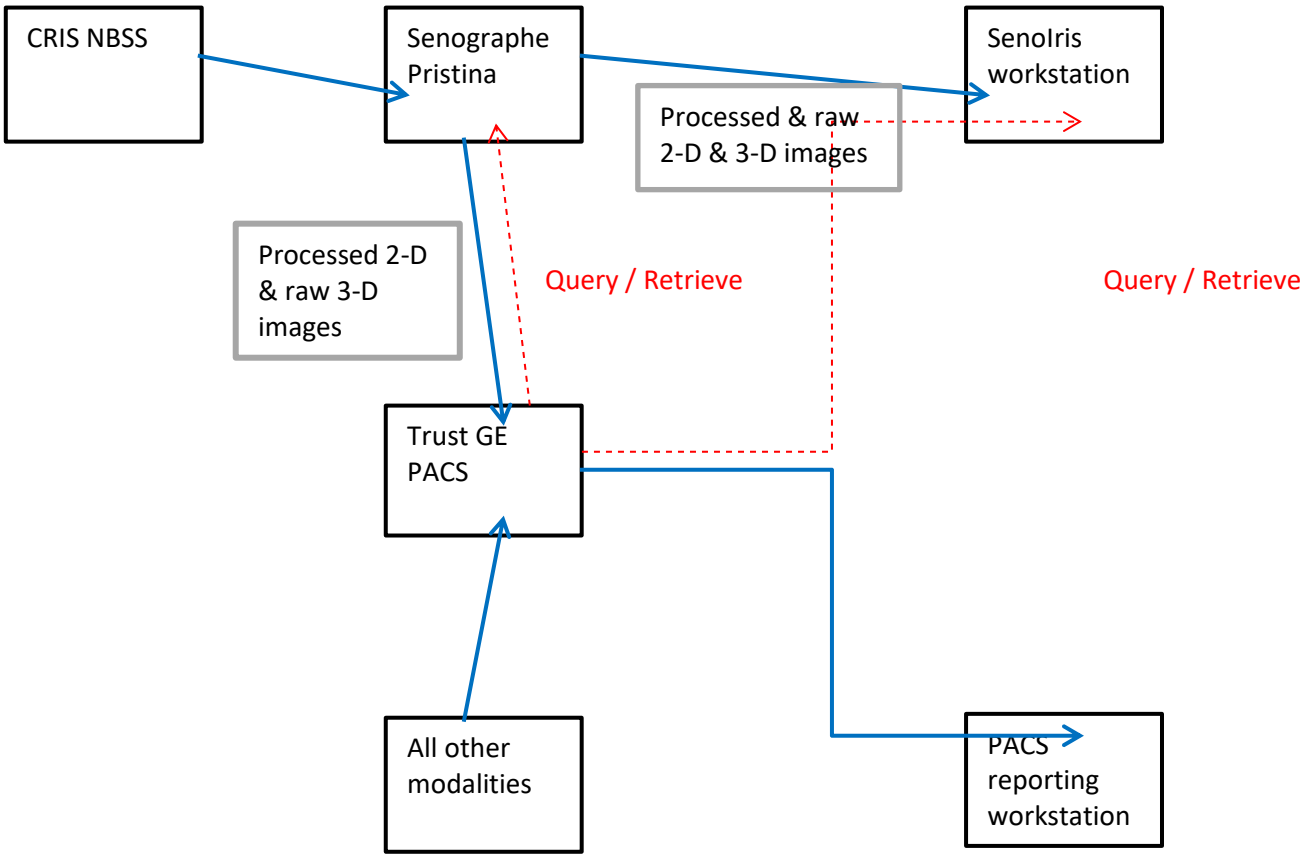

Figure 26: Workflow configuration

9.2 Reporting workstation

The SenoIris in Diagnose mode is a soft-copy reporting workstation. It is suitable for reading digital mammograms & digital breast tomosynthesis images, along with images from other breast imaging modalities such as ultrasound and MRI.
It comprises of a 1MP digital display for patient and report management and either dual 5MP monitors or a single 10MP monitor for image display and review. The dual monitors were exchanged for a 10MP single display monitor during the evaluation period.

The SenoIris workstation provides easy visual identification of the series of tomosynthesis planes and slabs with a variety of tools to aid image review. These include cine-loop, localiser and a breast height ruler. Hanging protocols are fully customisable.

The system was operated with the usual keyboard and mouse configuration, along with the option to use a keypad which can be programmed to a user's preferences, or rollerball tracker.

The system uses a Window's 7 professional operating system and a 4 core central procession unit (CPU).

9.3 Image sizes

The image size for 2-D images is 34MB for the 19cm x 23cm format and 52MB for the 24cm x 29cm format.

The 3-D images are in the DICOM standard BTO format and are made up of reconstructed planes and slabs. For the purpose of this evaluation an average compressed breast thickness for 10 patients was calculated and was taken as being 51mm. The associated file sizes can be viewed in table 3.

Table 3: Average file sizes of images

Image type	Image size (MB) 2-view single breast	Image size (MB) 2-view both breasts
single raw tomosynthesis image	252	504
complete tomosynthesis series including raw projections, slabs and planes	751	1502

10. Confidentiality and security issues

The evaluation was fully compliant with the NHS Cancer Screening Programmes Confidentiality and Disclosure Policy.[8]

11. Security issues

There were no security issues. The Senographe Pristina was located in a static unit which was locked and security protected out of hours. The unit was password protected when not in use.

All electronic patient data was stored within NBSS, the SenoIris workstation and GE PACS systems. All systems are only accessible by authorised users and are password protected.

12. Training

All staff groups already had a wide experience of the use of digital mammography and tomosynthesis on GE equipment in the screening setting. Tomosynthesis has also been in routine use in the assessment of screen detected abnormalities for 3 years, initially as part of a trial comparing digital breast tomosynthesis to standard supplementary mammographic views and latterly as the standard of care in the screening assessment clinic.

12.1 Radiographer Training

Training for 2-D and tomosynthesis was provided by a GE applications specialist. Half of the mammography team received this training which took one day and covered all aspects of machine use and quality control. This training was then cascaded to the rest of the team over a 2-week period.

The radiography team were already familiar with GE reporting workstations. The latest reporting software (SenoIris) was already in use in the department’s breast education centre at the time of the evaluation; so many staff already had a wide knowledge of its functionality.

The applications specialist was on site for the first week of machine use and for the weekly screening assessment clinics for the first 3 weeks to resolve any issues with both 2-D mammography and tomosynthesis acquisition and reporting.

12.2 Reader Training

All 6 consultant radiologist had a wide experience of the use of tomosynthesis in breast diagnosis at the time of the evaluation. All radiologists had previously attended an appropriate training course either externally or the ‘in-house’ NHSBSP approved tomosynthesis training course. This covers the principles of tomosynthesis, the evidence for its use in breast screening and diagnosis and hands on workstation-based training on 80 cases. The training workstations at the centre run the latest SenoIris software so all the consultants were familiar with its use and functionality for displaying and reporting 2-D and tomosynthesis studies.

The applications specialist was available during installation and was in the department for the first week of image acquisition and for the weekly screening assessment clinic in the first 3 weeks of the evaluation. Individual appointments could be made to cover any issues arising from image acquisition and workstation use from the knowledgeable and highly experienced GE trainer. One of the radiologists is also a ‘superuser’ and so can trouble shoot and deal with any workstation training issues when necessary for both radiologists and radiographers.

13. Discussion

13.1 Equipment

Overall the Senographe Pristina in tomosynthesis mode was well received by the mammography team. They said that it was aesthetically pleasing and easy to handle. The omission of the foot pedal in the new design makes the system simpler to operate and the universal face shield improves patient comfort during the exposure. Both were both welcomed improvements. The remote angulation function was also positively commented on by a number of the team.

As within the 2-D Senographe Pristina evaluation many mammographers agreed that angulation of the tube head into a tube park position has potential ergonomic benefits for a mammographer who positions whilst standing. However some commented that they did not use this feature due to the glare which reflected from the compression paddle resulting with the breast being difficult to visualise. If this glare was resolved those who commented adversely have confirmed that they would use this feature regularly.

The sensitivity of the touch-screen console was inconsistent throughout the evaluation with some of the team commenting that selecting laterality could sometimes be problematic. The sensitivity of the console was improved by cleaning the screen twice a day. A software upgrade completed after the evaluation period improved this further and eliminated the requirement for twice daily cleaning.

The radiology team were already familiar with using a GE workstation to review tomosynthesis images so found the SenoIris workstation easy to use and navigate. The single 10MP monitor was considered an improvement to the dual 5MP display option.

The image quality was reported as being excellent by the entire team and the pre-set slabs and planes were considered more than adequate for image review without the need to alter the slab thickness. Although setting the hanging protocols for initial use was time-consuming, the benefit of being able to configure individual preferences was well received. Once set up, changing between protocols was considered easy.

A retrospective review of the cases imaged as part of this assessment resulted with 75% of lesions to be considered to be better demonstrated with tomosynthesis than with the standard 2-D mammogram and in 85% of cases tomosynthesis was considered to have been a significant or useful aid to diagnosis. An increased confidence in decision making when using tomosynthesis was reported.

13.2 Physics and QA

There were a number of QA tests required in tomosynthesis mode and although the team found the testing relatively easy to complete some commented that the tests were very time-consuming due to the need to analyse the images on the SenoIris workstation. However there were no reported delays in clinic due to this.

13.3 Screening Assessment

The Senographe Pristina operated well within the screening assessment clinic. The DICOM headers indicated that the average time taken from the start of the exposure to the last image being displayed was 107 seconds, with the majority of this time being related to patient care and positioning. No delays to clinic workflow were described during the evaluation period and the radiology team reported that by using tomosynthesis they had an increase in confidence in decision making during screening assessment clinics in comparison to using only traditional spot compression imaging.

13.4 Image transfer and storage

The transfer of images from the Senographe Pristina to the SenoIris workstation could sometimes take up to 2 minutes to complete which was slightly detrimental to workflow in a particularly busy clinic but once the images were stored in the cache image review was very quick. The slow image transfer could possibly have been due internal networking.

No storage issues were identified.

13.5 Reliability

The machine was generally reliable during the evaluation period with the main mechanical issue relating to the paddles becoming jammed on the unit. This was resolved completely with a new paddle lock mechanism. Engineering support was available both remotely and on-site when applicable.

13.6 Radiographer views

Overall the radiographers commented positively about using the Senographe Pristina in tomosynthesis mode. No longer needing to swap the bucky to use the machine in

tomosynthesis mode was well received and some of the team commented that this enabled them to work more quickly in a busy clinic.

Some commented adversely about the tube park position and the glare that is produced from the light beam shining onto the compression paddle; however they also said that if these issues were resolved that they would use this function more frequently as they could see the ergonomic benefits.

General comments received from the radiographers were all positive. They found the machine quick and easy to use and mentioned that some of the patients had also commented on how impressed they were with the machine.

13.7 Radiologist views

The radiology team reported the SenoIris reporting workstation to be easy to be use and that the tomosynthesis images had excellent image quality. All the expected image handling tools were present, with the cine-loop being reported as being a little fast by one radiologist. The image navigator was reported to enable quick and efficient review of the tomosynthesis and 2-D studies side by side and the navigation between image slices was considered easy. The pre-set slabs and planes were considered more than adequate for image review without the need for additional alterations.

A retrospective review of the cases imaged as part of this assessment resulted with 75% of lesions considered to be better demonstrated with tomosynthesis than with the standard 2-D mammogram and in 85% of cases tomosynthesis was considered to have been a significant or useful aid to diagnosis. An increased confidence in decision making when using tomosynthesis was reported.

14. Conclusions and recommendations

The Senographe Pristina has been generally reliable for the duration of the evaluation. All mechanical and technical issues were completely resolved and the downtime was minimal. The engineering team was easy to contact and were quick to respond. There were no integration issues between the machine, NBSS or PACS throughout the evaluation period. The machine worked effectively within the screening assessment environment and met all the key throughput requirements of the service.

The radiographers welcomed the integrated 2-D/3-D functionality along with the universal face shield and the remote angulation function. The radiographers found the machine in tomosynthesis mode to be quick and easy to use but some would welcome improvements to the tube park function.

The radiologists reported that they found the SenoIris workstation to be easy to navigate and the pre-set slabs and planes were found to be more than adequate for reviewing the images without the need to make additional adjustments. One radiologist said that they had an increase in confidence in decision making during screening assessment clinics in comparison to using only traditional spot compression imaging. No recommendations for improvements to the modality workstation have been made.

References

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7. Dance DR, Young KC, van Engen RE. Further factors for the estimation of mean glandular dose using the UK, European and IAEA breast dosimetry protocols. Physics in Medicine and Biology, 2009, 54(14): 4361-4372

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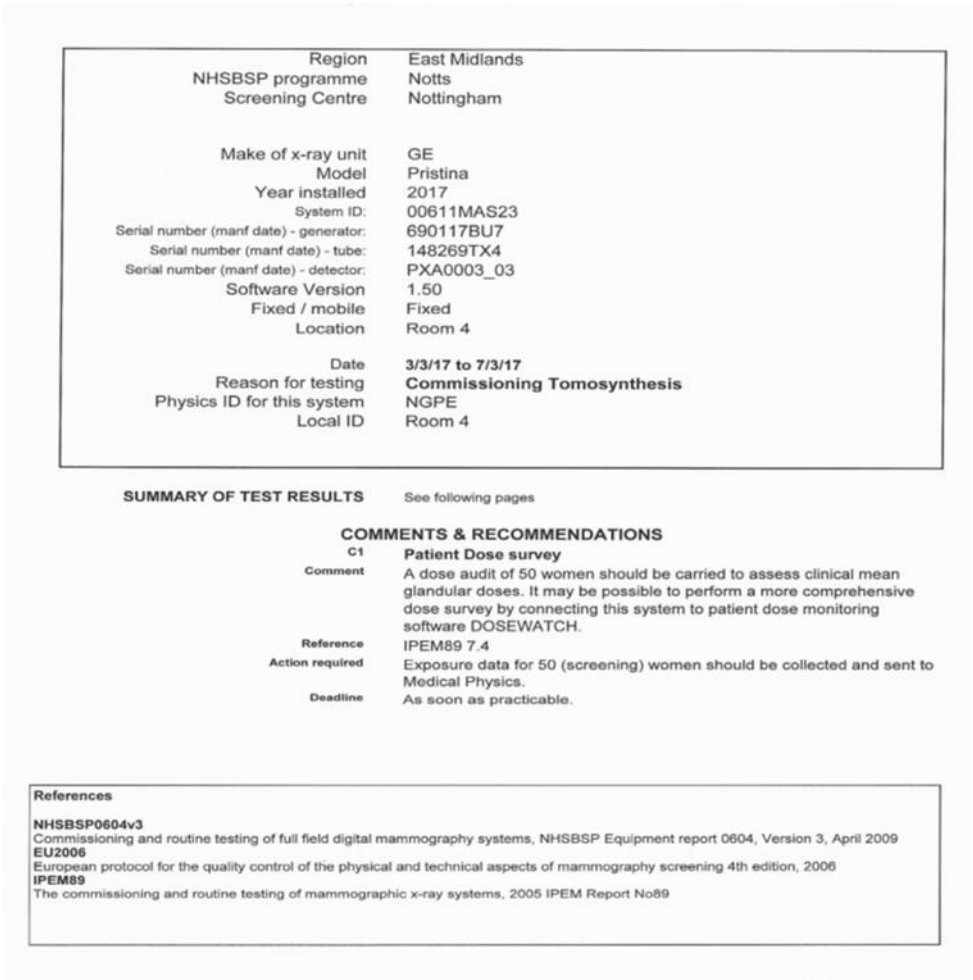
Appendix 1: Physics commissioning reports



Region	East Midlands
NHSBSP programme	Notts
Screening Centre	Nottingham
Make of x-ray unit	GE
Model	Pristina
Year installed	2017
System ID:	00611MAS23
Serial number (manf date) - generator:	690117BU7
Serial number (manf date) - tube:	148269TX4
Serial number (manf date) - detector:	PXA0003_03
Software Version	1.50
Fixed / mobile	Fixed
Location	Room 4
Date	**3/3/17 to 7/3/17**
Reason for testing	**Commissioning Tomosynthesis**
Physics ID for this system	NGPE
Local ID	Room 4

SUMMARY OF TEST RESULTS See following pages

COMMENTS & RECOMMENDATIONS

C1	**Patient Dose survey**
Comment	A dose audit of 50 women should be carried to assess clinical mean glandular doses. It may be possible to perform a more comprehensive dose survey by connecting this system to patient dose monitoring software DOSEWATCH.
Reference	IPEM89 7.4
Action required	Exposure data for 50 (screening) women should be collected and sent to Medical Physics.
Deadline	As soon as practicable.

References

NHSBSP0604v3
Commissioning and routine testing of full field digital mammography systems, NHSBSP Equipment report 0604, Version 3, April 2009
EU2006
European protocol for the quality control of the physical and technical aspects of mammography screening 4th edition, 2006
IPEM89
The commissioning and routine testing of mammographic x-ray systems, 2005 IPEM Report No89

NOPE1703 TOMO2 (Repaired) Comments Medical Physical Dept, Northampton GH

Alignment

Test	Reference	Limiting values	Result				Acceptable?	Comments
Alignment of x-ray field to the light field	Draft NHSBSP TOMO protocol – Section 3.1	**Remedial:** No limiting values		CWE	Left	Right	Acceptable	-
			TF,24x30,-,Mo	-4	2	-1		
			TF,24x30,-,Rh	-3	1	-1		
			TF,18x24,C,Mo	-4	5	2		
			TF,18x24,C,Rh	-3	4	1		
Alignment of x-ray field to imaged field / detector	Draft NHSBSP TOMO protocol – Section 3.1	**Remedial:** >5mm or <0mm overlap of image by x-ray field on chest wall edge Restriction of lateral and nipple edges: The primary x-ray beam must be blocked by the detector and its surrounding structure.		CWE	Left	Right	Acceptable	-
			TF,24x30,-,Mo	2	3	3		
			TF,24x30,-,Rh	3	2	3		
			TF,18x24,C,Mo	2	4	4		
			TF,18x24,C,Rh	3	3	3		
Alignment of reconstructed image volume to target volume	Draft NHSBSP TOMO protocol – Section 3.1	**Remedial:** All markers at the top and bottom of the target volume should be brought into focus within the range of the reconstructed volume.	Aluminium in focus in slices 9 and 70 of 81 and slabs 2 and 8 of 8				Acceptable	

Detector Performance

Artefacts	Draft NHSBSP TOMO protocol - section 3.3	Any clinically significant artefacts	Artefacts?	No evidence of significant artefacts				-
Detector resolution: Limiting spatial resolution	Draft NHSBSP TOMO protocol - Section 3.8.2	Limiting spatial resolution: significantly lower than baseline value	1.8 x 1.8 lp/mm	Baseline:		- lp/mm	Baseline	-
Geometric Distortion and Artefact Spread	Draft NHSBSP TOMO protocol - Section 3.5		Nominal Height	12.5	32.5	52.5		-
		Height of best focus	Average Slice	36	75	115.8		
		Investigate if >2mm change from Baseline	Max deviation from average	0.55	1.1	0.8		
		Positional accuracy	Max X Difference from mean (mm)	3.8	3.8	3.9		
			Max Y difference from mean (mm)	2.7	2.8	2.9	Baseline	
		Distortion (ratio of mean seperation): >5% change from baseline	Distortion within focal plane	1.0	1.0	1.0		
		Artefact Spread	X Artefact Spread	0.6	0.6	0.6		
			Y Artefact Spread	0.3	0.3	0.3		
		Z FWHM: >20% change from Baseline	Z resolution (slices)	14.09	13.61	13.10		

AEC

Test	Reference	Limiting values	Result	Acceptable?	Comments
AEC repeatability	Draft NHSBSP TOMO protocol - Section 3.6.1	**Remedial**: Max dev in mAs or SNR from mean: >5% **Suspension**: Max dev in mAs or SNR from mean: >10%	Max mAs deviation = 0% mAx SNR deviation = 1%	Acceptable	-

AEC performance - Automatic mode	Draft NHSBSP TOMO protocol - Section 3.7	CNR: ±20% baseline	Auto 3D Slices	Perspex thickness	TFkV, mAs	CNR	%baseline		-
				2	MoMo26, 22.3	6.8	-		
				3	MoMo26, 48.4	5.9	-		
				4	RhAg34, 27.3	4.2	-		
				4.5	RhAg34, 31.6	4.0	-		
				5	RhAg34, 38.3	3.9	-		
				6	RhAg34, 55.3	3.8	-		
				7	RhAg34, 87.7	3.7	-		
		CNR: ±20% baseline	Auto 3D Slabs	Perspex thickness	TFkV, mAs	CNR	%baseline		
				2	,	6.1	-		
				3	,	5.4	-		
				4	,	3.9	-		
				4.5	,	3.7	-	Baseline	
				5	,	3.6	-		
				6	,	3.5	-		
				7	,	3.5	-		
		CNR: ±20% baseline	Central axis projection	Perspex thickness	TFkV, mAs	CNR	%baseline		
				2	,	4.4	-		
				3	,	4.6	-		
				4	,	5.4	-		
				4.5	,	5.7	-		
				5	,	6.3	-		
				6	,	7.8	-		
				7	,	8.3	-		

				Estimated Total Scan Time		
Exposure time	Draft EUREF Tomo protocol V0.10 - Section 2.5	No limiting values – Tomo exposures are expected to be significantly longer than FFDM	Exp time 4.5cm	8	Baseline	-
			Exp time 4cm	9		
			Exp time 6cm	11		

Test	Reference	Limiting values	Result	Acceptable?	Comments
Image Quality					
Threshold contrast visibility - CDMAM	Draft NHSBSP Tomo Protocol - Section 3.8.1	**Remedial level:** Significant change from baseline. FFDM levels given below for information Threshold gold thickness for FFDM Detail diameter / acceptable / achievable 2 / 0.069 / 0.038 1 / 0.091 / 0.056 0.5 / 0.15 / 0.103 0.25 / 0.352 / 0.244 0.1 / 1.68 / 1.10	Fit to predicted gold thickness RhAg34, 36mAs, 1.45mGy, Planes / Slabs / V-Preview n/a / n/a / n/a 0.10 / 0.10 / 0.19 0.13 / 0.18 / 0.35 0.25 / 0.40 / 0.74 1.54 / 2.16 / 5.36	Baseline	-
Regular IQ tests - TORMAX	Draft NHSBSP Tomo Protocol - Section 3.8.2	**Remedial**: Number of details detected significantly less than baseline. FFDM limits given for info. Target / Min std / Remedial / Suspension 6mm: <0.8% / <1.2% / <1.4% 0.5mm: <3% / <5% / <8% 0.25mm: <5% / <8% / <11%	MoMo28, 86mAs 0.5% 3% 6%	Acceptable	-
Regular IQ tests - TORMAM	Draft NHSBSP Tomo Protocol - Section 3.8.2	**Remedial**: Visibility of details is significantly inferier to baseline	RhAg34, 30mAs Planes / Slabs / V-Preview 83 / 56 / 50	Baseline	-
Dose					
Dose to the standard breast	Draft NHSBSP Tomo Protocol - Section 3.8.1 Draft EUREF Tomo protocol V0.10 - Section 2.5 Remedial levels relate to FFDM	Perspex thickness / Remedial (NHSBSP), Acceptable (EU2006) / Achievable (EU2006) 2 / 1.0 / <0.6 3 / 1.5 / <1.0 4 / 2.0 / <1.6 4.5 / 2.5 / <2.0 5 / 3.0 / <2.4 6 / 4.5 / <3.6 7 / 6.5 / <5.1	Auto 3D Slices / - / - 0.61 / - / - 1.00 / - / - 1.25 / - / - 1.36 / - / - 1.52 / - / - 1.94 / - / - 2.70 / - / -	Acceptable	-

physics ID	NGP1
Local ID / location	Room 4
Centre	Nottingham
Digital make	GE
Digital model	Pristina
Date	07 March 2017
manufacturer of X-ray set	
model of X-ray set	
model of CR plate	

Tomo Slabs		
added px	4	cm
spacer	0	cm
mode	Slab	
kV	34	
target	Rh	
filter	Ag	
mAs	36.4	
MGD	1.45	mGy

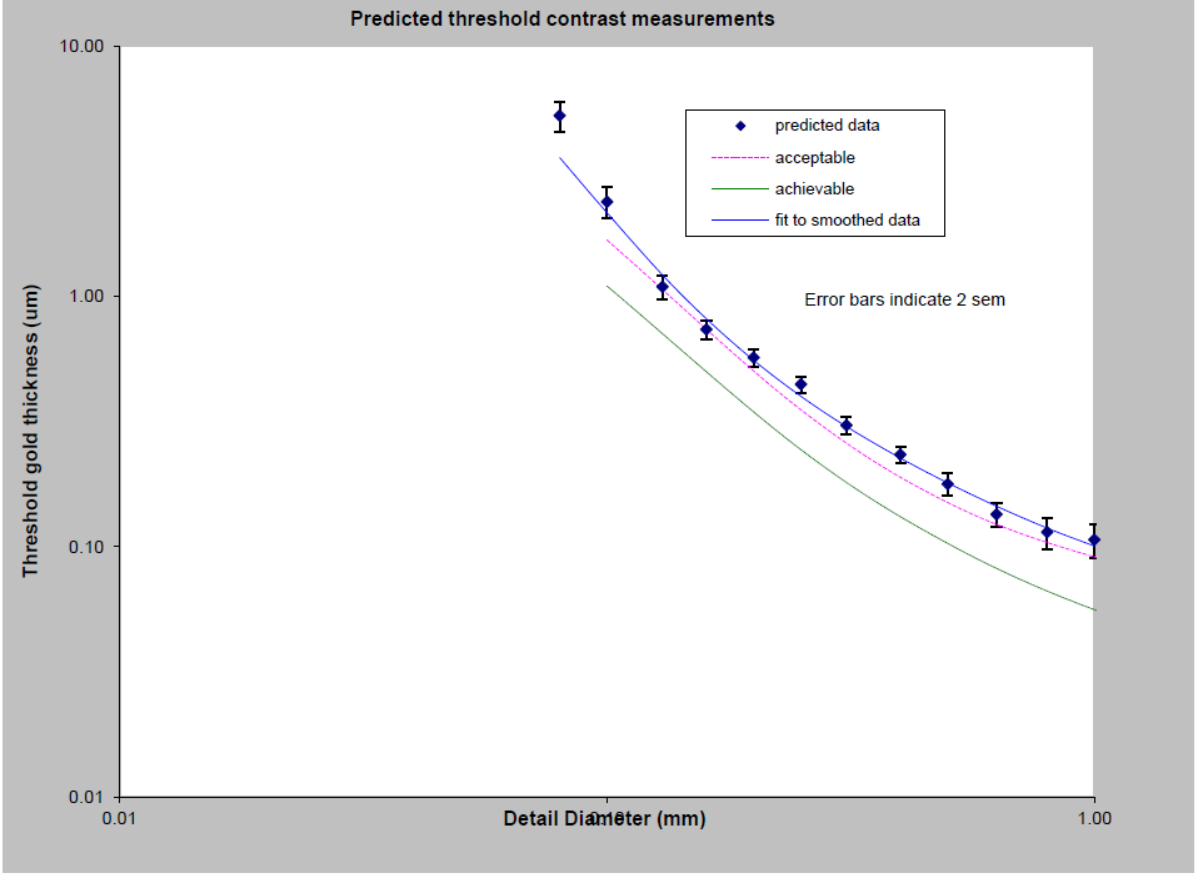
Comments: **SN 1074**

Predicted CD curve for human observer

Diameter (mm)	threshold gold thickness	2 sem	fitted curve
1.00	**0.11**	**0.016**	**0.10**
0.80	0.11	0.017	0.12
0.63	0.13	0.014	0.14
0.50	**0.18**	**0.018**	**0.18**
0.40	0.23	0.018	0.23
0.31	0.31	0.024	0.30
0.25	**0.44**	**0.032**	**0.40**
0.20	0.57	0.044	0.56
0.16	0.74	0.065	0.81
0.13	1.09	0.122	1.22
0.10	**2.39**	**0.345**	**2.16**

Limits in protocol

	Threshold gold thickness		predicted gold thickness	fit to predicted gold thickness	2 sem for fitted value
diameter	acceptable	achievable			
2	0.069	0.038	n/a	n/a	n/a
1	0.091	0.056	**0.11**	**0.10**	**0.016**
0.5	0.15	0.103	**0.18**	**0.18**	**0.018**
0.25	0.352	0.244	**0.44**	**0.40**	**0.032**
0.1	1.68	1.1	**2.39**	**2.16**	**0.345**



physics ID	NGP1
Local ID / location	Room 4
Centre	Nottingham
Digital make	GE
Digital model	Pristina
Date	07 March 2017
manufacturer of X-ray set	
model of X-ray set	
model of CR plate	

Tomo Planes		
added px	4	cm
spacer	0	cm
mode	Planes	
kV	34	
target	Rh	
filter	Ag	
mAs	36.4	
MGD	1.45	mGy

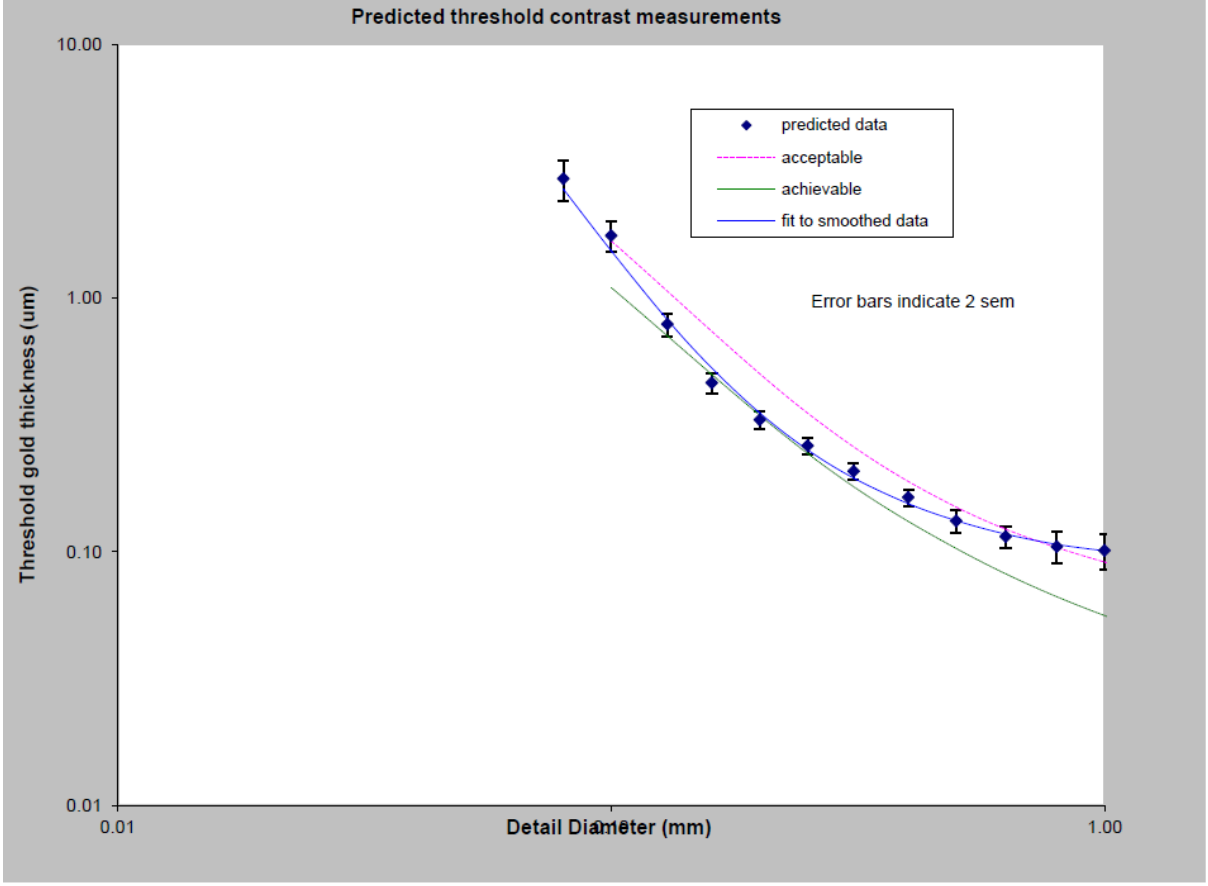
Comments: **SN 1074**

Predicted CD curve for human observer

Diameter (mm)	threshold gold thickness	2 sem	fitted curve
1.00	**0.10**	**0.016**	**0.10**
0.80	0.10	0.015	0.11
0.63	0.11	0.012	0.12
0.50	**0.13**	**0.013**	**0.13**
0.40	0.16	0.012	0.15
0.31	0.21	0.016	0.20
0.25	**0.26**	**0.020**	**0.25**
0.20	0.33	0.028	0.35
0.16	0.46	0.042	0.53
0.13	0.79	0.082	0.82
0.10	**1.76**	**0.246**	**1.54**

Limits in protocol

	Threshold gold thickness		predicted gold thickness	fit to predicted gold thickness	2 sem for fitted value
diameter	acceptable	achievable			
2	0.069	0.038	n/a	n/a	n/a
1	0.091	0.056	**0.10**	**0.10**	**0.016**
0.5	0.15	0.103	**0.13**	**0.13**	**0.013**
0.25	0.352	0.244	**0.26**	**0.25**	**0.020**
0.1	1.68	1.1	**1.76**	**1.54**	**0.246**



Appendix 2: 2D clinical dose survey & DBT clinical breast dose survey

NHSBSP Breast Dose Survey

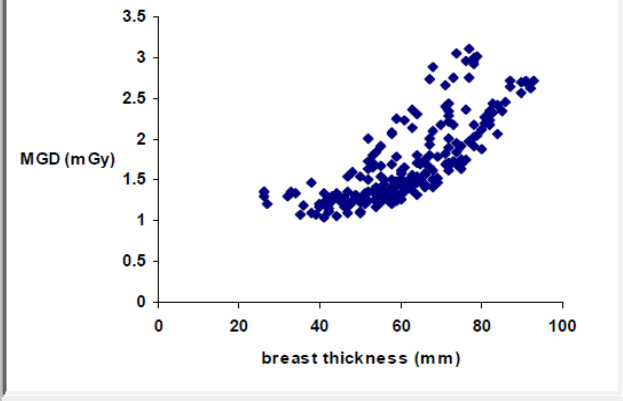
Survey No:	1049	Processor make:	digital (2D)
Centre:	Nottingham	Processor ID:	
Date of first exam:		Developer:	
Date of last exam:	26/10/2017	Fixer:	
X-ray make	GE	Dev Temp (deg C):	
Model:	Pristina	Proc time (s):	0
Local id:	NGPE (2D)	Cassette make:	
Installation:	fixed	Film make:	
kV mode:	auto	Screen make:	
standard kV:	0		
Routine/age trial:	routine screening		

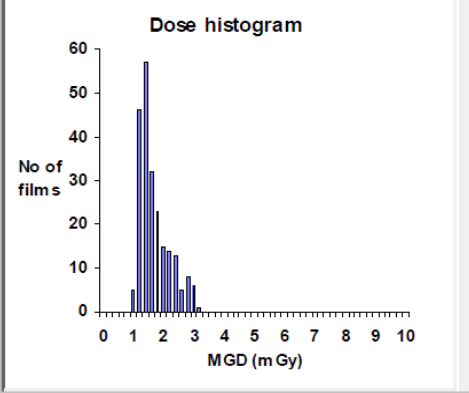
24x30 cassettes available: ☑

Block mAs:	
Block density:	
physics service	Northampton
Physicist	V Jones

MGD to standard breast

auto/manual kV:	auto	PMMA thickness:	45mm
auto/AEC setting:	STD	MGD mAs:	33.5
kV set:	34	HVL:	0.578
target:	Rh	MGD:	1.39
filter:	Ag	film density:	





Count of films

view	main films	Extra films
CC	108	
OB	107	8

Summary of X-ray factors selected

Anode	Filter	kV	films
Mo	Mo	26	3
Rh	Ag	34	222

Average doses for main films

view	No of films	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	108	1.05	3.05	1.63	59
OB	107	1.08	3.11	1.71	62

Average doses per screening examination

	No of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
One view	2	0.73	1.85	1.29
Two view	58	1.46	6.94	3.23

Average dose for 50-60mm thick breasts

View	No of films	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
OB	32	1.46	0.08	56

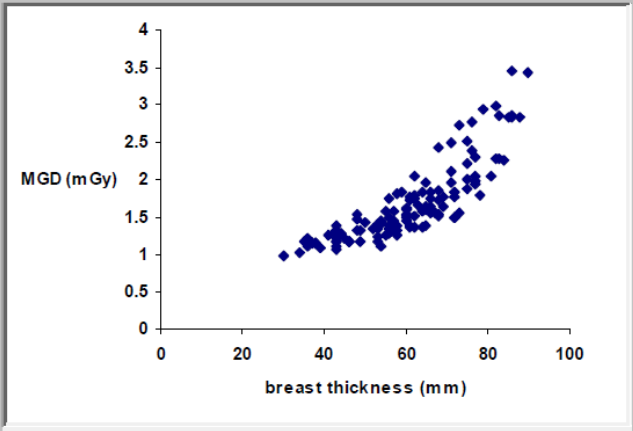
NHSBSP Breast Dose Survey

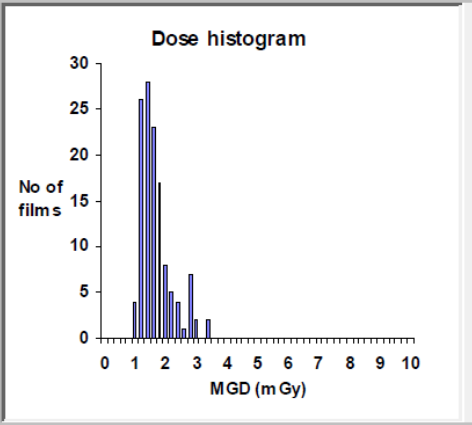
Survey No:	1055
Centre:	Nottingham
Date of first exam:	
Date of last exam:	
X-ray make	GE
Model:	Pristina
Local id:	
Installation:	fixed
kV mode:	auto
standard kV:	0
Routine/age trial:	

Tomo mode: Tomo

MGD to standard breast

auto/manual kV:	auto	PMMA thickness:	45mm
auto/AEC setting:	STD	MGD mAs:	32.7
kV set:	34	HVL:	0.570
target:	Rh	MGD:	1.39
filter:	Ag		





Count of images

view	main films	Extra films
CC	63	
OB	63	1

Summary of X-ray factors selected

Anode	Filter	kV	films
MO	MO	26	2
RH	Ag	34	125

Average doses for main images

view	No of films	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	63	0.97	3.44	1.63	60
OB	63	1.02	3.43	1.70	61

Average doses per examination

	No of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
Two view	61	1.00	4.82	1.74

Average dose for 50-60mm thick breasts

View	No of films	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
OB	11	1.46	0.10	57

Appendix 3: Manufacturer specific QC tests

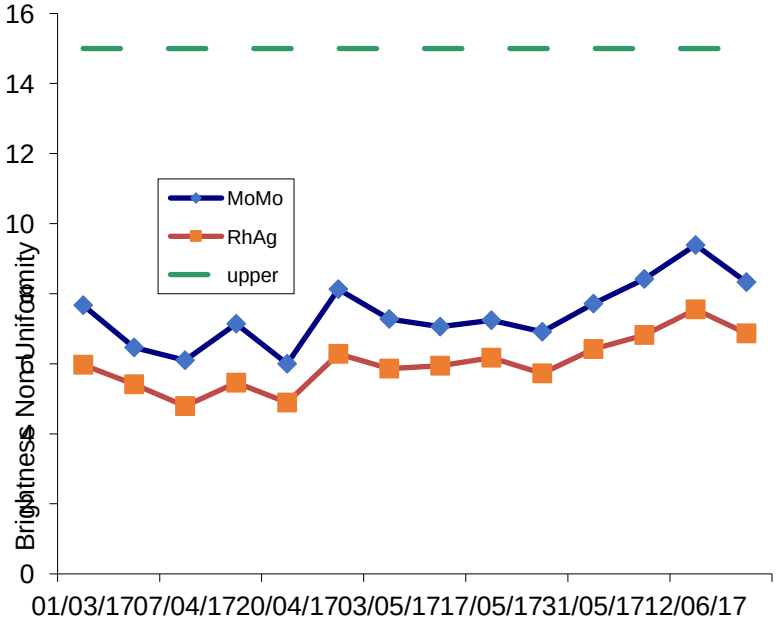
A3.1 Reconstructed image uniformity tests

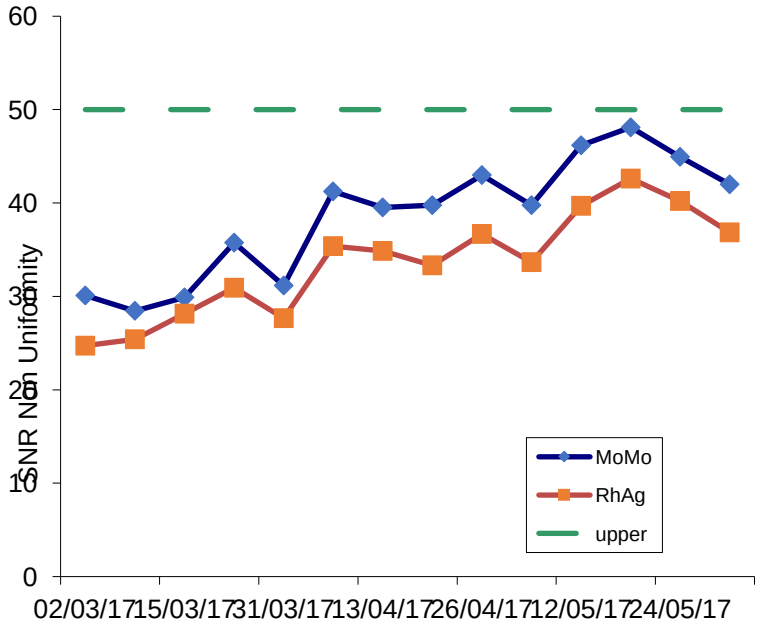
The purpose of this test is to ensure flatness and homogeneity of the reconstructed Flat Field phantom planes.

Two parameters are measured: - Brightness non–uniformity and SNR non–uniformity

The 24x29cm phantom used was supplied by GE and the test was performed weekly in the following configurations: 3D contact Mo/Mo and 3D contact Rh/Ag.

Results for Brightness Non-Uniformity and SNR Non-Uniformity are shown. The results were all within GE limits.





Appendix 4: Image review form

Case No:	

Density	
Fatty	
Mixed	
Dense	

Visualisation on tomo compared to 2D	
BETTER	
EQUAL	

POORER	

Sign	
Mass	
microcalcification	
Distortion	
Assymetry	
Normal	

Outcome	
Malignant	
Benign	
Normal	

Visualisation on tomo compared to 2D	
BETTER	
EQUAL	
POORER	

Usefulness of Tomo	
No additional help	
Useful aid to diagnosis	

Significant aid to diagnosis	

How did TOMO help (tick all that apply)	
Margin characterisation	
Extent	
Multifocality **Other (specify)**	

Appendix 5: Fault reports requiring engineer visits

Date	Fault	Solution	Total Downtime
23rd March 2017	Error message E11 – acquisition refused	Error logs checked. Exposure failed with grid sync error but no other error logged. Unable to reproduce fault. AOP checks and test exposure all passed.	Less than half a day
27th March 2017	Large compression paddle stuck on machine – release button stuck down.	Removed by engineer	No downtime
30th May 2017	Machine would not switch on correctly – error message	Software reloaded and system re-booted.	Half a day.
31st May 2017	Large compression paddle stuck on machine – release button stuck down.	Paddle lock mechanism replaced.	No downtime

Appendix 6: Radiographers' answers to questionnaire

This appendix is a table listing all the questions on the radiographers' questionnaire with answers and comments.

	Question	Comments / Observations	Compared to 2-D
1	How do you rate the supplier's operator manual (if used)?	3 Good, 2 average, 6 n/a The majority commented that they had not seen the manual or that they had not needed to use it.	4 Same, 6 n/a
2	Did you prefer an in-house simplified version?	6 Yes, 1 No, 1 Don't mind. 3 n/a One commented that simplified versions are good for new users.	
3	How good was the clinical applications training for tomosynthesis provided by the supplier for:	8 Excellent, 9 Good	
	I. Modality	3 Excellent, 6 Good, 2 n/a 2 members of the team had the training cascaded to them by colleagues.	9 Same, 2 n/a
	II. Acquisition Workstation	3 Excellent, 6 Good, 3 n/a 2 members of the team had the training cascaded to them by colleagues.	8 Same, 3 n/a

4	How do you rate the unit's ease of use for tomosynthesis?	11 Excellent One commented that it is very quick to use and another commented that it is much easier than previous equipment as the tube positions automatically and no foot pedal is required.	
5	How easy was it to attach/remove any special tomosynthesis device used with the x-ray equipment for example, faceplate, bucky?	2 Excellent, 7 Good, 1 Average, 1 Satisfactory One commented that the tomosynthesis faceplate can be a bit stiff to remove. Two commented that the paddle can be stiff to remove.	
6	How do you find carrying out:		
	I. Special QA tests for tomosynthesis?	5 Average, 6 Easy One commented that they felt there were too many tests and the requirement to use the workstation was time-consuming.	
	II. Calibration tests for tomosynthesis?	4 Average, 3 Easy,	
	III. Reporting workstation	1 Difficult, 3 Average, 3 Easy One commented that there was no formal training for QA on the SenoIris but that advice was sought from the medical physics team. One commented that is was time-consuming due to the number of images.	
7	Were the compression times acceptable for each exposure?	11 Yes One commented that the exposure times were short.	2 Better, 9 Same

8	Did the unit performance limit patient throughput?	11 No Two commented that it takes less time to take a DBT image as the 3-D is integrated and the tube aligns automatically.	4 Better, 7 Same
9	How do you rate the comfort of women during tomosynthesis exposures, including acceptability of gantry motion?	7 Excellent, 4 Good Two commented that as less time is taken for the DBT examination and as the face shield does not move with the gantry motion that that it was more comfortable. One commented that the gantry motion is still not smooth as it is a stop start motion.	
10	Range of controls and indicators (on-screen icons) for tomosynthesis:		
	I. Were all the expected controls present?	11 yes	1 Better, 10 Same
	II. Were they easy to find?	11 Yes	1 Better, 10 Same
	III. Were the icons easy to use?	11 Yes One commented that the controls were easy to use and well laid out.	1 Better, 10 Same
11	How do you rate the time for:		
	I. An image to appear on the workstation?	3 Excellent, 8 Good	11 Same
	II. Storage of the image?	1 Excellent, 7 Good, 1 Average, 2 n/a	9 Same

	III. Auto-deleting an image?	One commented that it seemed to take a while for the images to appear on the SenoIris. 4 good, 7 n/a	4 same
12	How do you rate image handling at the acquisition workstation:		
	I. Scrolling through the image levels?	2 Excellent, 6 Good, 2 Average, 1 n/a	2 Better, 8 Same, 1 n/a
	II. The processing facilities	2 Excellent, 9 Good, 1 Average	1 Better, 10 Same
	III. Use of query/retrieve?	1 Excellent, 8 Good, 1 Average, 1 n/a	10 Same, 1 n/a
13	How easy was it to use, for tomosyntheses, the following:		
	I. Keyboard?	2 Excellent, 8 Good, 1 n/a	1 Better, 8 Same, 1 n/a
	II. Touchscreen?	2 Excellent, 4 good, 2 Average, 1 Poor, 2 n/a Three commented that often the touchscreen was unresponsive to touch.	1 Better, 7 Same, 1 Worse, 2 n/a
	III. Trackerball?	3 Excellent, 1 Good, 7 n/a	1 Better, 3 Same
	IV. Wheel scrolling through the tomosynthesis slices?	1 Excellent, 8 Good, 2 n/a One commented that this was very easy and quick to use.	2 Good, 5 Same
14	How do you rate the following:		
	I. Image quality at the acquisition workstation for tomosynthesis images?	3 Excellent, 7 Same, 1 Average One commented that the images were too high contrast.	

	II. Overall image quality of this system in tomosynthesis mode?	4 Excellent, 6 Good, 1 Unsure One commented that they liked the level of contrast.	
15	What was your level of confidence in the unit?	5 Excellent, 6 Good	3 Better, 8 Same
16	Were there any potential hazards with use in tomosynthesis mode to:		
	I. You?	1 Yes, 10 No One commented on the glare reflected from the compression paddle when the tube head is angled.	11 Same
	II. The woman?	1 Yes, 10 No One commented that is the small face guard is left on after using 2-D mode it will move as the tube head moves. This will move the client's head, cause blurring and shock the lady.	10 Same, 1 Worse
17	Additional comments	Very easy operation Decreased exam time as there is no need to change the bucky. The independent movement of the tube head in relation to the face shield is a lot better as ladies do not need to pull their head back. It is much easier to position and more comfortable for the patient as the face shield is static during the tomo. It is quicker and easier to use. A high quality piece of kit which is especially efficient for tomo.	

Women have commented on how impressed they are with the machine.

If I move the tube I see glare from the light beam which obscures my view; if I use the stool the large face shield obscures my view.

Much quicker than the previous model. The movements are much smoother.

Excellent face shield; make positioning easier.

A lovely piece of equipment.

The glare reflected on the paddle is “off-putting” and makes it difficult to see the breast as you are positioning. I find myself moving my head around the paddle to avoid the glare which defeats the purpose. If the glare was fixed by replacing the bulb, I would use the home position more often.

If a steeper angle is used the edges of the paddle (or something) are displaced on the field of view whilst positioning, which can also be a distraction.

The paddles are a bit stiff to detach

The auto start position for tomosynthesis is a welcomed improvement!

Very user friendly, positive comments from patients. Looks good and the tube is quiet unlike other machines in department.

Appendix 7: Readers' answers to questionnaire

This appendix is a table listing all the questions on the readers' questionnaire with answers and comments.

	Question	Responses
1	How good were the operator's manual instructions for tomosynthesis?	1 Good, 3 n/a
2	How good was the application's training for tomosynthesis provided by the supplier?	2 Excellent, 1 Good, 1 n/a
3	Did you attend and external training course for the tomosynthesis? If so, please enter training centre in the comments	3 Yes, 1 No 2 attended at King's College Hospital and 1 attended GE Headquarters in Paris, France.
4	How do you rate the use of the reporting workstation controls for tomosynthesis?	
	a) Mouse/trackerball	1 Excellent, 2 Good, 1 n/a
	b) Keyboard	2 Excellent, 1 Good, 1 n/a
	c) Keypad	2 Excellent, 1 Good, 1 n/a
5	How do you rate the image handling tools (zoom, for example) for tomosynthesis?	3 Excellent, 1 Good
6	How do you rate the special tomosynthesis image handling tools such as the slider or cine?	3 Excellent, 1 Good One commented that the cine loop is a little quick.
7	How do you rate the visibility and usability of on-screen icons for tomosynthesis?	3 Excellent, 1 Good
8	Did you sometimes change the slab thickness when reviewing the tomosynthesis images?	4 No

		One commented that they only use the pre-set thin and thick slabs which are more than adequate for viewing studies. They also commented that they preferred to view the thin slices rather than the slabs.
9	How do you rate the reading/reporting flow pattern in tomosynthesis?	2 Excellent, 1 Good, 1 n/a One commented that the did not use the reporting function.
10	How do you rate the time for an image to appear on the screen in tomosynthesis mode?	
	a) New patient selection	2 Excellent, 2 Good One commented that it can be slow to transfer data from the machine to the workstation. Another commented that once the images are in the cache then viewing different images or patient is very quick. It can take a couple of minutes for the images to come from the acquisition station to the reporting workstation.
	b) In-examination change	2 Excellent, 2 Good
11	How easy was it to record findings for tomosynthesis on NBSS?	1 Easy, 3 n/a We do not specifically record the findings of tomosynthesis studies on NBSS.
12	How easy is it to adjust the height and angle of the monitors to suit the user?	2 Easy, 1 Average, 1 n/a
13	How easy was it to navigate between the tomosynthesis slices?	4 Easy
14	How easy was it to set up different hanging protocols in tomosynthesis?	1 Average, 3 n/a Three commented that they did not set up hanging protocols themselves. One commented that it is a bit time consuming to set up individual hanging protocols and takes some practice. The hanging protocols are completely

		configurable to suit all user preferences.
15	How easy was it to change from one hanging protocol to another in tomosynthesis?	2 Easy, 2 n/a One commented that it was very easy once the hanging protocol is set up.
16	How do you rate the following properties of the tomosynthesis images?	
	a) Contrast	4 Excellent
	b) Sharpness	4 Excellent
17	What is your impression of the quality of images provided by the tomosynthesis system?	4 Excellent
18	What is your overall level of satisfaction with using this tomosynthesis system for assessments?	4 Excellent One commented that they have much more confidence in decision making in assessment when viewing tomosynthesis images compared to the traditional spot views.
19	Additional comments	None made.

Appendix 8: Manufacturer’s comments

None submitted