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NHS Breast Screening Programme Equipment Report

Practical evaluation of 'GE Healthcare Senographe Pristina' 2D digital mammography 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 function of the GE Senographe Pristina mammography machine, in 2-D mode, for use for breast screening within the NHSBSP. The SenoIris reporting workstation was also included.

The evaluation took place at the Nottingham Breast Institut`e and the system was fully integrated with NBSS 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 to use commenting positively on features such as the slim breast support table and the wider face shield. Examination times averaged at just under five-and-a-half minutes. 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.

The image quality was reported as excellent and good and the SenoIris reporting workstation was found to be easy to navigate.

A dose survey was carried out for the 2-view 2-D mode. The average mean glandular dose for the MLO view of 50-60mm breast was 1.44 mGy.

The evaluation team found the Senographe Pristina, used in 2-D mode, to be suitable for use within the NHS Breast Screening Programme.

1. Introduction

1.1 Evaluation centre

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].

1.2 Equipment evaluated

1.2.1 X-ray set and workstation

The Senographe Pristina is a full-field digital mammography unit with both 2-D and tomosynthesis capabilities. The gantry comprises of a gantry arm assembly, tube head, image receptor and breast support table. The gantry offers 3 types of movement:

1. Angulation -the tube head can be angled independently +/- 33° to allow for more accessible positioning
2. Lift – vertical movement of the complete arm assembly up and down the column
3. Rotation – rotation of the complete arm assembly.

The movements are controlled via button controls on both sides of the gantry and there is 1-touch access to pre-set rotation. There is also a foot control pedal which controls the lift movement along with the compression plate height. 2 face shields are available, universal and standard. The universal face shield remains stationary whereas the standard face shield moves with the tube head.

At the foot of the gantry is a LCD display which shows the rotation angle and mode of operation (that is, 2-D or tomosynthesis). On application of a compression force it automatically indicates the compressed breast thickness in mm, the compression force in daN and the angulation position.

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. There are 2 options that can be selected by the system according to the compressed breast thickness: 26kV Mo/Mo or 34kV Rh/Ag. A universal grid compatible with both 2-D and tomosynthesis imaging is also used.

Figure 1- Photo - Gantry

The unit uses a touch screen console with additional buttons for power, preparation and x-ray exposure and emergency stop. There is no emergency compression release button on the console. The protective lead shield was 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 2 - Photo - Console

Software MGA-1.2.0-2 and Operating system MG Helios-6.6.2-1.3 has been used throughout the evaluation.

1.2.2 Automatic Optimisation of Parameters

The Automatic Optimisation of Parameters (AOP) is an automated system which offers 4 operation modes:

1. Standard
2. Dose -
3. Standard +
4. Auto Implants

A manual option is also available.

The AOP in Standard, Standard + and Dose - modes operates using a pre-exposure to determine the attenuation parameters of the breast. A full exposure is automatically completed immediately afterwards.

The Auto Implants mode uses the mechanical thickness of the compressed breast to determine the acquisition parameters without a pre-exposure image.

This evaluation was completed using the Standard and Auto Implants Options.

1.2.3 Paddles

Four standard paddles were available for use along with additional spot compression paddles for supplementary views. Each paddle was recognised automatically when inserted into the machine.

Standard and flexible paddles were available in both 24cm x 29cm and 19cm x 23cm sizes. The smaller paddle can be offset against the centre of the breast support plate to optimise positioning. The pre-exposure sensing area is automatically reduced to the field-of-view (FOV) in use as selected by compression paddle size. In contrast to the standard paddle which is intended to remain parallel to the image receptor the flexible paddle offers a more uniform compression. It compresses in both the medial–lateral and superior-inferior plane by tilting in respect to the breast support plate.

There are spot compression paddles and a magnification table also available but these were not evaluated.

Figure 3 - Photo - Paddles

1.2.4 eContrast

All images could be presented using a choice of 6 pre-set contrast levels. Designated as eContrast 1 – 6 these levels make automatic adjustments to image brightness and contrast. They can be selected both pre and post image acquisition and a default setting can also be programmed. eContrast 3 was used as the default setting for this evaluation.

All breasts imaged on the Auto Implants mode are automatically processed on the highest contrast setting, eContrast6, if the Implant label is checked on the Patient Examination Card.

All image processing default settings can be adjusted to suit user preferences.

1.2.5 Workstation

The SenoIris in Diagnose mode is a soft-copy reporting workstation. It is suitable for reading digital mammograms and 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 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.

All images can be presented using the eContrast levels. eContrast3 was agreed as the default level for the purpose of the evaluation, but could be adjusted by the user as necessary.

The dual monitors were exchanged for a 10MP single display monitor during the evaluation.

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

Figure 4 - Photo - Workstation

1.2.6 Self compression

A self-compression device was also supplied. The device allows the patient to compress her own breast once the mammographer has reached a pre-set threshold. This device did not form part of this evaluation.

1.2.7 Integration with NBSS and PACS

The Senographe Pristina was fully integrated into the existing GE PACS system enabling the images to be reported alongside images taken from other machines. NBSS was already well established in the unit with the breast screening worklist being transferred directly to the machine. Clients were selected from the worklist and images were transferred directly to GE PACS and the SenoIris workstation. There were no setup or operational issues. The 2-D images were reported via GE PACS.

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 seperated by a single processing area. Due to the parallel digital breast tomosynthesis evalation on the same unit it was agreed to locate the machine in the symptomatic end of the imaging department.

Usual practice is for breast screening clients to be imaged in a room directly linked to the breast screening waiting room. As the Senographe Pristina was in trhe sympotmatic end of the unit initially these clients were being taken from the dedicated breast screening waiting

area down a corridor to the machine. This impacted slightly on workflow but a change in working practice, by seating the women in a different waiting area, addressed this.

1.4 Objectives

The primary objective of this evaluation was to assess the 2-D suitability of the Senographe Pristina and SenoIris within breast screening, to:

- assess the reliability of the Senographe Pristina within a busy breast screening environment
- 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
- assess how well the machine connects to and funtions with other systems such as NBSS and PACS

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]. An artefact was picked up very early in the testing routine, which was corrected by replacement of the filtration mechanism. The engineer followed GE procedures and the equipment was handed back to physics with only a short delay. Acceptance testing and commissioning continued without any further problems The machine was tested in relation to image quality and dose in the Standard and Standard and 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. Routine quality control

The quality control tests were completed daily, weekly and monthly during the evaluation period in accordance to the NHSBSP guidelines[3, 4]. The testing was completed alongside the testing of the other machines in the department and did not take any longer. The tests were completed by different mammographers each day.

3.1 Daily QC tests

A 4.5cm thick block of Perspex was imaged using the Standard setting daily. The mAs and SNR (signal-to-noise ratio) were recorded and shown in figures 5 and 6. All the recorded values lie within the recommended limits.

All the values remained within the recommended limits as demonstrated in figures 5 to 7.

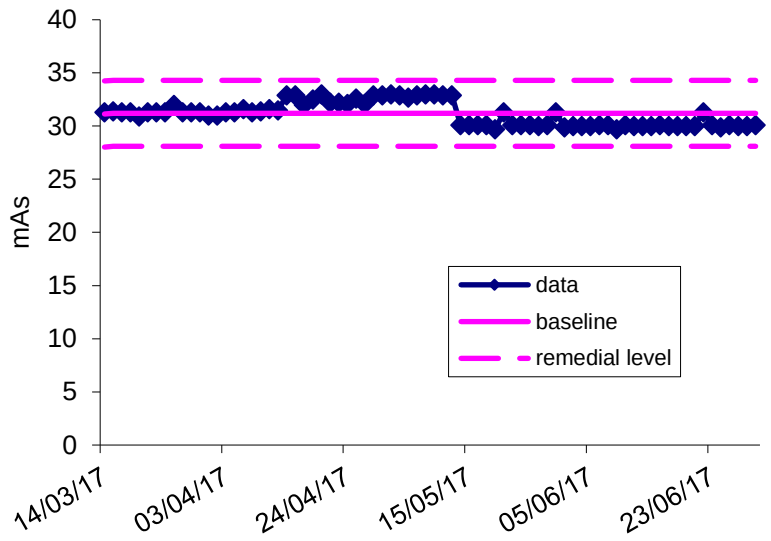

Figure 5 mAs recorded daily for 45mm of Perspex

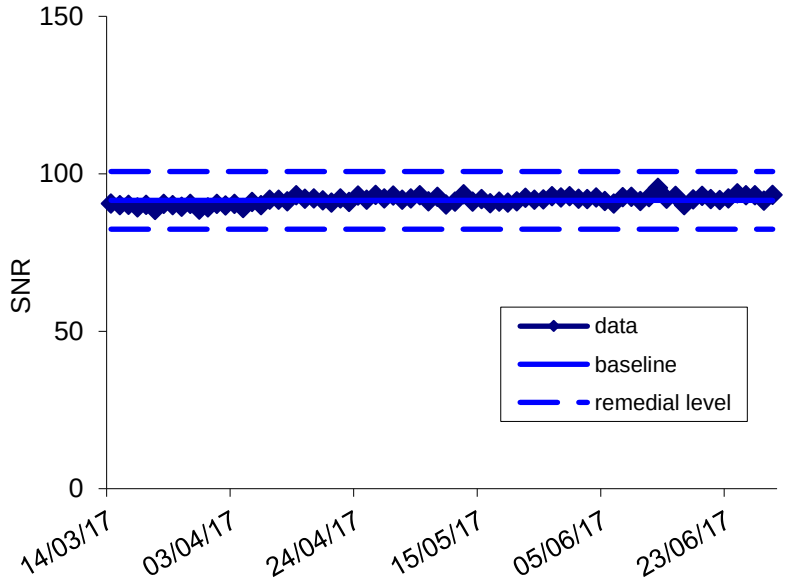

Figure 6 SNR recorded daily for 45mm of Perspex

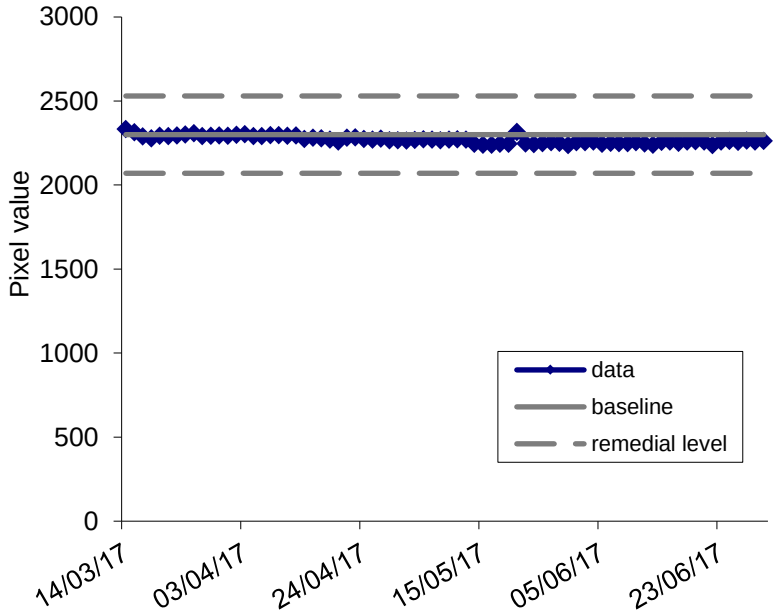

Figure 7 Mean pixel value recorded daily for 45mm of Perspex

3.2 Weekly QC tests

Weekly CNR (contrast to noise ratio) testing was completed and the results can be seen in figure 8. All the results were within the recommended limits.

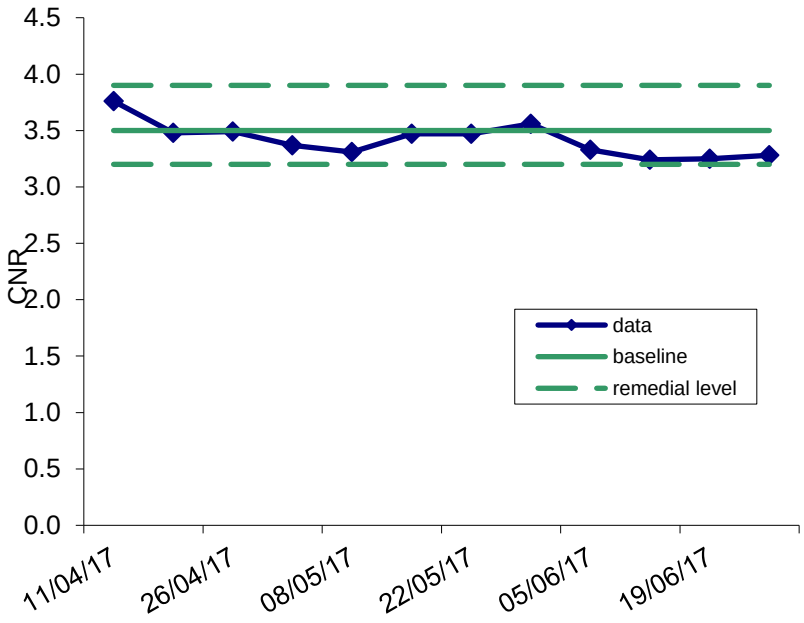

Figure 8 Weekly CNR measurements for 45mm Perspex

Uniformity was monitored by logging the visual insepction of the full field daily image. The GE uniformity tests were also performed weekly which includes both target filter combinations used clinically (MoMo and RhAg). These results are included in Appendix 3.

Figure 10 shows the results from the weekly image quality assessment measured with the TORMAM which was interpreted by 2 experienced Quality Assurance radiographers. The variation in the scoring is most likely to be due to reader subjectivity but all results were acceptable.

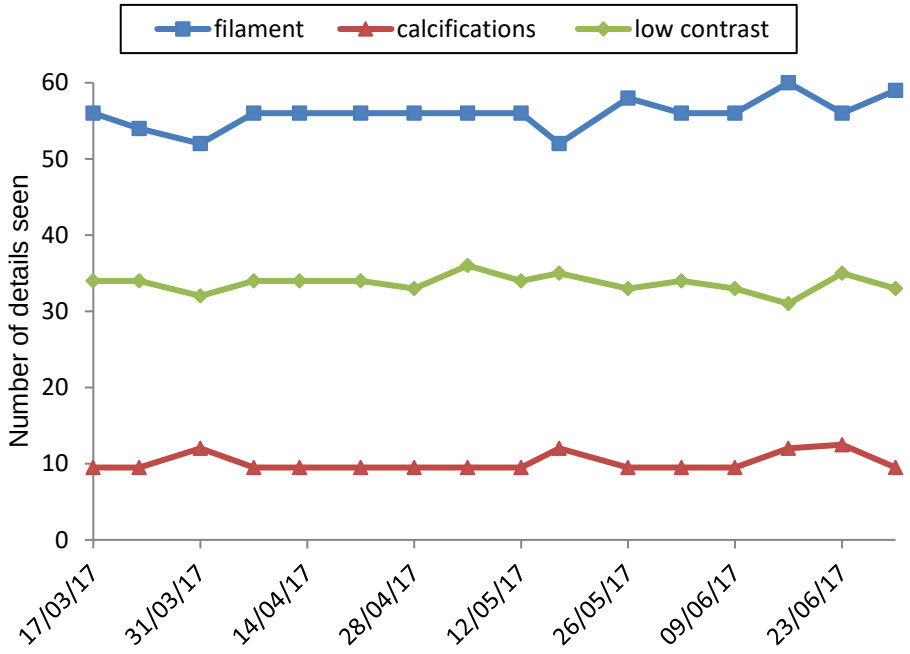

Figure 9 Weekly tests of image quality measured with TORMAM test object

3.3 Monthly QC tests

The GE QC routine was followed for the monthly test. The test now only comprises of 2 thicknesss' of 20mm and 50mm which covers the range of beam qualities used by the machine clinically.

The results can be seen in figures 10 to 13. All results remained consistent throughout the evaluation and are all within the recommended limits.

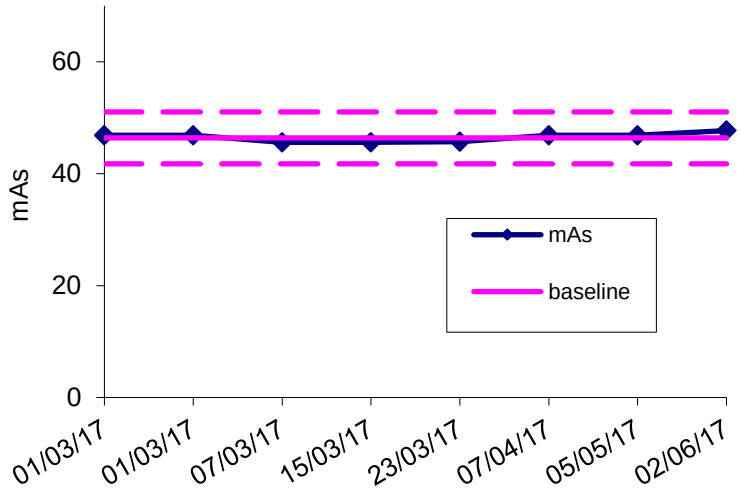

Figure 10 mAs recorded monthly for 30mm Perspex

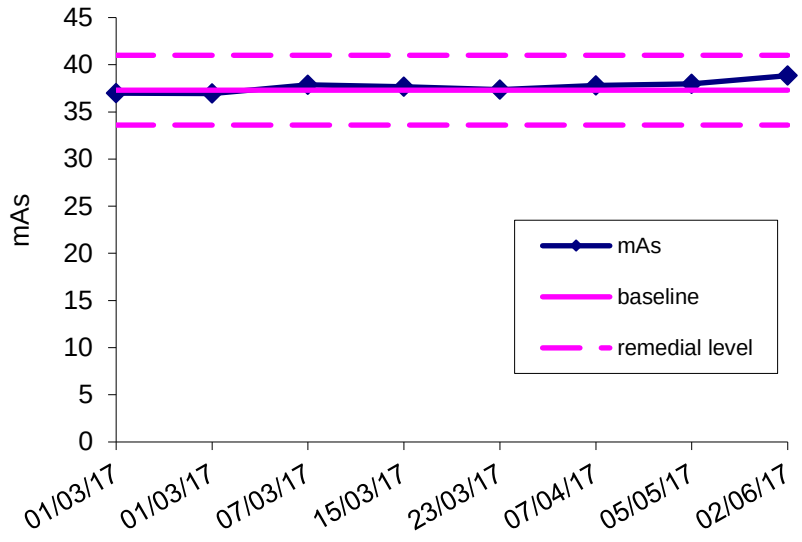

Figure 11 mAs recorded monthly for 50mm Perspex

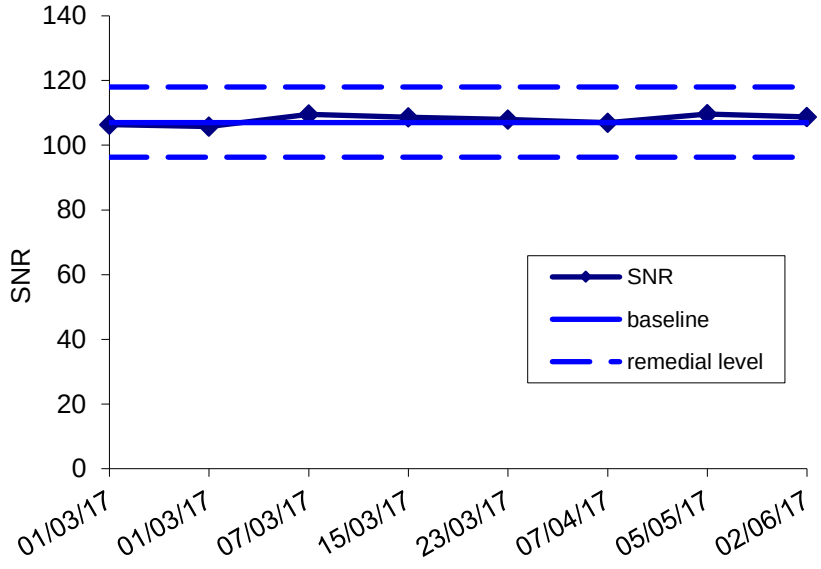

Figure 12 Monthly SNR measurements for 30mm Perspex

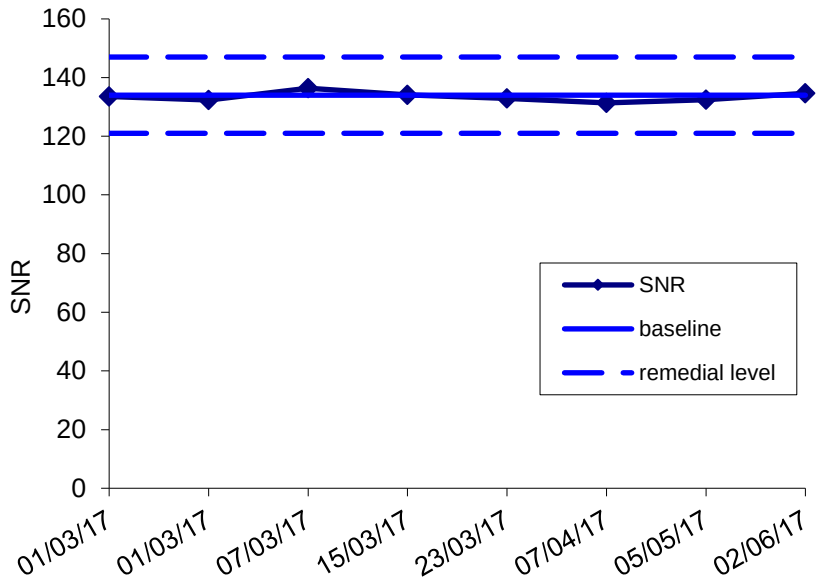

Figure 13 Monthly SNR measurements for 50mm Perspex

4. Data on screening carried out

4.1 Clinic throughput

Screening clinics were scheduled 5 days per week, but the Senographe Pristina was only used for 2-D screening four-and-a-half days per week. This was due to the requirement of digital breast tomosynthesis imaging during screening assessment clinics.

Screening clinics operated from 9am to 4.40pm on full days and from 2pm to 4.40pm on a half day. Approximately 50 appointments were booked per day and this machine was used in preference to the usual screening machines to ensure constant throughput whenever possible.

4.2 Clinical dose audit

The exposure data from 500 were recorded following the exposure. This data was entered into the NHSBSP dose calculation database.

The detailed results of the dose survey is presented in Appendix 3. The average mean glandular dose (MGD) and compressed breast thickness (CBT) are summarised in Table 1. MGDs were calculated using data published by Dance at al.[8,9]

Table 1. Average values of MGD for different components of exposure

View	Group of women	Average MGD (mGy)	Average CBT (mm)
CC	all	1.51	60
MLO	all	1.67	64
MLO	CBT 50-60mm	1.44	55

The National diagnostic reference level (DRL) for mammography is 3.5mGy mean glandular dose to a lateral oblique view of 55 mm compressed breast. The dose audit found an average dose to 50 to 60mm MLO of 1.44mGy which is well within the DRL.

4.2.1 Comparison of displayed AGD with calculated MGD

The calculated MGDs were compared with the doses displayed on the acquisition workstation. Displayed AGD was plotted against calculated MGD in figure 14. Trend lines were plotted and indicated a gradient of 0.86. Although this is within both the GE specification and IPEM guidance this was not as expected for a newly installed system.

After further investigation it became apparent that there was a discrepancy between the half value thickness measurement and the value stored on the system. An additional visit was made to site by GE and medical physics to repeat measures and investigate the discrepancy. It was concluded that the change of the filter system to remedy the artefact provided an explanation for the discrepancy. Once a calibration had been done there was much closer agreement between calculated and displayed doses.

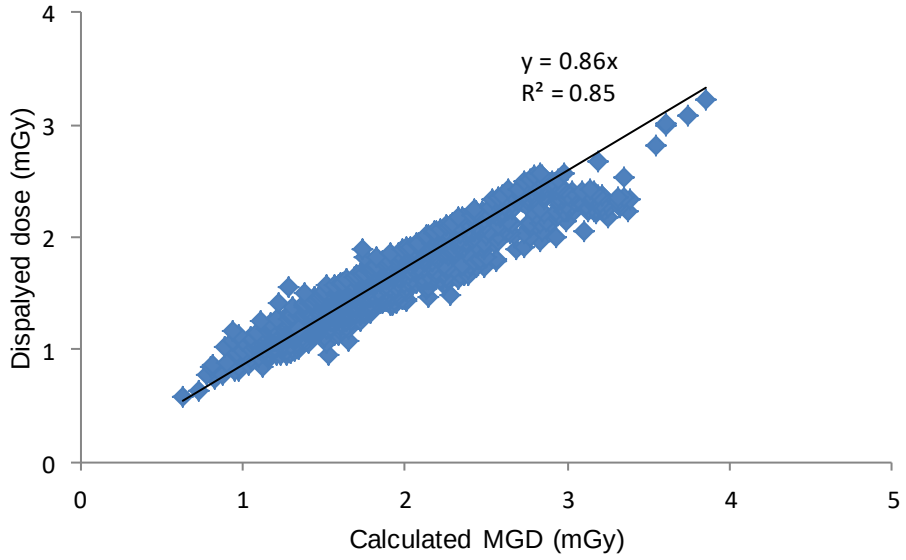

Figure 14 Displayed AGD vs Calculated MGD

A second smaller dose audit was performed to confirm this. On this smaller sample the average dose to 50 to 60 mm MLO was found to be 1.37, but there was much better agreement between the AGD and the MGD. Trend lines were plotted with a gradient of 0.96, Figure 15.

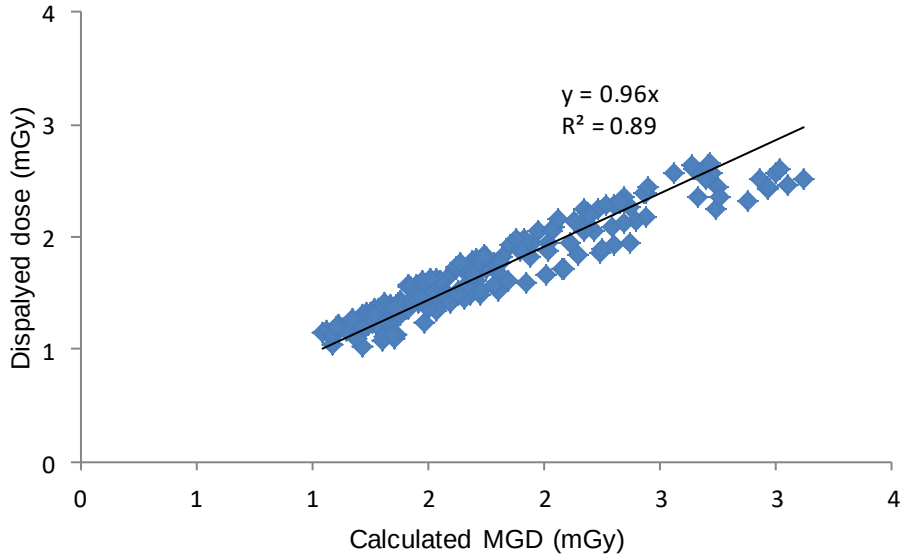

Figure 15 Displayed AGD vs Calculated MGD after recalibration

4.3 Imaging times

The mammographers were asked to record the time taken for each screening examination. The times varied from three-and-a-half minutes to 9 minutes with the average screening examination time of 5 minutes 23 seconds.

The examinations which took longer than the average time were reported to be due to:

- Eklund views being required
- assistance required with mobility or dressing
- a discussion about clinical signs and symptoms with the lady

None of the delays experienced were reported as being related to the machine functionality.

It was also reported that the exposure time was shorter than with the existing GE Senographe models.

4.4 Image quality

Image quality produced by the Senographe Pristina was assessed and evaluated by 1 consultant radiologist and 2 radiographer film readers. Their comments were recorded using NHSBSP Equipment Evaluation Form 8. 20 complete sets of mammography images were evaluated. To ensure a representative sample the sample comprised both incident and prevalent screens.

An assessment of breast density was completed by the assessors for each case. The cases were classified as fatty (0% to 33% fibro-glandular tissue), mixed (43% to 66% fibro-glandular tissue) and dense (67% to 100% fibro-glandular tissue). The cases were categorised as:

- fatty – 6 cases – 30%
- mixed – 12 cases – 60%
- dense – 2 cases – 10%

The results can be seen in Figure 16 pie chart.

All 20 sets of images were considered to demonstrate satisfactory contrast and the assessment for image processing was judged to be Excellent in 60% of the cases and as Good for the remaining 40%.

The overall diagnostic value was reported as being Excellent in 92% of the cases and Good for the remaining 8% and the diagnostic zoom was reported as being Excellent in

85% of the cases and Good for the remaining 15%. No images were reported as being poor or inadequate in any of the assessments.

The results of these assessments can be found in figures 17 to 20. All 20 sets of images were considered to have acceptable image sharpness and noise levels.

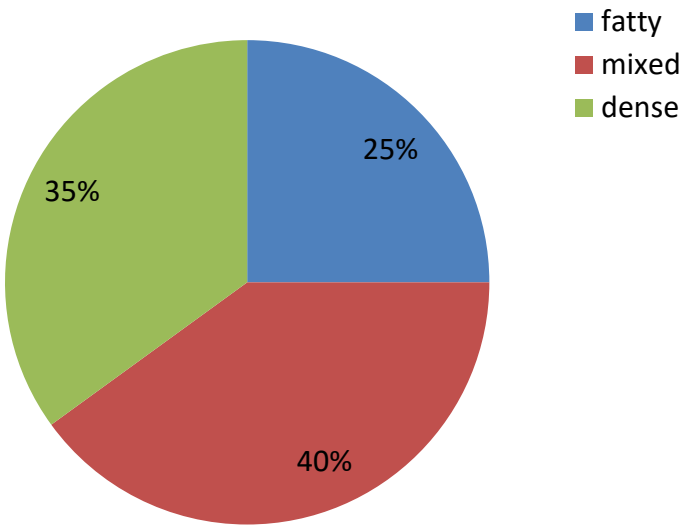

Figure 16 Readers' estimates of breast density

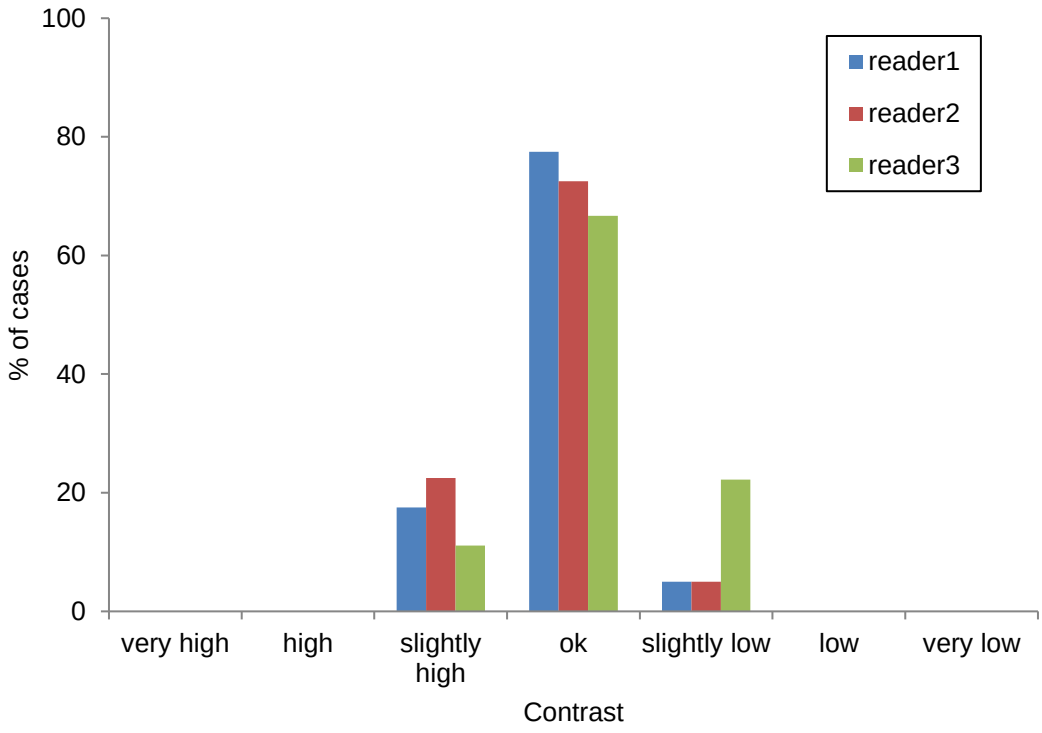

Figure 17 Readers' assessment of contrast

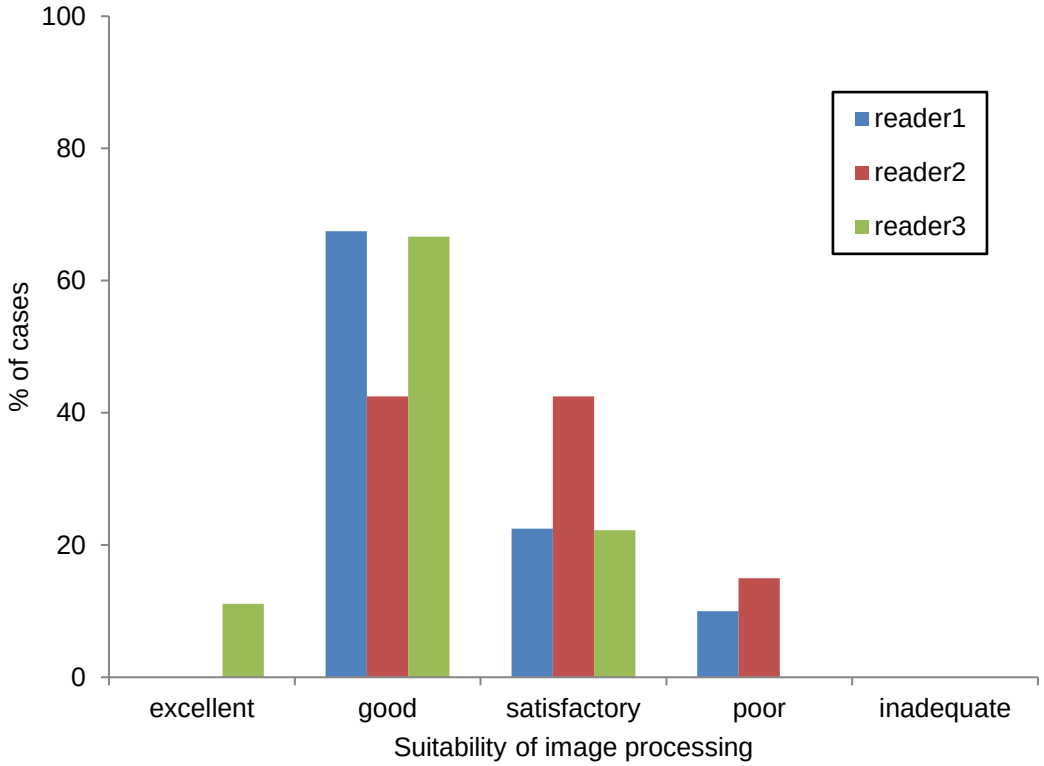

Figure 18 Readers' assessment of suitability of image processing

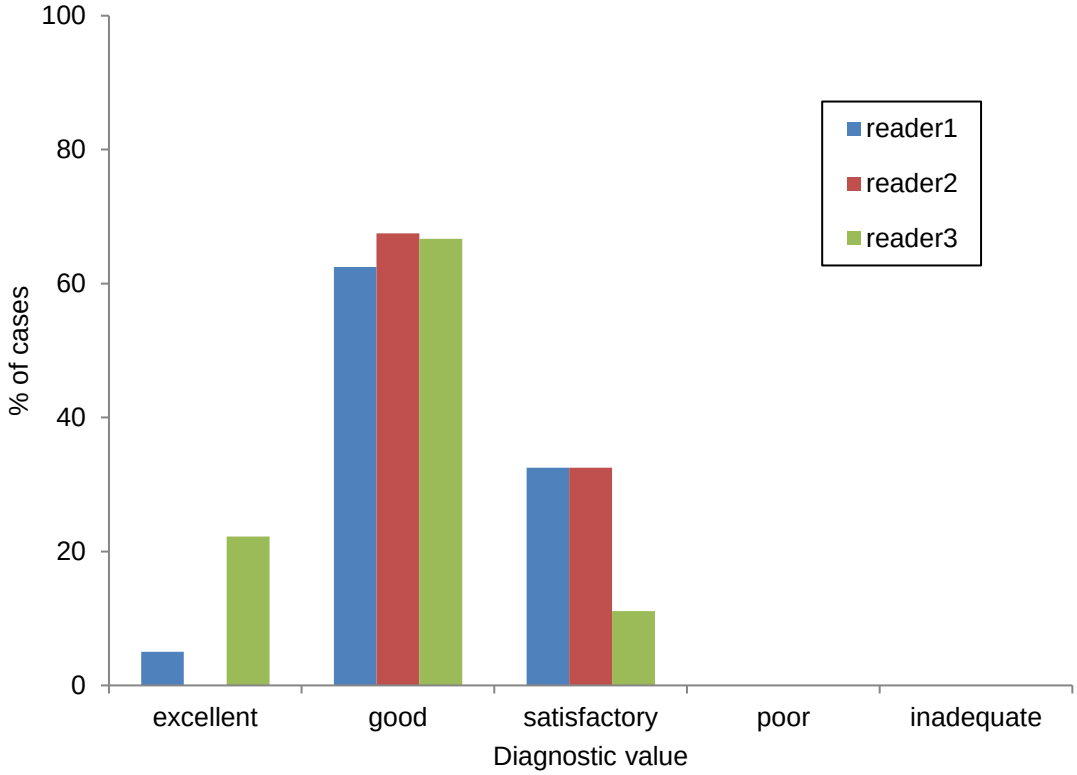

Figure 19 Readers' assessment of overall diagnostic value

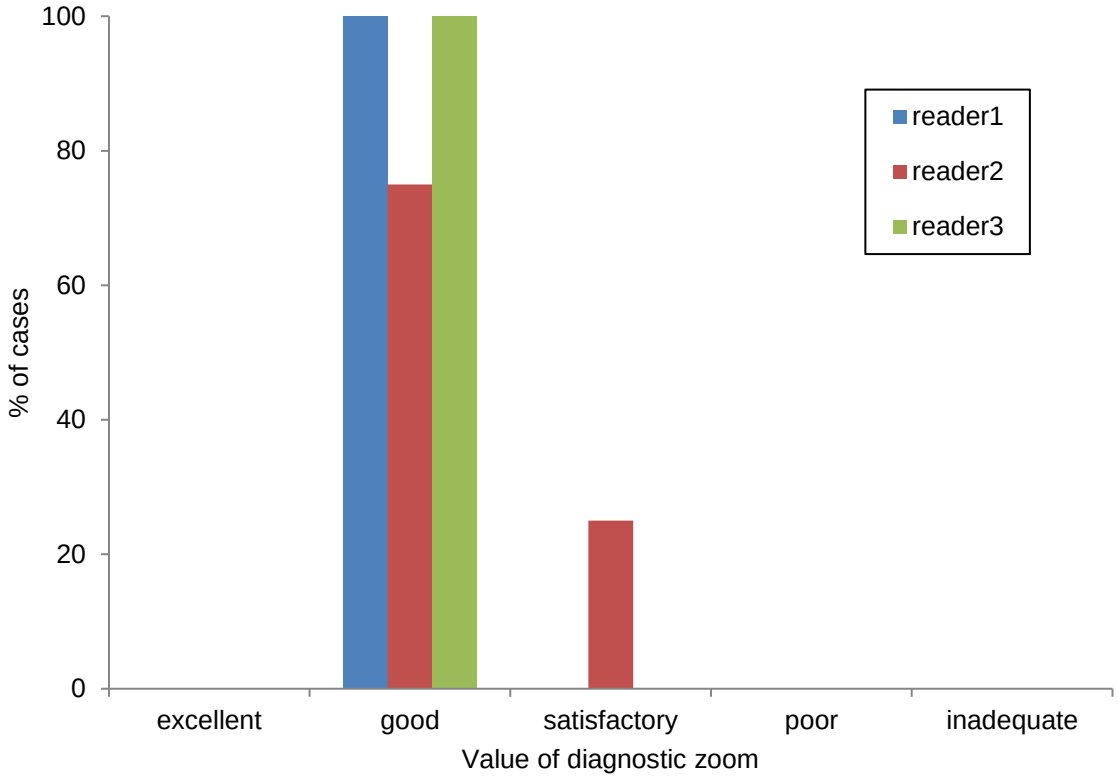

Figure 20 Readers' assessment of diagnostic zoom

5. Data on assessment conducted

The compression paddles and magnification table were not included within this practical evaluation. The digital breast tomosynthesis feature was evaluated separately.

6. 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 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.

Details of faults reported are summarized in an Appendix 4.

7. Electrical and mechanical robustness

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

8. Mammographers' comments and observations

The radiographer's and assistant practitioner's comments and observations were collected using the NHSBSP Equipment Evaluation form 6. The full details of their observations can be found in Appendix 5.

8.1 Operator's manual

Soft-copy versions of the operator manual were available on the acquisition 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. One commented that they had only seen a hard-copy extract from the manual and that they had not received any training on where to access the soft-copy version.

Of those who did access the operator manual 5 commented that it was good and 1 commented that it was average.

8.2 Training

10 members of the team received applications directly from the GE application's specialist. This was a mix of band 6 and band 7 radiography staff. This training was cascaded to the remainder of the team.

The training was rated as Excellent (4) and as Good (6) by those who were trained by GE. However, 1 commented that although the training was good that incorrect information regarding the use of the Auto Implants setting was provided.

As the use of the SenoIris workstation was mainly for use by the radiologists training was by request. The training was rated as Excellent (1) and Good (3) by the radiographer's who received it.

8.3 Ease of use of the unit

The unit was rated as Excellent (8) and Good (9) for ease of use. This was probably aided by the staff's familiarity with GE mammography units.

8.4 Exposure times

All 17 respondents indicated that the exposure times were acceptable. Two commented that the exposure times were shorter than those on the GE Senographe Essential unit.

8.5 Setting radiographic views

The support arm rotation was reported as Excellent (8) and Good (9).

The visibility of the set angle was generally acceptable being rated as Excellent (6) and Good (8) but it was also rated as average (1) and as Satisfactory (2). One respondent said that that the visibility could be better.

8.6 Setting the positioning height for the breast support table

The majority of the team found this to be acceptable rating it as Excellent (5) and Good (11). 1 radiographer reported it as Poor with the comment that the buttons are too high in the oblique position leading to over-stretching.

8.7 The machine's range of movements

The range of movements were found to be acceptable being rated as Excellent (9) and Good (8). Two commented that there is an occasional "grinding/juddering" noise when raising the machine up and down.

8.8 Effectiveness of brakes/locks

Most of the respondents rated the brakes and locks as excellent (6) or Good (9). Due to the compression paddle becoming stuck on the machine on 2 occasions the locks were also rated as Average (1) and Poor (1).

8.9 Suitability of environmental conditions for equipment use

All respondents commented that the environmental conditions for the machine use as Excellent (6) or Good (11). However it was remarked that using the unit over a longer time period and through Winter would allow for a more comprehensive response.

8.10 Compression

Overall the compression system was well received with its effectiveness being rated as Excellent (6), Good (10) and Average (1) and 1 respondent commenting that it operated with a “smooth motion”.

One stated that they found that the flexible paddle doesn’t hold the larger/heavier breast well in the oblique position in contrast to 1 commenting that they found the compression tighter than with other GE models. Another commented that the manual compression was stiff.

Several commented that the large compression paddle had often become difficult to remove and jammed on several occasions which required engineering support. One commented that the sliding and locking of the small paddle in place could also be difficult.

The visibility of the compression force on the gantry digital display was documented as Excellent (5), Good (10), Average (1) and Satisfactory (1). One commented that the display was not as clear as on the GE Senographe Essential due to the split screen making the writing smaller. One respondent noted that she found visibility difficult due to wearing bifocal glasses.

8.11 Comfort for the women

Overall the unit was deemed comfortable for the women being imaged with the respondents rating it as either Excellent (7) or Good (10). One commented that 2 women had positively commented on the curved edges of the breast support table and that this was an improvement as it was more comfortable.

Another commented that although mostly positive comments had been received from the women that as the fixed paddle was sometimes required to hold the larger breast that a small number of women had mentioned that they found this more uncomfortable.

One woman telephoned to inform us that she had suffered with painful ribs and thread veins beneath her breast since her breast screening. She said that she felt they were caused by the machine and that she has not had problems with previous mammograms.

8.12 Range of controls and indicators

14 responded that all the expected controls were present and 3 responded that there was no emergency compression release button on the console.

All 17 indicated that they found the control and indicator easy to use. One commented that they initially found it unclear which gantry button controlled the tube/bucky angulation and which 1 moved the tube to tube park position.

8.13 Choice of paddles/collimators for spot compression

Spot compression is not routinely used so was not evaluated. However, some of the radiography staff are experienced with completing these views and responded to this question. 7 staff indicated that they thought that the range of paddles available was Excellent (4) or Good (3).

8.14 Time taken for an image to appear at the acquisition workstation

The time taken for the image to appear at the acquisition workstation was considered acceptable with Excellent (6), Good (10) and Satisfactory (1) responses being noted. Eight respondents commented that they felt the image disappeared too quickly after being initially displayed which prevented initial quality control checks.

8.15 Image handling and processing facilities at the acquisition workstation

15 recorded this as Good. Two did not respond as they had not used these features.

8.16 Overall image quality at the acquisition workstation

The image quality at the acquisition monitor was recorded as Excellent (4), Good (10), Average (2) and Satisfactory (1).

One commented that they felt that the image quality was excellent due to the images being high contrast whereas 2 commented that they would prefer less contrast on the images. Two respondents commented that they felt the images always looked dark and 2 commented that the images look very different to the other GE units we use.

eContrast 3 was used as the default contrast level and no respondents commented that they had re-processed their images using a different eContrast setting to suit their individual preferences.

Overall it was agreed that you get used to the chosen default setting quickly and that it is sufficient for checking image quality.

8.17 Ease of transferring images to the reporting workstation

Screening images are set to transfer automatically to the reporting workstation. Therefore 5 respondents indicated this as non-applicable. The remaining respondents reported the ease of the process to be Excellent (4), Good (7) and Average (1). One commented that it could be quite slow when waiting for quality control images to transfer across.

8.18 Level of confidence in the Senographe Pristina

The respondents indicated their confident levels as Excellent (4) and Good (13).

8.19 Potentially hazardous areas

Whilst the majority of respondents (16) 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.

All respondents agreed that there was no hazard to the women.

8.20 Equipment cleaning

The machine was considered easy to clean by all the respondents with the responses being Excellent (10), Good (7). Due to the operator manual being soft-copy 9 commented that they did not know if there we instructions in the manual and therefore if they were compliant with infection control requirements. The remaining 8 confirmed that there were both present and compliant.

8.21 Patient and exposure information on images

All 17 agreed that all the necessary information was transferred to the images.

8.22 Patient throughput

All 17 agreed that patient throughout was not limited by the machine’s performance. One commented that it took longer to check image quality at the end of the exam due to not being able to complete an initial check between exposures. One commented that throughput was better due to faster acquisition times.

8.23 Additional comments on performance

8.23.1 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.

8.23.2 Console and acquisition monitor

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

Some of the team have commented that the screen is sometimes unresponsive to touch when selecting laterality which delays 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).

One radiographer commented that the exposure buttons are very similar to and near to the power buttons which has resulted with the machine accidently being powered down whilst preparing for a test exposure on 1 occasion.

All staff found the performance of the acquisition monitor to be acceptable. One radiographer commented that when entering details into referring physician box it is possible for the ‘delete’ bar to scroll too far out of the edit box and select the wrong patient from the worklist behind it. There was 1 incidence of this during the evaluation period.

8.23.3 AutoImplants setting

The AutoImplant setting has been reported as producing a good image quality by the radiographers. However, some of the radiographers' commented negatively on the need to re-select the AutoImplants setting prior to each exposure. This was in part due to the inconsistent touch-screen sensitivity resulting with the breast remaining compressed for a longer period than necessary.

8.23.5 Breast support table

One radiographer commented that by the Senographe Pristina having a smaller field-of-view (24cm x 29cm) that some larger breasts may require an additional image that would not have been required on previous GE models with 24cm x 30cm FOV.

8.24 General comments

A number of general comments were made on the questionnaire and overall the machine was well received by the staff who found it easy to use. Positive comments included:

> "Machine is nice to use – looks good with the pink colouring and seems less bulky for the patients."
>
> "A delightful machine."
>
> "A nice slim detector makes it easier especially for larger women."
>
> "A pleasure to use, easiness of handling."
>
> "The large faceplate is good as patients are less likely to lean to the side (CC's)."
>
> "I find the machine very easy to use."

The negative comments were mainly related to the following issues:

- the glare related to using the tube park feature
- the inconsistency with the touch-screen console
- the re-selection of the AutoImplants mode prior to each exposure
- shorter display time of the images on the acquisition monitor than on the previous GE models.

9. Readers' comments and observations

The readers' comments and observations were collected using the NHSBSP Equipment Evaluation form 9. The full details of their observations can be found in Appendix 6.

9.1 Operator's manual

A soft-copy version of the operator manual was available on the SenoIris. Only 1 of the respondents accessed the manual and reported it a Good. A hard-copy of the manual was requested and provided after the evaluation.

One respondent commented that as they already had experience with other GE workstations that she was already familiar with the main functions.

9.2 Application's training

Due to the radiology team's familiarity with GE workstations applications training was provided by the GE application's specialist on request. 3 of the radiologist's accessed this training and rated it as Good.

9.3 Adjustment of the monitors

The ease of adjustment of the height and angle of the reporting monitor was described as Excellent (2) and Average (1) with 1 respondent indicating that they did not adjust the monitor.

The adjustment of the database monitor was also reported at Excellent (2), Average (1) and as N/A (1).

9.4 Ease of use of the workstation controls

Mouse, keyboard, keypad and rollerball tracker controls were available for use with the SenoIris workstation. 3 of the respondents reported using the mouse, keyboard and keypad options and 1 respondent reported only using the mouse control. None of the reader's used the rollerball tracker. All the tested control types were considered to be easy to use:

1. Mouse – Excellent (3), Good (1)
2. Keyboard – Excellent (2), Good (1)
3. Keypad – Excellent (2), Good (1)

9.5 Image handling tools

The image handling tools available included image zoom, distance, angle and area measurements and image inversion. They were rated as Excellent (3) and Good (2).

9.6 On-screen icons

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

9.7 Post-processing image manipulation

Post-processing image manipulation was rated as Excellent (3) and Good (1). The econtrast3 setting was used as the default setting throughout this evaluation.

9.8 Reporting flow pattern

The SenoIris workstation was not used for screen reading and the images were read via the GE PACS system. However, 3 respondents commented that they did not feel that reported workflow would be negatively affected if the SenoIris was used, reporting the reporting flow pattern as Excellent (2) and Good (1).

9.9 Hanging protocols

Three of the respondents reported that they were involved with the setting up of hanging protocols and they rated the ease of this process to be Excellent (1) and Good (2). One respondent commented that it took a bit of time to learn how to set up the hanging protocols yourself, but that they could be configured to accommodate all user preferences.

Displaying images beyond the standard 4 images was found to be straightforward by the readers, being rated as Excellent (3) and Good (1). One commented that the images are easily dragged from the navigator onto the screen.

9.10 Time taken for image to display

The time taken for the image to display on the display monitor for both a New Patient selection and an In-Exam change was rated as Excellent (2) and Good (2).

9.11 Ambient lighting around workstation

None of the respondents reported there being a problem with the light from the database screen causing unacceptable ambient lighting around the workstation.

One commented that they found no issues with the inbuilt light and that the light which comes on at the bottom of the screen is very useful for completing paper work and does not interfere with image viewing

9.12 Hazards

No hazards were identified.

9.13 Level of satisfaction

The level of satisfaction with the workstation was rated as Excellent (3) and Good (1).

9.14 General comments

All additional comments were very positive:

> “I find the workstation very easy to use and intuitive. However I already use the GE workstation for our other mammography machines and it is very similar”

> “The SenoIris is very easy to use”

> “I really enjoyed using the 10Megapixel monitor – much better than 2 x 5 Megapixels”

10. Confidentiality

The evaluation was fully compliant with the NHS Cancer Screening Programmes Confidentiality and Disclosure Policy.[5]

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

Training was provided by the GE applications specialist. Half of the mammography team received this training. This training was then cascaded to the rest of the team over a 2-week period. The training took 1 day and covered all aspects of machine use and quality control.

As the team were already familiar with using a GE workstation training for the SenoIris was by request.

13. Discussion

13.1 Equipment

Overall the Senographe Pristina was well received by the mammography team. They said that it was aesthetically pleasing and easy to handle, commenting positively on features such as the slim breast support table and wider face-guard.

Many mammographers agreed that the separate angulation of the tube head into a tube park position has potential ergonomic benefits for the 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 have confirmed that they would use this feature regularly.

The sensitivity of the touch-screen console was inconsistent with some of the team commenting that selecting laterality could sometimes be problematic. This was said to be especially noticeable when using the AutoImplants mode which requires re-selection prior to each exposure along with laterality selection. Several commented that they would prefer the AutoImplants setting to remain selected until manually de-selected. Unfortunately the re-selection of the AutoImplants setting prior to each exposure was not covered in the training and there was 1 instance of a necessary early termination of exposure due to the console defaulting back to the Standard setting.

The sensitivity of the console was improved by cleaning the screen twice a day.

The mammographers also reported that the acquired images did not remain on the acquisition monitor for as long as on the previous GE model. This prevented the usual practice of completing initial image quality checks during the examination in addition to a full assessment at the end. However, completing image quality checks only at the end of the examination was not reported as adding any significant time to the overall examination length.

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.

The SenoIris workstation was found to be easy to navigate and the ability to setup individual user preferences was well received. Although the workstation was not used for screen reading during this evaluation period the single 10MP monitor was considered to be an improvement to the dual 5MP display option.

13.2 QA testing

Acceptance testing and commissioning was completed post installation in accordance the NHSBSP protocols[2]. The machine was tested in relation to image quality and dose in the Standard and Standard + AOP modes, was found to be in acceptable ranges and was reported as satisfactory for clinical use.

Throughout the evaluation the Quality Control testing was completed on a daily, weekly and monthly basis in accordance with NHSBSP guidelines [3,4]. All test results were within accepted limits with the exception of a single mean pixel value. Any variations with the TORMAM scoring were considered most likely to be due to reader subjectivity. No problems with completing the tests were reported.

13.3 Clinical assessment

Image quality for a set of 20 randomly selected was reviewed by a team of film readers. The image quality was assessed as being satisfactory for all images with the diagnostic value for 92% of the cases being excellent. No images were considered to be poor or inadequate demonstrating that the Senographe Pristina performs well for all breast compositions.

13.4 Mammographer and reader comments

The radiographers were generally satisfied with the training they received although there were some concerns about accessing to the soft-copy operator’s manual. A small number of mammographers expressed some negative comments about problems they had experienced relating to using the tube park position and the sensitivity of the touch-screen console. However, overall the machine was found to be easy to use and was well received.

The readers were satisfied with the training they received and with the functionality of the workstation. Only positive comments were received.

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 environment and met all the key throughput requirements of the service.

The image quality was deemed to be of a suitable standard for image evaluation, and the eContrast settings were well received. The SenoIris was found to be easy to use, but this may have been in part due to the radiologists' familiarity with GE workstations.

Overall the mammographers found the Senographe Pristina pleasant and easy to use but some would welcome improvements to the touch-screen console sensitivity and the tube park function.

Mean glandular doses were found to be well below the national DRL.
The evaluation team found the Senographe Pristina, used in 2-D mode, to be suitable for use within the NHS Breast Screening Programme.

References

1. Baxter G, Jones V, Milnes V et al. *Guidance notes for equipment evaluation of imaging equipment for mammographic screening and assessment*. (NHSBSP Equipment Report 1411). Sheffield: NHS Cancer Screening Programmes, 2014

2. Kulama E, Burch A, Castellano I et al. *Commissioning and routine testing of full field digital mammography systems*. (NHSBSP Equipment Report 0604, version 3). Sheffield: NHS Cancer Screening Programmes, 2009

3. Baxter G, Jones V, Milnes V, Oduko J, Phillips, Sellars S, Vegnuti Z. *Routine quality control tests for full field digital mammography systems, 4th Edition*. (NHSBSP Equipment Report 1303). Sheffield: NHS Cancer Screening Programmes, 2013

4. National Quality Assurance Coordinating Group for Radiography. *Quality Assurance guidelines for mammography: Including radiographic quality control*. (NHSBSP Publication No 63). Sheffield: NHS Cancer Screening Programmes, 2006

5. McCorry P, Jones A. Confidentiality and disclosure policy, version 4. Sheffield: NHS Cancer Screening Programmes, 2011

Appendix 1: Physics reports

The commissioning report

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	**03 March 2017**
Reason for testing	**Commissioning**
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.
C2	**AOP Mode**
Comment	Image quality and dose are within acceptable ranges for both STD and STD+ AOP modes.

References

NHSBSP0604v3
Commissioning and routine testing of full field digital mammography systems, NHSBSP Equipment report 0604, Version 3, April 2 009
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

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kV calibration

Test	Reference	Limiting values	Result			Acceptable?	Comments
				B MoMo	B RhAg		
Max kV error in useful clinical range (25-32 kV)	IPEM89 5.6.7	Remedial: ±1kV	Maximum error:	0.3	0.1	Acceptable	-
kV with set kV=29		Suspension: ±2kV	kV at Mo29 and Rh34 set:	28.7	34.1		

HVL and filtration

MoMo, 30kV, CP out		<0.3 or >0.4 mmAl (for MoMo, 30kV)	0.35			Acceptable	-

Tube output

Output repeatability - MoMo - compression plate in	IPEM89 5.6.9	>±5% mean	0.3%			Acceptable	-
µGy/mAs @ 50cm (MoMo)		>120µGy/mAs @50cm	192			Acceptable	
Variation of output with tube voltage - MoMo		The relationship between kV and output should be near linear	OP@29kV	53.3	µGy/mAs at 1m	Acceptable	
Variation of output with tube voltage - RhAg			OP@34kV	56.5	µGy/mAs at 1m	Acceptable	
Variation with mAs - broad focus		±10%	0.1%			Acceptable	

Safety checks

Mechanical and safety function	IPEM89 5.3					Acceptable	-

Compression

Maximum	IPEM89 5.6.5	<130N, >200N	Force =	200	at set maximum -20	Acceptable	-
Thickness gauge accuracy		±5mm	Maximum error =	2	mm	Acceptable	-

Focal spot

					Length	Width		
Broad focus	IPEM89 5.6.6		Mo	Broad	0.38	0.44	Acceptable	-
			Rh	Broad	0.38	0.41		

Alignment

Alignment of x-ray field to the light field	NHSBSP0604v3 3.1.1	**Remedial:** Misalignment >5mm along any edge		CWE	Nipple edge	Left	Right	Acceptable	-
			BF,24x30,-,Mo	-4	-1	-1	-3		
			BF,24x30,-,Rh	-3	0	-1	-2		
			BF,18x24,C,Mo	-3	-1	-2	-4		
			BF,18x24,C,Rh	-3	-1.5	-2	-3		
			BF,18x24,L,Mo	-4	0	0	-5		
			BF,18x24,L,Rh	-3	0	0	-5		
			BF,18x24,R,Mo	-4	-1	-2	-2		
			BF,18x24,R,Rh	-3	-2	-3	-2		
Alignment of x-ray field to imaged field / detector	NHSBSP0604v3 3.1.1	**Remedial:** >5mm or <0mm overlap of image by x-ray field on all sides **Suspension:** >10mm overlap or >2mm unexposed border along CW edge with respect to image >10mm overlap along left or right edge with respect to image		CWE	Nipple edge	Left	Right	Acceptable	-
			BF,24x30,-,Mo	3	4	4	5		
			BF,24x30,-,Rh	4	4	3	5		
			BF,18x24,C,Mo	3	3	3	4		
			BF,18x24,C,Rh	3	2.5	3	5		
			BF,18x24,L,Mo	2	3	4	4		
			BF,18x24,L,Rh	3	3	4	4		
			BF,18x24,R,Mo	3	5	4	5		
			BF,18x24,R,Rh	4	2	3	5		
Separation between image edge and the chest wall edge of the breast support platform	NHSBSP0604v3 3.1.3	**Remedial:** > 5mm between edge of the image and front edge of the BST		24x30	-5	mm		Acceptable	-

Detector Performance

Test	Reference	Limiting values	Result					Acceptable?	Comments
Uniformity	NHSBSP0604v3 3.2.3	Maximum deviation from centre mean > 10%		CW-L	CW-R	Back-L	Back-R	Acceptable	-
		24x30	MoMo28	0%	0%	8%	8%		
			RhAg34	1%	0%	6%	5%		
		Fine focus	MoMo28	4%	3%	7%	5%		
			RhAg34	3%	2%	5%	4%		
Artefacts and dead pixel dropout	NHSBSP0604v3 3.2.4	See manufacturer's spec	Artefacts?						-
Detector response	NHSBSP0604v3 3.2.5	Detector reference air kerma >20% change from commissioning value	RhAg34	Measured	Baseline	%change		Baselines	-
				85.0	-	-			
		SNR change >10%		111	-	-			
Detector resolution: Square wave contrast transfer factor	NHSBSP0604v3 3.2.6.1	**Remedial**: Measured SWCTF(f) > 10% change from commissioning	MoMo26, 14mAs	Bars parallel to a-c axis				Baseline	-
				Measured	%baseline				
			SWCTF(1)	0.394	-				
			SWCTF(4)	0.149	-				
Spatial discontinuity and resolution homogeneity	NHSBSP0604v3 3.2.7	Any evidence of discontinuities	No Evidence of discontinuities					Acceptable	-
Image retention	NHSBSP0604v3 3.2.8	Image retention factor > 0.3	Image retention factor = -0.01					Acceptable	-

AEC

Test	Reference	Limiting values	Result					Acceptable?	Comments
AEC repeatability	NHSBSP0604v3 3.3.1	**Remedial**: Max dev in mAs from mean: >5% **Suspension**: Max dev in mAs from mean: >10%	Max deviation =		0%			Acceptable	-
AEC performance - Automatic mode	NHSBSP0604v3 3.3.2	CNR: ±10% baseline	STD	Perspex thickness	TFkV, mAs	CNR	%baseline	Baseline	-
				2	MoMo26, 23.2	25.9	-		
				3	MoMo26, 51.9	25.3	-		
				4	RhAg34, 27.6	19.1	-		
				4.5	RhAg34, 32.1	18.0	-		
				5	RhAg34, 38.8	16.6	-		
				6	RhAg34, 57	14.7	-		
				7	RhAg34, 87.1	13.5	-		
		CNR: ±10% baseline	Dose-	Perspex thickness	TFkV, mAs	CNR	%baseline		
				2	MoMo26, 16.2	22.3	-		
				3	MoMo26, 36.4	21.2	-		
				4	RhAg34, 20.9	16.9	-		
				4.5	RhAg34, 24.8	15.9	-		
				5	RhAg34, 29.9	14.9	-		
				6	RhAg34, 44.4	13.0	-		
				7	RhAg34, 68.9	12.1	-		
		CNR: ±10% baseline	Standard+	Perspex thickness	TFkV, mAs	CNR	%baseline		
				2	MoMo26, 23.6	27.1	-		
				3	MoMo26, 54.6	27.5	-		
				4	RhAg34, 38.2	22.3	-		
				4.5	RhAg34, 50.9	21.6	-		
				5	RhAg34, 62.8	21.0	-		
				6	RhAg34, 89.5	18.9	-		
				7	RhAg34, 107.8	14.7	-		
			Mag 1.5 STD	Perspex thickness	TFkV, mAs	CNR	%baseline		
				2	MoMo29, 19.9	29.9	-		
				4	RhAg34, 32.8	20.2	-		
				6	RhAg34, 59.1	14.5	-		
			Mag 1.8 STD	Perspex thickness	TFkV, mAs	CNR	%baseline		
				2	MoMo29, 20.8	29.6	-		
				4	RhAg34, 35	22.1	-		
				6	RhAg34, 61.9	15.3	-		
			Implants	Perspex thickness	TFkV, mAs	CNR	%baseline		
				2	MoMo26, 32.4	31.9	-		
				4	RhAg34, 40.1	19.3	-		
				6	RhAg34, 81.5	12.8	-		
Exposure time	EU2006 2.4.3	All clinical modes with standard (4.5cm) thickness			STD	Dose-	Standard+	Acceptable	-
		Acceptable < 2s, Achievable <1.5s	Exp time 4.5cm		0.59	0.46	0.94		
	IPEM89 5.7.3	>1s for 4cm perspex	Exp time 4cm		0.51	0.39	0.71		

		>4s for 6cm perspex	Exp time 6cm	1.06	0.82	1.66		

Test	Reference	Limiting values	Result	Acceptable?	Comments
Image Quality					
Threshold contrast visibility - CDMAM	NHSBSP0604v3 3.5.1	Threshold gold thickness 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, 1.46mGy STD n/a 0.08 0.12 0.24 1.07 RhAg34, 58mAs, 2.34mGy STD+ n/a 0.06 0.10 0.21 0.79	Acceptable	-
Regular IQ tests - TORMAX	NHSBSP0604v3 3.5.1	**Remedial**: No of details detected should meet NHSBSP standards for film-screen systems & be unchanged from baseline Target / Min std / Remedial / Suspension 6mm <0.8% <1.2% <1.4% 0.5mm <3% <5% <8% 0.25mm <5% <8% <11%	MoMo28, 100mAs 0.5% 3% 6%	Acceptable	-
Regular IQ tests - TORMAM	NHSBSP0604v3 3.5.1	**Remedial**: Visibility of details should be unchanged form baseline	RhAg34, 31mAs STD 100 RhAg34, 47mAs STD+ 104	Baseline	-
Dose					
Dose to the standard breast	NHSBSP0604v3 3.6.1 EU2006 2.5.1	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	STD / Dose- / Standard+ 0.64 / 0.44 / 0.65 1.08 / 0.76 / 1.14 1.28 / 0.97 / 1.77 1.39 / 1.08 / 2.21 1.56 / 1.20 / 2.53 2.03 / 1.58 / 3.19 2.72 / 2.15 / 3.36	Acceptable	-

Summary of Results of Automatic CDMAM reading

physics ID	**NGPE**
Local ID / location	Room 4
Centre	Nottingham
Digital make	GE
Digital model	Pristina
Date	03 March 2017
manufacturer of X-ray set	
model of X-ray set	
model of CR plate	

unprocessed		
added px	4	cm
spacer	0	cm
mode	STD	
kV	34	
target	Rh	
filter	Ag	
mAs	36.2	
MGD	1.46	mGy

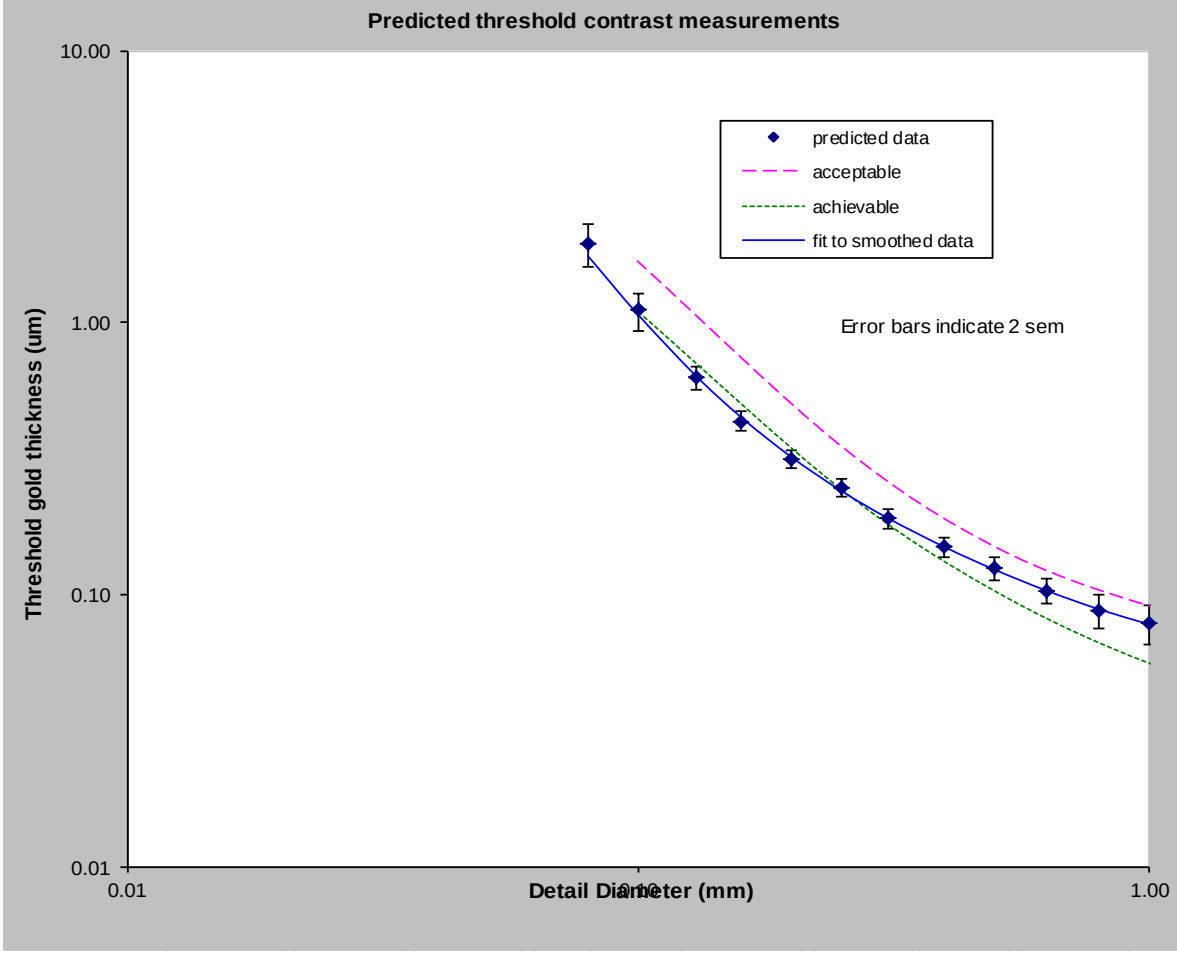
Comments: **SN 1074**

Predicted CD curve for human observer

Diameter (mm)	threshold gold thickness	2 sem	fitted curve
1.00	**0.08**	**0.012**	**0.08**
0.80	0.09	0.012	0.09
0.63	0.10	0.010	0.10
0.50	**0.13**	**0.012**	**0.12**
0.40	0.15	0.012	0.15
0.31	0.19	0.015	0.19
0.25	**0.25**	**0.019**	**0.24**
0.20	0.32	0.026	0.32
0.16	0.43	0.036	0.45
0.13	0.63	0.064	0.64
0.10	**1.11**	**0.172**	**1.07**

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	**0.08**	**0.08**	**0.012**
0.5	0.15	0.103	**0.13**	**0.12**	**0.012**
0.25	0.352	0.244	**0.25**	**0.24**	**0.019**
0.1	1.68	1.1	**1.11**	**1.07**	**0.172**



Summary of Results of Automatic CDMAM reading

physics ID	**NGPE**
Local ID / location	0
Centre	Nottingham
Digital make	GE
Digital model	Pristina
Date	03 March 2017
manufacturer of X-ray set	
model of X-ray set	
model of CR plate	

unprocessed		
added px	4	cm
spacer	0	cm
mode	STD+	
kV	34	
target	Rh	
filter	Ag	
mAs	58.0	
MGD	2.34	mGy

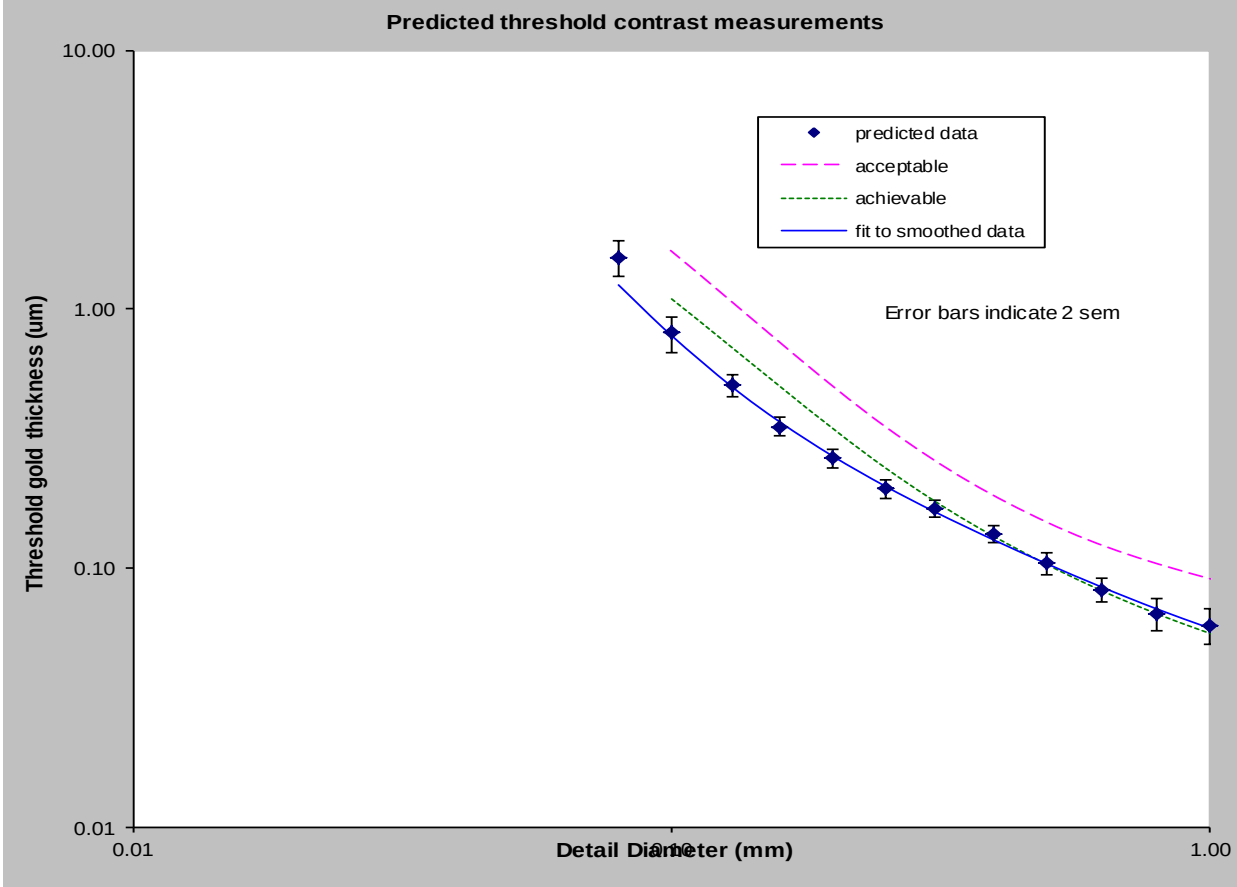
Comments: **s/n 1074**

Predicted CD curve for human observer

Diameter (mm)	threshold gold thickness	2 sem	fitted curve
1.00	**0.06**	**0.009**	**0.06**
0.80	0.07	0.010	0.07
0.63	0.08	0.008	0.08
0.50	**0.10**	**0.010**	**0.10**
0.40	0.14	0.010	0.13
0.31	0.17	0.013	0.16
0.25	**0.20**	**0.017**	**0.21**
0.20	0.26	0.022	0.27
0.16	0.35	0.029	0.36
0.13	0.51	0.050	0.50
0.10	**0.81**	**0.127**	**0.79**

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	**0.06**	**0.06**	**0.009**
0.5	0.15	0.103	**0.10**	**0.10**	**0.010**
0.25	0.352	0.244	**0.20**	**0.21**	**0.017**
0.1	1.68	1.1	**0.81**	**0.79**	**0.127**



Appendix 2: Clinical breast dose survey

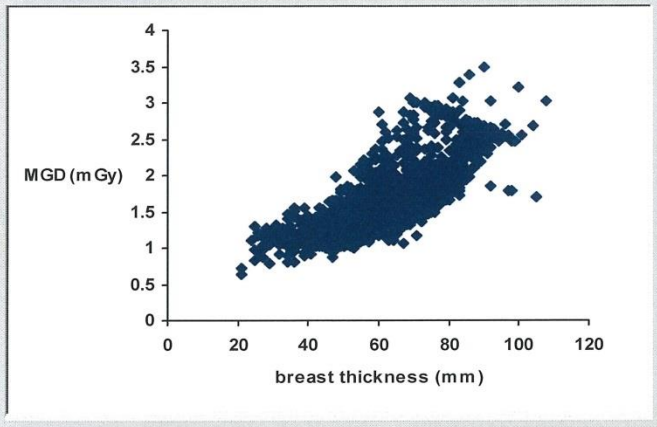
NHSBSP Breast Dose Survey

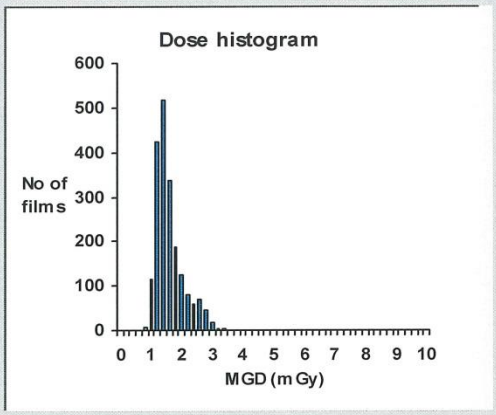
Survey No:	1010
Centre:	Nottingham
Date of first exam:	
Date of last exam:	07/06/2017
X-ray make	GE
Model:	Pristina
Local id:	NGPE
Installation:	fixed
kV mode:	auto
standard kV:	0
Routine/age trial:	routine screening
24x30 cassettes available:	☑
Block mAs:	
Block density:	
physics service	Northampton
Physicist	V Jones

Processor make:	digital (2D)
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	PMMA thickness:	45mm
auto/AEC setting:	STD	MGD mAs:	32.1
kV set:	34	HVL:	0.570
target:	Rh	MGD:	1.39
filter:	Ag	film density:	





Count of films

view	main films	Extra films
CC	980	8
OB	979	16

Summary of X-ray factors selected

Anode	Filter	kV	films
Mo	Mo	26	38
Rh	Ag	34	1948

Average doses for main films

view	No of films	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	980	0.78	3.27	1.51	60
OB	979	0.63	3.50	1.67	64

Average doses per screening examination

	No of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
Two view	493	1.15	11.13	3.22

Average dose for 50-60mm thick breasts

View	No of films	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
OB	222	1.44	0.03	56

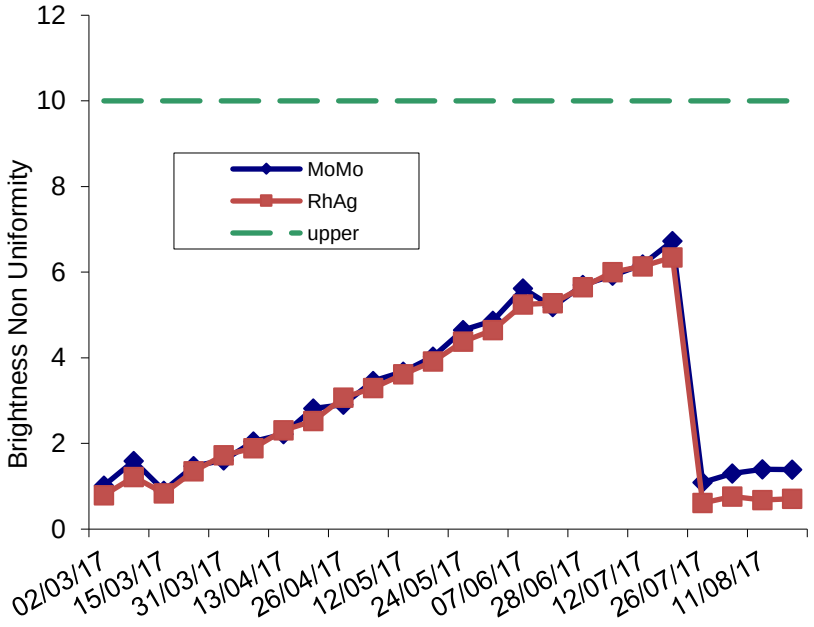
Appendix 3: Manufacturer specific QC tests

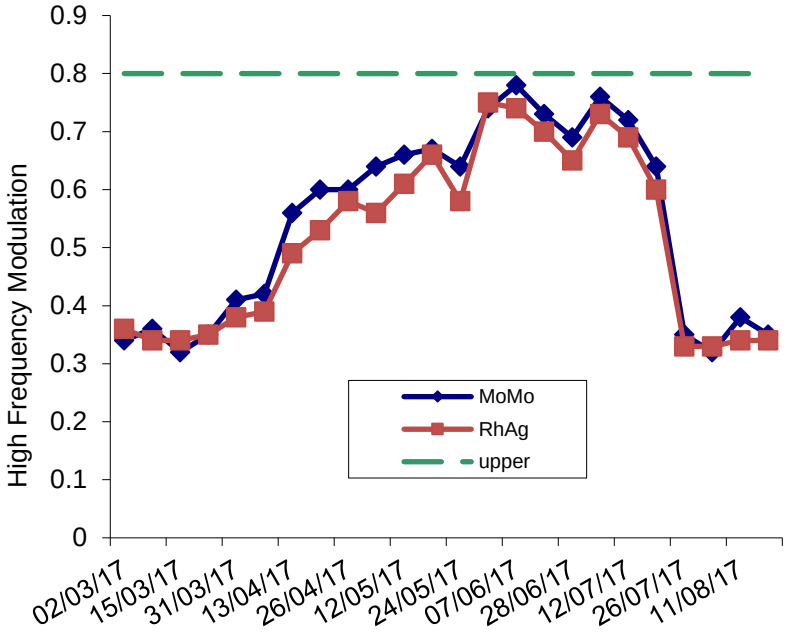
A3.1 Image uniformity and bad pixels (flatfield) test

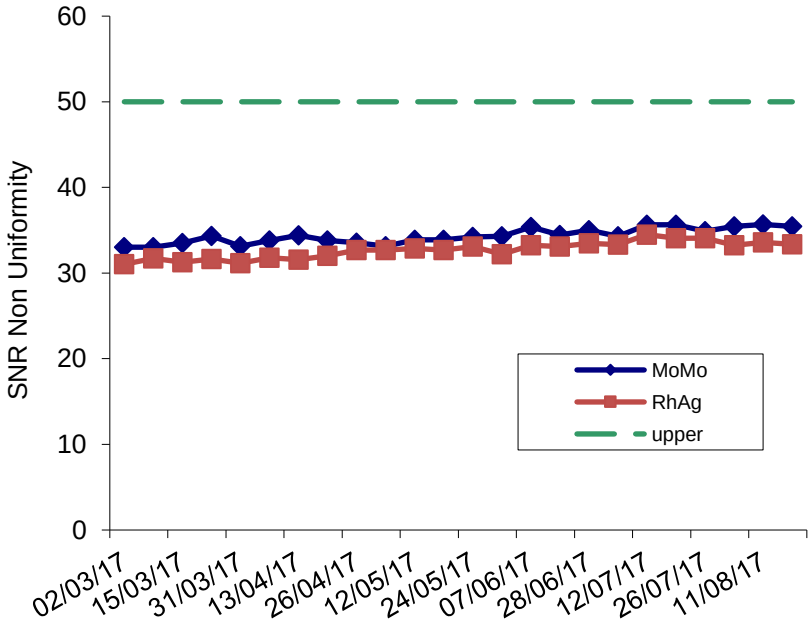
The purpose of this test is to check the uniformity of signal and noise over the entire image receptor and also to check for the presence of uncorrected defective detector elements.

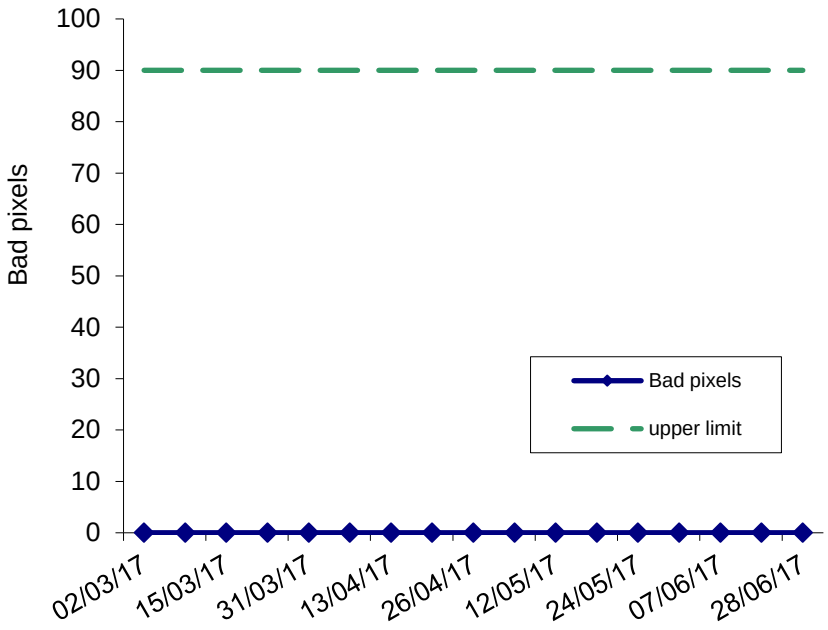
The 24x29cm phantom used was supplied by GE and the test was performed in the following configurations: 2D contact Mo/Mo (grid) and 2D contact Rh/Ag (grid). Results for Brightness Non-Uniformity, SNR Non-Uniformity and High Frequency Modulation are shown below and include the period after the evaluation. The results were all within GE limits. The decrease in BUU and HFM corresponded to software update in July 2017, it then remains stable.

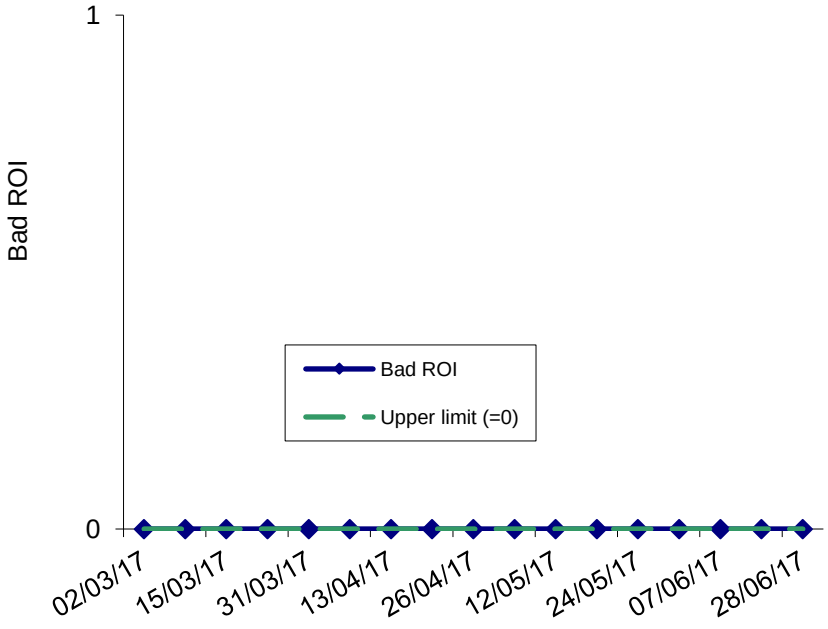
Results for Bad Pixel and Bad ROI are also shown and are within limits.




High Frequency Modulation
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
MoMo
RhAg
upper
02/03/17
15/03/17
31/03/17
13/04/17
26/04/17
12/05/17
24/05/17
07/06/17
28/06/17
12/07/17
26/07/17
11/08/17


SNR Non Uniformity
60
50
40
30
20
10
0
MoMo
RhAg
upper
02/03/17
15/03/17
31/03/17
13/04/17
26/04/17
12/05/17
24/05/17
07/06/17
28/06/17
12/07/17
26/07/17
11/08/17

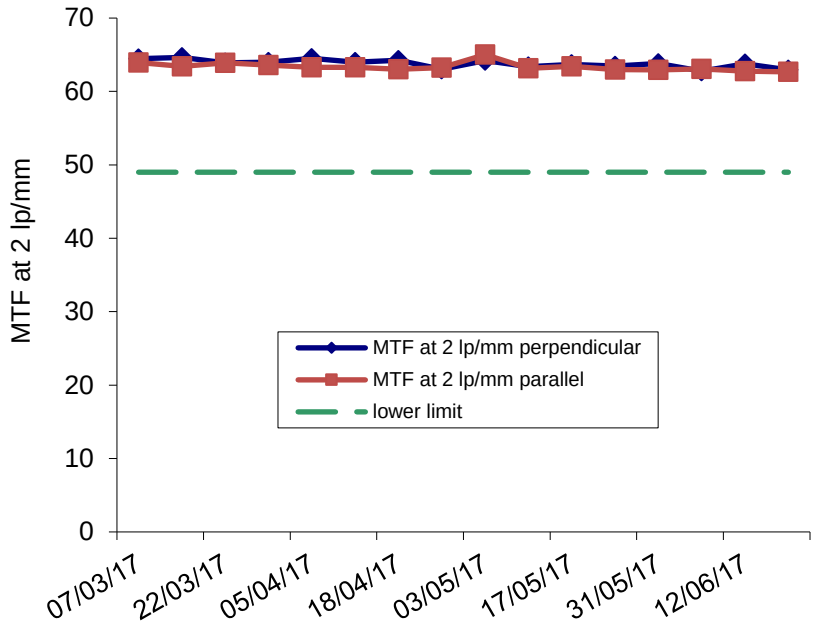

Bad pixels
100
90
80
70
60
50
40
30
20
10
0
Bad pixels
upper limit
02/03/17
15/03/17
31/03/17
13/04/17
26/04/17
12/05/17
24/05/17
07/06/17
28/06/17

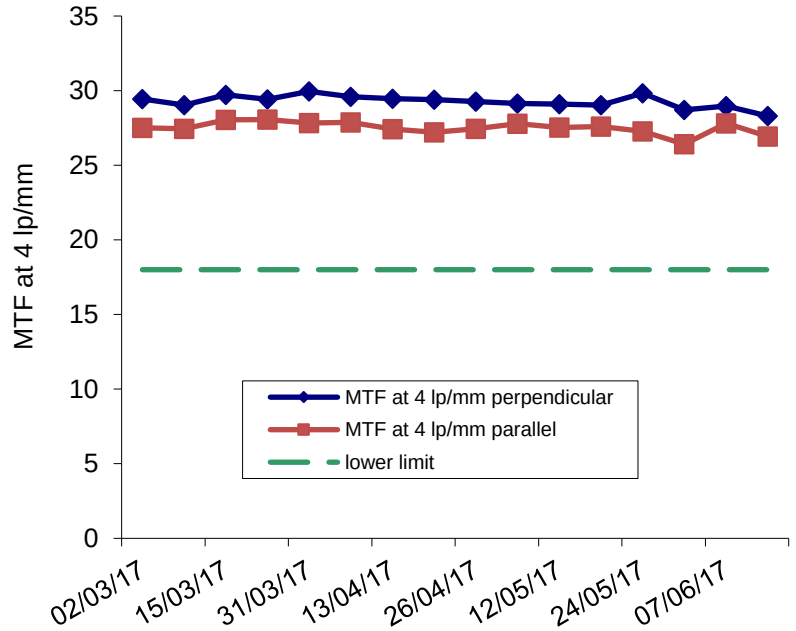

Bad ROI
1
0
Bad ROI
Upper limit (=0)
02/03/17
15/03/17
31/03/17
13/04/17
26/04/17
12/05/17
24/05/17
07/06/17
28/06/17

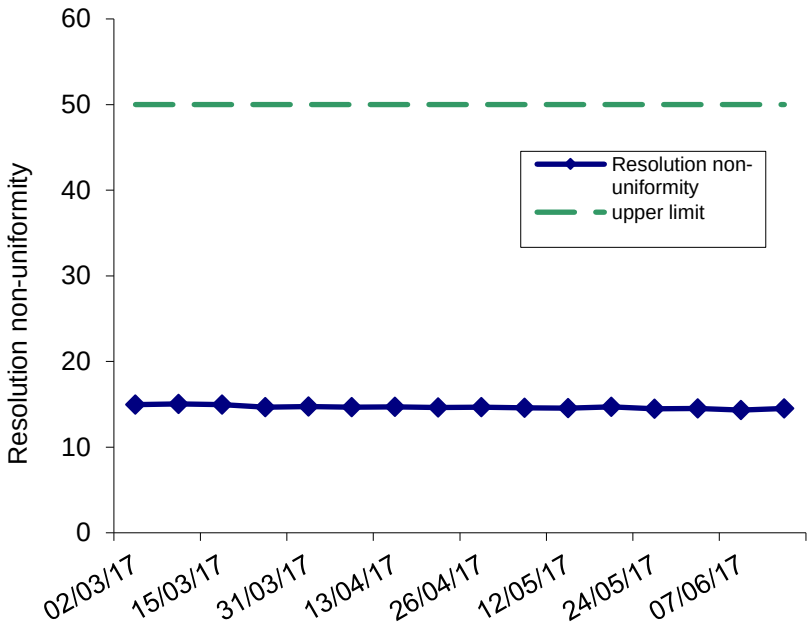
A3.2 GE IQST test

This test is designed to check that the MTF (Modulation Transfer Function) values at 2 lp/mm and 4 lp/mm and the resolution uniformity over the entire image receptor conforms to GE specifications.

The IQST phantom is supplied by GE. The test is performed weekly and results are all within limits and shown below.






60
50
40
30
20
10
0
Resolution non-uniformity
Resolution non-uniformity
upper limit
02/03/17
15/03/17
31/03/17
13/04/17
26/04/17
12/05/17
24/05/17
07/06/17

Appendix 4: Fault reports requiring engineer visit

If there are any details of faults reported on the NHSBSP Fault Reporting system, details of these should be listed in this appendix. Number of day's downtime should be included.

Date	Fault	Solution
23 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.
27 March 2017	Large compression paddle stuck on machine – release button stuck down.	Removed by engineer
30 May 2017	Machine would not switch on correctly – error message	Software reloaded and system re-booted.
31 May 2017	Large compression paddle stuck on machine – release button stuck down.	Paddle lock mechanism replaced.

Appendix 5: Radiographers' answers to questionnaire

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

	Question	Comments / Observations
1	How good was the operator's manual?	5 Good, 1 average, 11 n/a The majority commented that they had not seen the manual or that they had not needed to use it. One commented that they only received an extract of the manual and that they had received no training on where to access it.
2	How good was the clinical applications training provided by supplier?	
	I. Modality	4 Excellent, 6 Good, 7 n/a Only part of the team had training directly form the manufacturer. This was cascaded to the remainder of the team. One commented that the training was good but full information was not provided at the time about the use of the AutoImplants mode
3	How do you rate the unit's ease of use?	8 Excellent, 9 Good
4	Were the X-ray exposure times acceptable?	17 Yes Two commented that is was shorter than on the GE Senographe essential machine
5	Setting for radiographic view	
	I. How do rate the rotation of the support arm?	8 Excellent, 9 Good
	II. How do you rate the visibility of the set angle?	6 Excellent, 8 good, 1 Average, 2 Satisfactory One said that the visibility of the angle could be better

	Question	Comments / Observations
6	How do you rate the facility for positioning the height of the breast support table?	5 Excellent, 11 Good, 1 Poor The radiographer who commented “Poor” said the buttons are too high in the oblique position and that she has to stretch to reach them.
7	How adequate was the range of movements offered by the unit?	9 Excellent, 8 Good Two commented that there is an occasional “grinding/juddering” noise when raising the machine up and down.
8	Effectiveness of brakes/locks: How well did the brakes work? (was there any backlash or movement, for example)	6 excellent, 9 good, 1 Average, 1 poor One commented that they were “smooth”. The “poor” comment related to the paddle changing lock being stiff and that is became stuck a few times.
9	Suitability of environmental conditions required to use this equipment.	6 Excellent, 11 Good One commented that using the machine for longer and through Winter would be required to give a full answer.
10	Compression	
	I. How effective was the compression system?	6 Excellent, 10 Good, 1 average One commented that the flexible paddle does not hold larger/heavier breast well in the MLO. One commented that the manual compression is very stiff. One said that sliding and locking the small paddle in place can be difficult. One commented that it operated with a smooth motion. One commented that they found the compression tighter that with other GE models. 3 commented that the large compression paddle often became stuck or difficult to remove.

	Question	Comments / Observations
	II. Visibility of compression force from the breast support table?	5 Excellent, 10 Good, 1 Average, 1 satisfactory One commented that it display was not as clear as the Essential. The split screen makes the writing smaller and that there is a lot of glare from the LBD. Another commented that visibility for the compression was difficult whilst wearing bifocal glasses.
11	How comfortable was the system for women?	7 Excellent, 10 Good One commented that the women found the curved edges an improvement and 2 said the women had thought it was more comfortable. One commented that although mostly positive comments were received, as the fixed paddle was required for larger breasts, that a small number had commented that it was more uncomfortable. One commented that 1 lady had commented negatively.
12	Range of controls and indicators	
	I. Were all the expected controls present?	14 yes, 3 no The 3 who indicated “No” commented on the lack of an emergency compression release button on the console.
13	How do you rate the choice of paddles/ collimators supplied for spot compression?	4 excellent, 3 Good, 10 n/a Spot compression is not routinely used.
14	How do you rate the time for an image to appear at the acquisition workstation?	6 Excellent, 10 Good, 1 Satisfactory Eight commented that the image disappears from the acquisition monitor too quickly after being displayed
15	How do you rate the image handling and processing facilities at the acquisition workstation?	15 Good, 2 n/a

	Question	Comments / Observations
16	How would you rate the overall image quality at the acquisition workstation?	4 Excellent, 10 Good, 2 Average, 1 Satisfactory 2 commented that the images always look dark. 2 commented that the images are very different to the other machines we use. 2 commented that they would prefer there to be less contrast - but you do quickly get used to it and adequate for checking position.
17	How easy was it to transfer images to the reporting workstation or to an encrypted hard drive, for example?	4 Excellent, 7 Good, 6 n/a 1 commented that this was quite slow when waiting for QA test images to transfer across
18	What was your level of confidence in good results from the machine?	4 Excellent, 13 Good
19	Were there any potentially hazardous areas accessible to:	
	I. you?	1 Yes, 16 no The “glare” from the LBD when the tube is “parked” is uncomfortable on the eyes.
	II. the woman?	17 No
20	Equipment cleaning	
	I. Ease of cleaning the machine? II.	10 Excellent, 7 Good
	III. Were there instructions in the manual? IV.	8 Yes, 9 did not know
	V. Does this meet the local Infection control requirements? VI.	8 Yes, 9 did not know

	Question	Comments / Observations
21	Was all necessary patient and exposure data available on the images?	17 Yes
22	Did the digital X-ray system performance limit patient throughput?	17 No 1 commented that time was lost due to checking the images at the end of the exam rather after each exposure, 1 commented that throughout was better due to faster acquisitions

23	General comments	Concerning the handle for women to hold when doing mlo - even when shown after being told, women still don't see where to hold as its not obvious Paddles do not remove easily, several instances of paddle becoming stuck Don't like how the previous image disappears from the acquisition monitor as soon as you start to expose for the next one. Would normally use this as an opportunity to quickly check for blurring/artefacts 1St Image disappears when exposure made for the next view (prefer Seno- Essential set up) and so unable multitask and check 1st image whilst making 2nd exposure. Being able to move the tube independently is an excellent feature although when the tube is moved the light shines too bright to properly see the collimated area. The large faceplate is good as patients are less likely to lean to the side (CC's) I find the machine very easy to use. Sometimes the touch screen aspect of the control panel will not recognise my finger so lady can be compressed while I am struggling to select R or L. Machine is nice to use – looks good with the pink colouring and seems less bulky for the patients. Image quality excellent as high contrast images. I believe this machine shows such good contrast between structures within the breast that it may have saved lives already!!!!!! LBD very bright – glares. Sometimes found large paddle difficult to remove, and then small paddle didn't lock into place for first CC position. Touch screen sometimes unresponsive for selecting L / R

		Need to select 3D on acquisition monitor, kept trying to press with finger instead of mouse! Good that it always automatically reverts to 2D after an examination is completed. Issue with x-raying implants – need to choose this option for each of the exposures/views. I like the large face shield I like being able to move the tube head out of way for positioning MLO's Lots of women commented on comfort and ease of the Pristina. I like the look and clean lines of the machine Manual compression knob not very smooth to use – is bit stiff and hard work on hands/wrists (would be nice if smoother/lighter) Image disappears off monitor bit too quickly, would be better if more of a delay to allow viewing of images in between, rather than just being able to see them at the end. When entering details into referring physician box, potential for the 'delete' bar to scroll too far out of the edit box and select the wrong patient from the worklist behind it. Having the edit box stand alone would prevent this. A pleasure to use, ergonomically and the general smoothness and easiness of handling, plus shorter exposure times – a lot less clunky than old machines and nice slim detector makes it easier especially for larger women. Much quieter too! Having a smaller 'large' paddle (24x29) has meant occasionally having to take extra images to get all the breast on some larger women who would have fitted fine on 24X30. The paddles are a bit stiff to detach. As a newly qualified film reader I like the image quality of the Pristina mammograms and feel that calcifications in

	Question	Comments / Observations
		particular are easier to distinguish, especially in dense breasts. I don't move the tube in the park position for my obliques as 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. Not much of an issue for me but 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. If the glare was fixed by replacing the bulb, I would use the home position more often. The compression feels a lot tighter than the other GE systems; I have not had a blurred image yet. The exposure buttons are very similar and near the power buttons! I have powered the machine down by accident whilst preparing for a test exposure. Auto setting for implants needs to be set for each exposure, might be better to use first exposure setting as a default for the rest of the examination Very user friendly, positive comments from patients. Looks good and the tube is quiet unlike other machines in department. A delightful machine

Appendix 6: 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 was the operator's manual?	1 Good, 3 N/A
		One reader respondent commented that as they already had experience with other GE workstations that she was already familiar with the main functions.
2	How good was the application's training provided by the supplier?	3 Good, 1 N/A
		Training was provided by request due to the reader's already being familiar with using GE workstations.
3	How easy is it to adjust the height and angle of the reporting monitor to suit the user?	2 Excellent, 1 Average, 1 N/A
		One commented that they had much preferred using the 10MP monitor compared to the dual 5MP monitors.
4	How easy is it to adjust the height and angle of the database monitor to suit the user?	3 Excellent, 1 Average, 1N/A
5	How do you rate the ease of use of the workstation controls?	
	a. Mouse/trackerball	3 Excellent, 1 Good
	b. Keyboard	2 Excellent, 1 Good
	c. Keypad	2 Excellent, 1 Good

	Question	Responses
		It was commented that the tracker ball was not used by 2 of the readers, and 1 commented that they only used the mouse.
6	How do you rate the image handling tools?	
	a. Visibility	3 Excellent, 1 Good
	b. Usability	3 Excellent, 1 Good
7	How do you rate the post processing image manipulation (window and level)?	3 Excellent, 1 Good
8	How do you rate the reading/reporting flow pattern?	3 Excellent, 1 Good
9	If there was a choice of hanging protocols, how easy was it to set these?	1 Excellent, 2 Good, 1 N/A
		One commented that it takes a bit of time to learn how to set up the hanging protocols yourself, but they can be configured to accommodate all users preferences
10	Within a hanging protocol, how easy was it to display a different choice of image, that is, images performed beyond the standard 4?	3 Excellent, 1 Good
		One commented that the images are easily dragged from the navigator onto the screen
11	How do you rate the time taken between an image or client being selected and appearing on screen?	
	a. New patient selection	2 Excellent, 2 Good

	Question	Responses
	b. In-exam change	2 Excellent, 2 Good
12	How much of a problem was light from the database screen raising ambient lighting around the workstation?	4 No problem
		None commented that the light which comes on at the bottom of the screen is very useful for completing paper work and does not interfere with image viewing
13	Did you identify and hazards associated with the workstation or its use?	4 No
14	What is your overall level of satisfaction with the workstation?	3 Excellent, 1 Good
15	General comments	Seno-iris is very easy to use. I find the workstation very easy to use and intuitive. However I already use the GE workstation for our other mammography machines and it is very similar.

Appendix 7: Manufacturer’s comments

Any comments from the manufacturer, after they have reviewed the report, are included in this appendix.