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NHS Breast Screening Programme Equipment Report

Practical evaluation of Hologic 3Dimensions digital mammography system in 2D mode

December 2019

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Contents

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Executive summary

The purpose of this evaluation was to assess the practical performance of the Hologic 3Dimensions™ digital mammography system in 2D imaging mode. The evaluation was carried out between October 2017 and June 2018.

The system was reliable and the quality control test results were stable and remained within the appropriate limits throughout the evaluation.

The system's performance was good and the radiographers found it easy to use. Image quality was assessed as good or excellent in the majority of cases.

Both standard flat paddles and curved paddles (SmartCurve™) were used in the evaluation. The average mean glandular dose (MGD) calculated for oblique views of 50-60mm thick breasts was well below the national dose reference level (DRL) of 2.5mGy. However, the average MGD for the 18cm x 24cm SmartCurve paddle was 1.76mGy, slightly but not significantly higher than the value for the 18cm x 24cm flat paddle,1.69mGy. For the 24cm x 29cm paddles, the average MGDs were 1.99mGy and 1.55mGy for SmartCurve and flat respectively, and this difference is significant.

The SmartCurve paddles are not currently recommended for use in cases of less than 50mm breast thickness due to positioning challenges, but they may be useful in selected cases. Using flat paddles, the Hologic 3Dimensions was found suitable for use in 2D mode in the NHSBSP.

1. Introduction

1.1 Evaluation centre and timeline

The evaluation centre is the Jarvis Breast Centre, which is a unit of the NHS Breast Screening Programme (NHSBSP). It serves the population of Surrey and North East Hampshire for women of normal screening age and also for the age extension. The centre invited over 55,000 women of screening age, between 47 and 73 years, during the year 2016-17. Of these, more than 42,000 were screened, resulting in more than 2,800 recalls for further assessment. Some 1,200 biopsies were performed during that period. The centre meets relevant national quality standards[1] for breast screening and meets the criteria for evaluation centres outlined in the Guidance Notes for Equipment Evaluation[2].

The evaluation of the Hologic 3Dimensions system, with the SmartCurve Breast Stabilisation System, took place over the period of October 2017 to June 2018. Both the 2D and tomosynthesis modes were under evaluation in the centre at the same time. The 18cm x 24cm SmartCurve paddle was installed in October 2017 and the 24cm x 29cm SmartCurve was made available in February 2018.

1.2 Equipment evaluated

1.2.1 X-ray set and acquisition workstation

The 3Dimensions was installed by Hologic on a loan basis for the duration of the evaluation. Hologic agreed to indemnify the equipment and provided both technical and applications support over the evaluation period.

The mammography gantry comprises of an automatically controlled C-arm with push button controls for gantry height and angle, and a knob to adjust compression manually. Gantry height and compression can also be controlled by foot pedals.

The 3Dimensions has an amorphous selenium detector, with rhodium, silver and aluminium filters. Only the rhodium and silver filters are used for 2D operation. The pixel size in 2D images is 70 microns.

The acquisition workstation (AWS) has a single 3MP monitor fixed on a console with ergonomic features of adjustable height and biometric login. The AWS can be set up to adjust the height automatically to suit the individual operator.

It has a keyboard and a separate touchscreen control pad with a mouse. There is a lead glass radiation shield attached to the console. In addition to the footswitch for exposure, there is also a single exposure button at the AWS.

Figure 1. Hologic 3Dimensions X-ray set

In the first few weeks, the touchscreen was found to be too sensitive, leading to occasional inadvertent selection of the wrong name. The problem was resolved by having an engineer to reduce the sensitivity.

1.2.2 Paddles

Three standard-size compression paddles were available for use as well as specialist paddles for use in assessment. All the different paddles were automatically recognised by the 3Dimensions once they were in position on the gantry.

The 24cm x 29cm and the 18cm x 24cm flat paddles were in routine use, with the small paddle (8cm x 24cm) used for women with small breasts. Specialist paddles such as the 7.5cm spot magnification paddles and a 10cm magnification paddle were also used in assessment, as required.

18cm x 24cm and 24cm x 29cm SmartCurve paddles were in general use as well as the flat paddles. Figure 2 shows a 24cm x 29cm SmartCurve paddle. The shape of the 18cm x 24cm is similar.

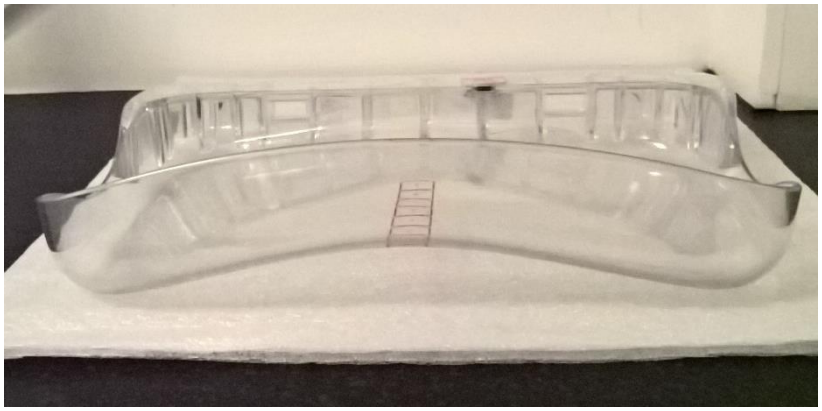

Figure 2. SmartCurve paddle, 24cm x 29cm version

1.2.3 Other accessories

A magnification table, which provided both 1.8x and 1.5x magnifications, was amongst different accessories available for the evaluation. It was normally used at 1.8x magnification.

1.3 Objectives

The main purpose of the evaluation was to determine the suitability and performance of the equipment for use within a breast screening unit.

The detailed objectives were as follows:

- to assess the reliability of the equipment in a busy screening environment
- to assess the user-friendliness of the equipment
- to assess image quality and dose against national standards
- to assess the suitability of the SmartCurve paddles for general usage

2. Acceptance testing, commissioning and performance testing

The 3Dimensions was installed in October 2017 in one of the imaging rooms in the Jarvis Breast Centre. It was used in place of one of the existing Hologic Selenia Dimensions systems, which was mothballed during the period of evaluation.

The installation was followed by the commissioning of the system, which included integration with the main PACS and also with a SecurView reporting workstation. The system was integrated with NBSS at the same time.

The acceptance and commissioning tests[3] were carried out by the local medical physics service and the physics reports are included at Appendix 1. This followed a technical evaluation[4] of the 3Dimensions by the National Coordinating Centre for the Physics of Mammography (NCCPM). The practical evaluation only proceeded after an interim recommendation to progress was received.

The local medical physics team also carried out a routine performance survey on the system in February 2018. The report from this survey is also included at Appendix 1.

3. Routine quality control

Routine quality control (QC) was carried out as detailed in the NHSBSP guidelines[5]. Tests were carried out daily, weekly and monthly. All test results were recorded on the QA spreadsheet provided by the local physics service.

Regular testing of the AWS monitor was carried out and gave satisfactory results. All monitors are tested monthly.

3.1 Daily QC tests

The following quantities were recorded daily during the entire evaluation period:

- mAs
- SNR (signal to noise ratio)
- mean pixel value
- CNR (contrast-to-noise ratio)

The results are presented in Figures 3 to 6. Measurements of CNR are only required weekly, but as the measurements were recorded daily, daily CNR is shown in Figure 6.

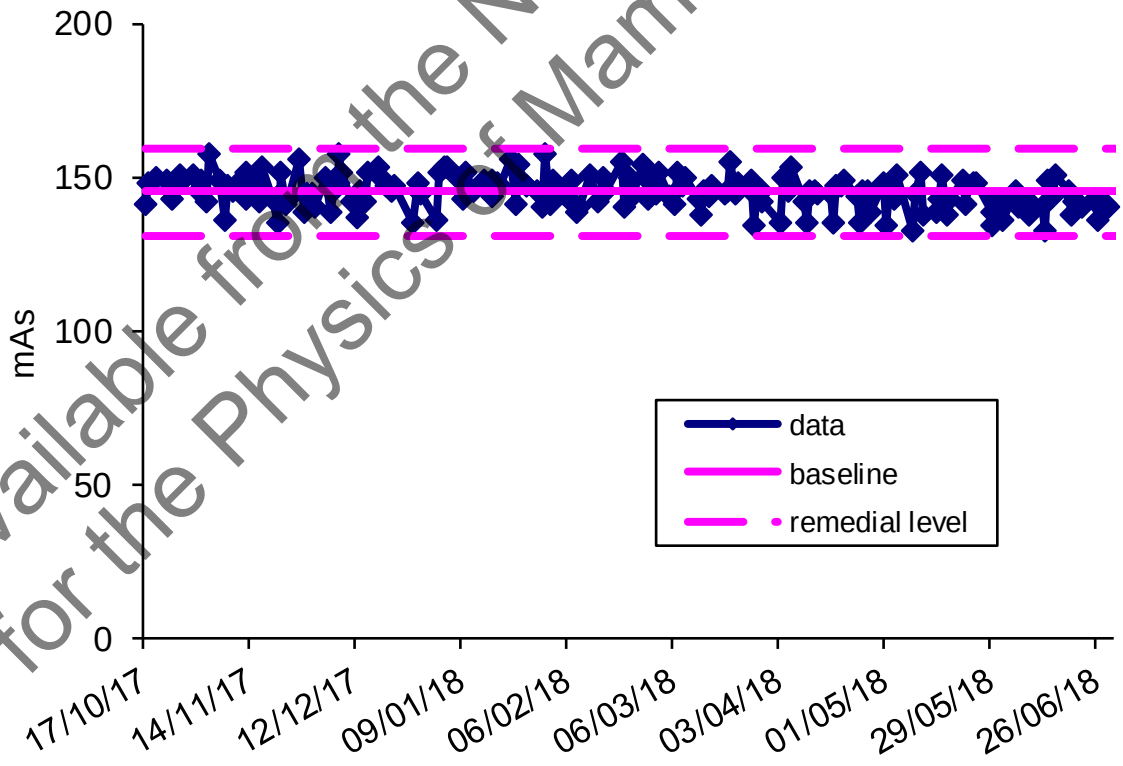

Figure 3. mAs recorded daily for 45mm of Perspex

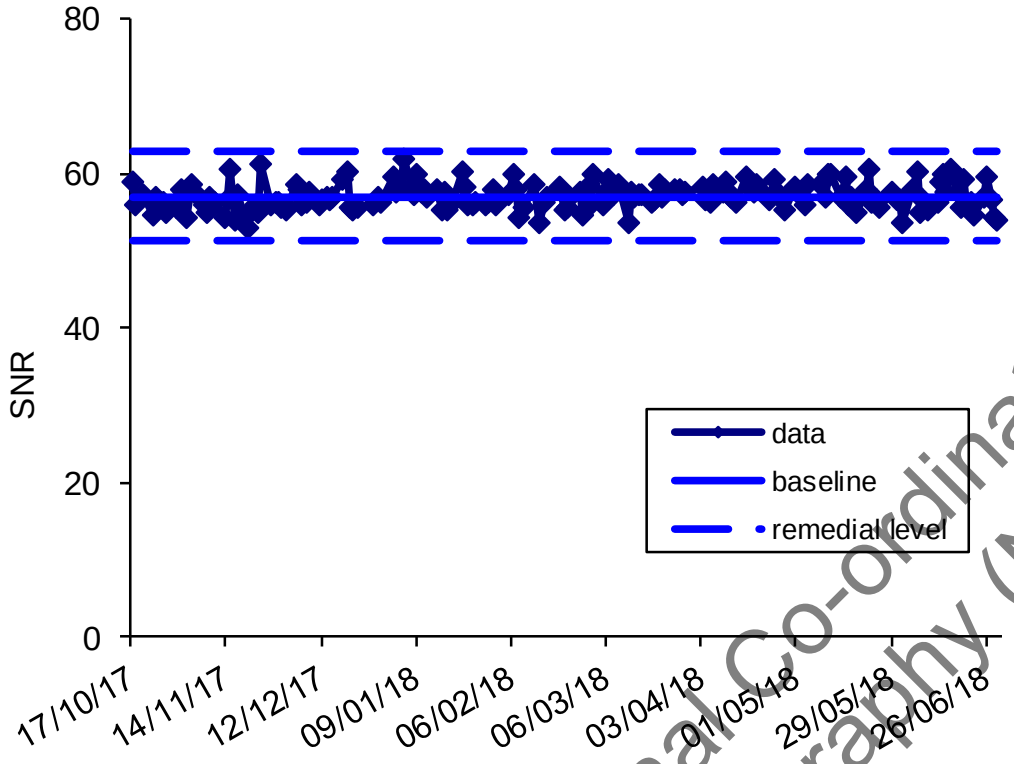

Figure 4. SNR recorded daily for 45mm of Perspex

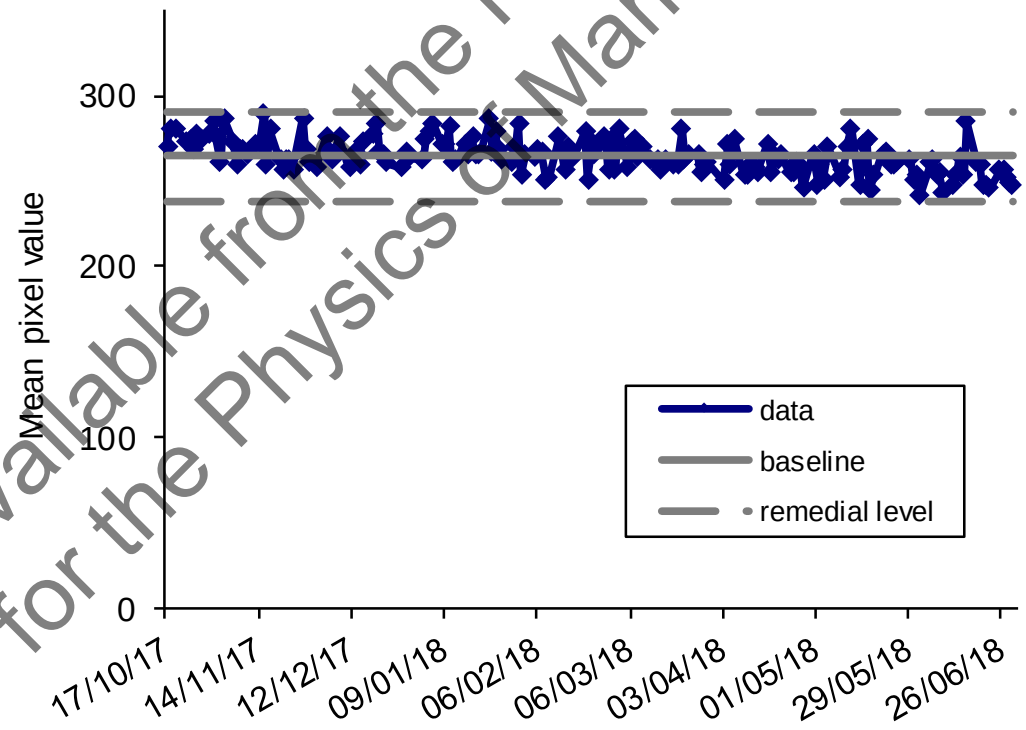

Figure 5. Mean pixel value recorded daily for 45mm of Perspex

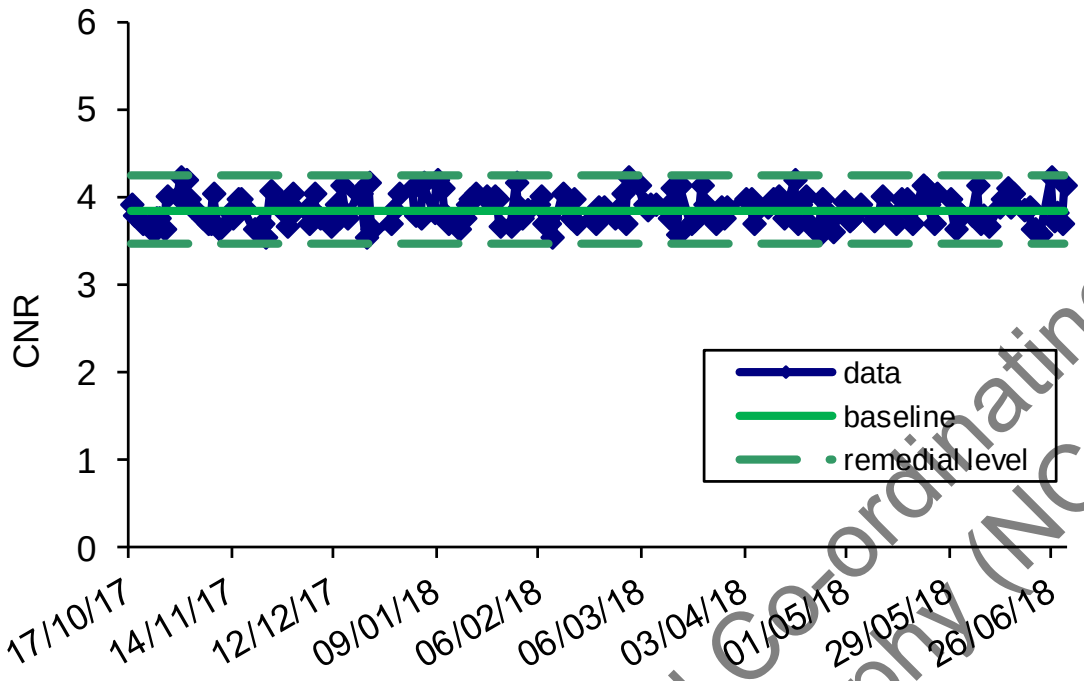

Figure 6. CNR recorded daily for 45mm of Perspex

3.2 Weekly QC tests

The results for the following were recorded weekly during the entire evaluation period:

- CNR
- uniformity
- image quality measured with a TORMAM

They are presented Figures 7 to 9. CNR is not usually measured daily as it was in this evaluation.

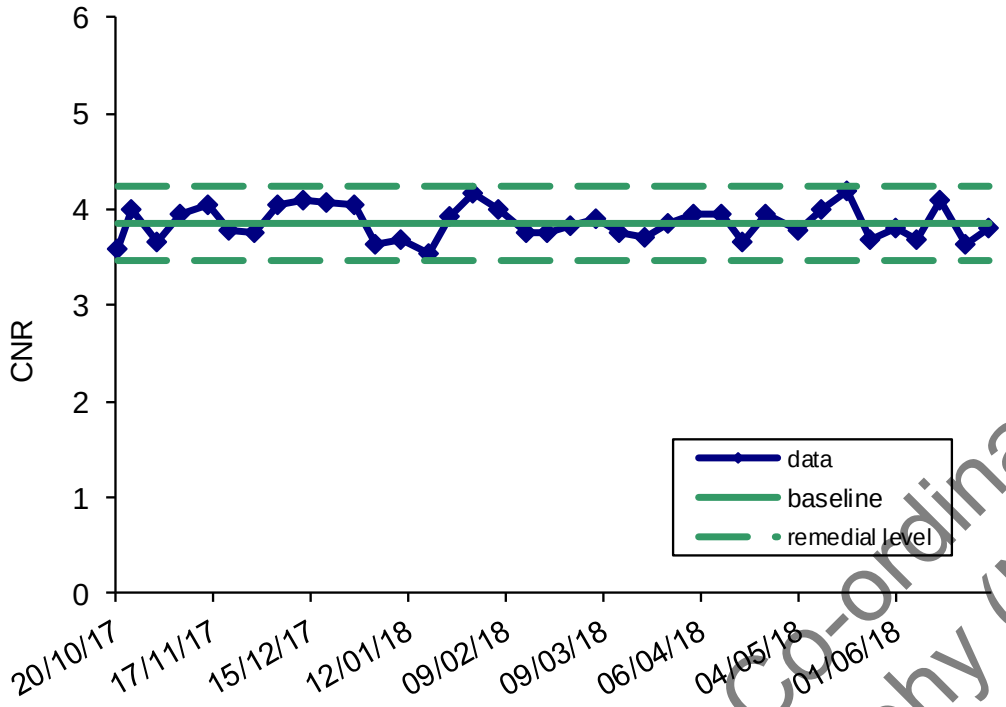

Figure 7. CNR recorded weekly for 45mm of Perspex

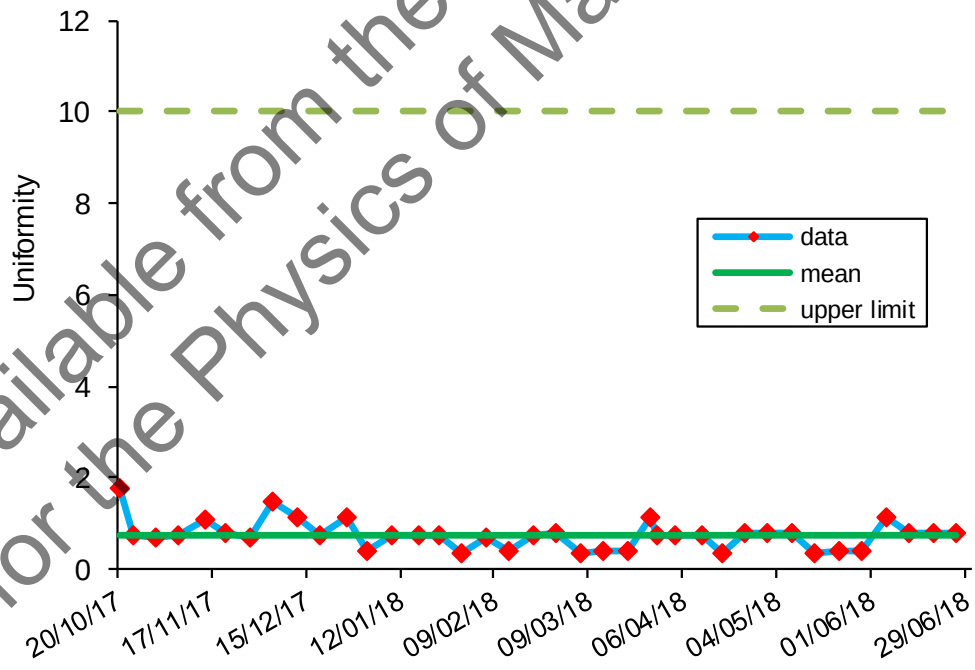

Figure 8. Uniformity measured weekly with 45mm of Perspex

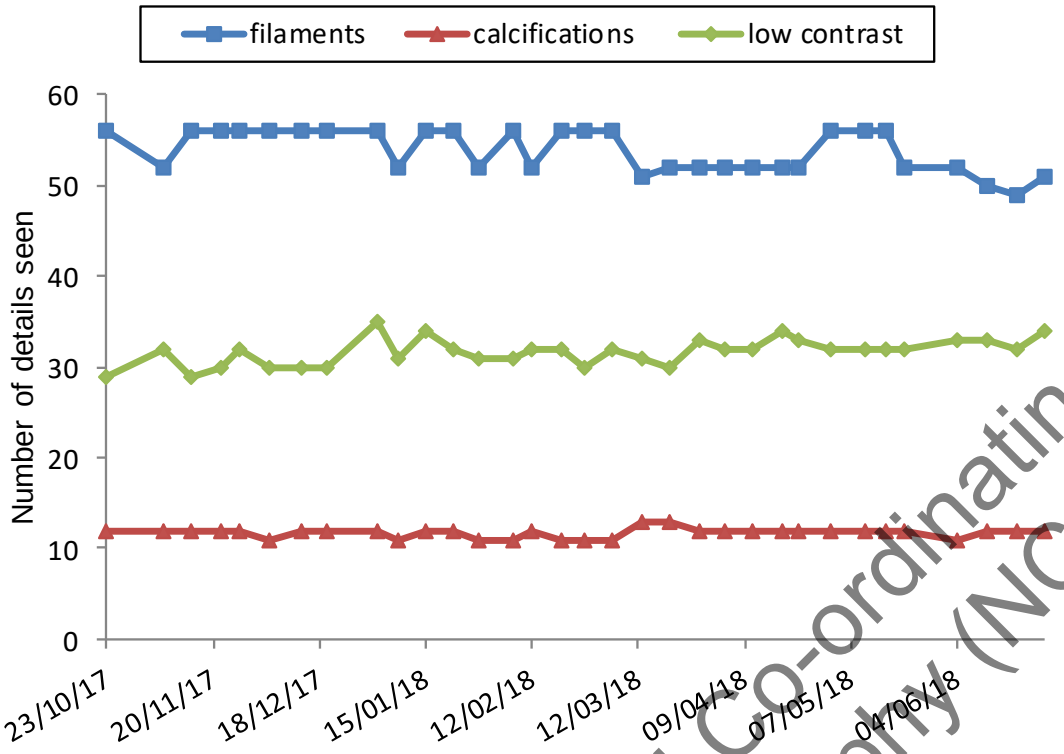

Figure 9. Image quality measured weekly with TORMAM test object

3.3 Monthly QC tests

The results for the following were recorded monthly during the entire evaluation period:

- mAs for 20mm and 70mm Perspex
- SNR for 20mm and 70mm Perspex
- CNR for 20mm and 70mm Perspex
- mean pixel value for 20mm and 70mm Perspex

They are presented in Figures 10 to 17.

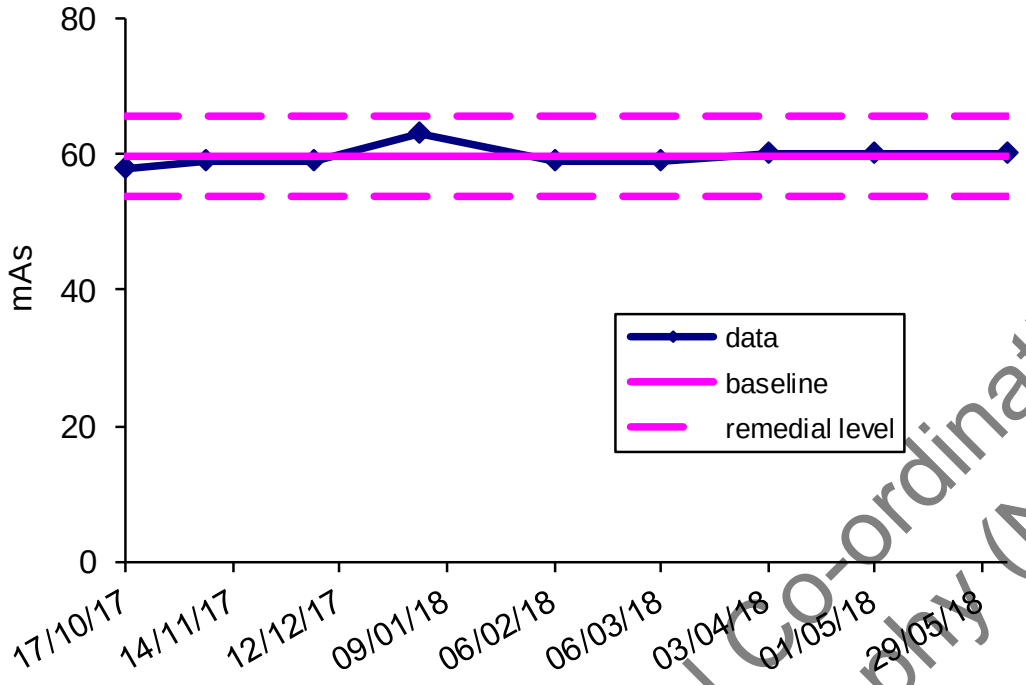

Figure 10. mAs recorded monthly for 20mm of Perspex

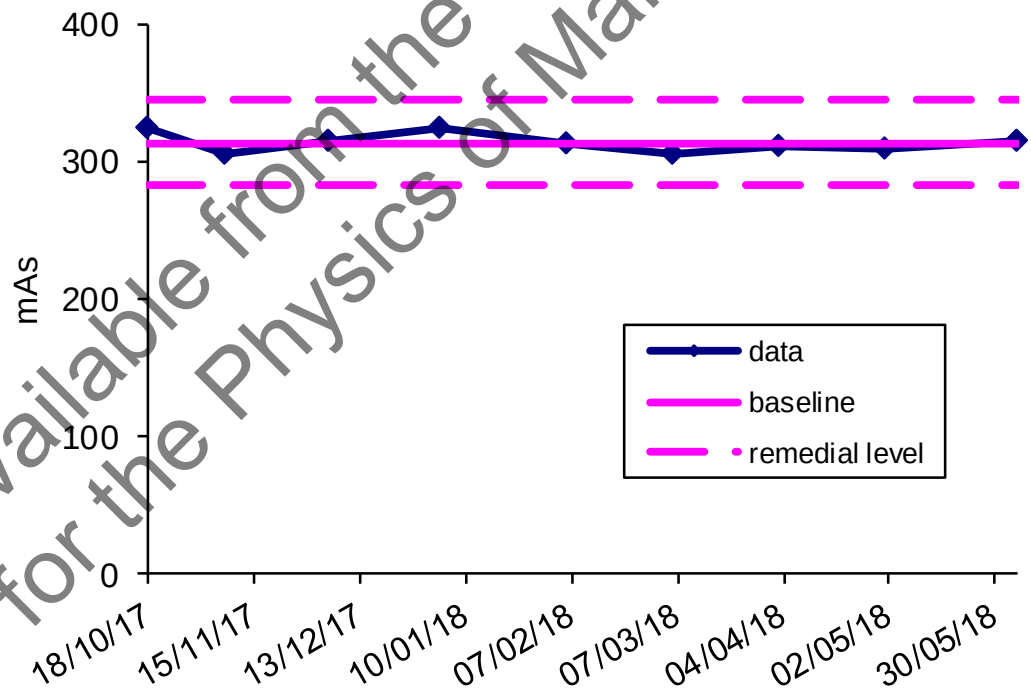

Figure 11. mAs recorded monthly for 70mm of Perspex

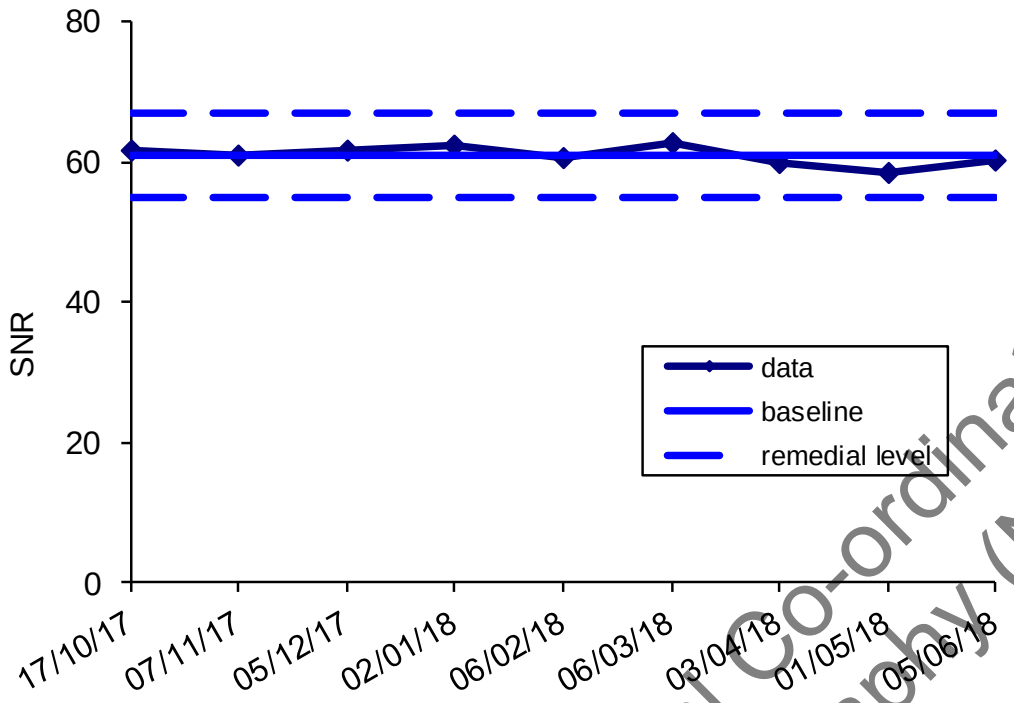

Figure 12. SNR recorded monthly for 20mm of Perspex

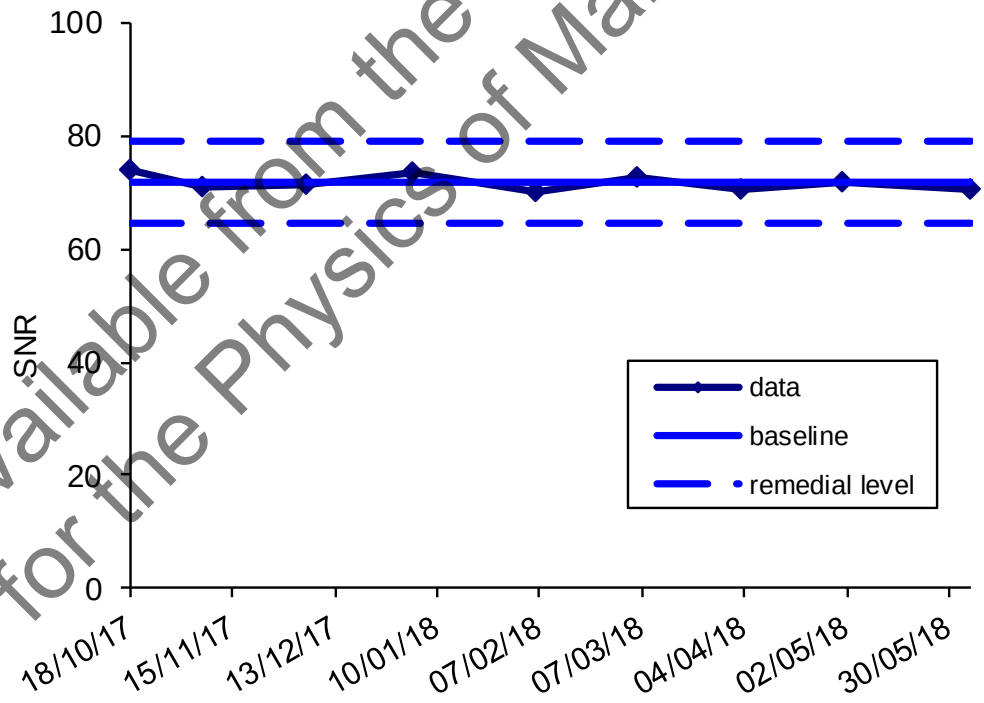

Figure 13. SNR recorded monthly for 70mm of Perspex

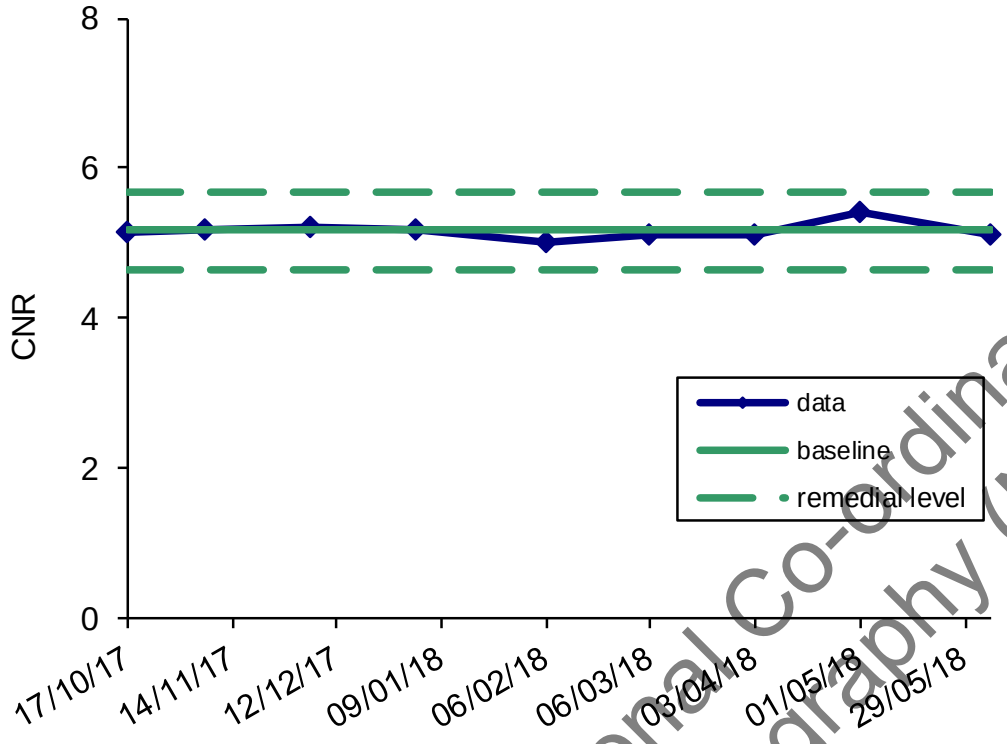

Figure 14. CNR recorded monthly for 20mm of Perspex

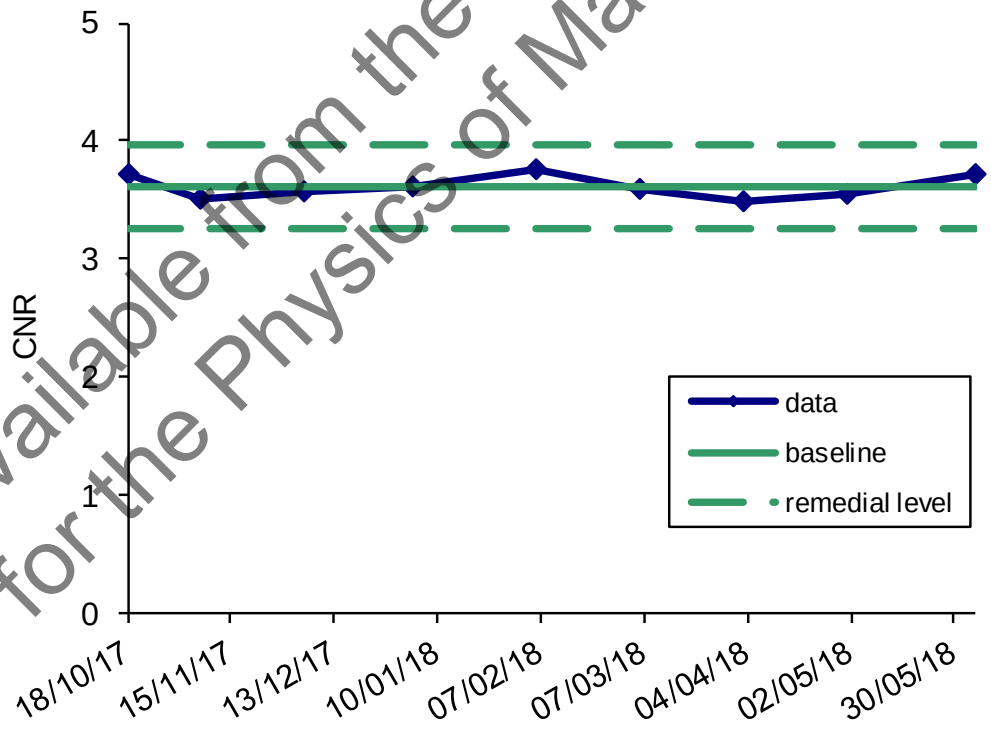

Figure 15. CNR recorded monthly for 70mm of Perspex

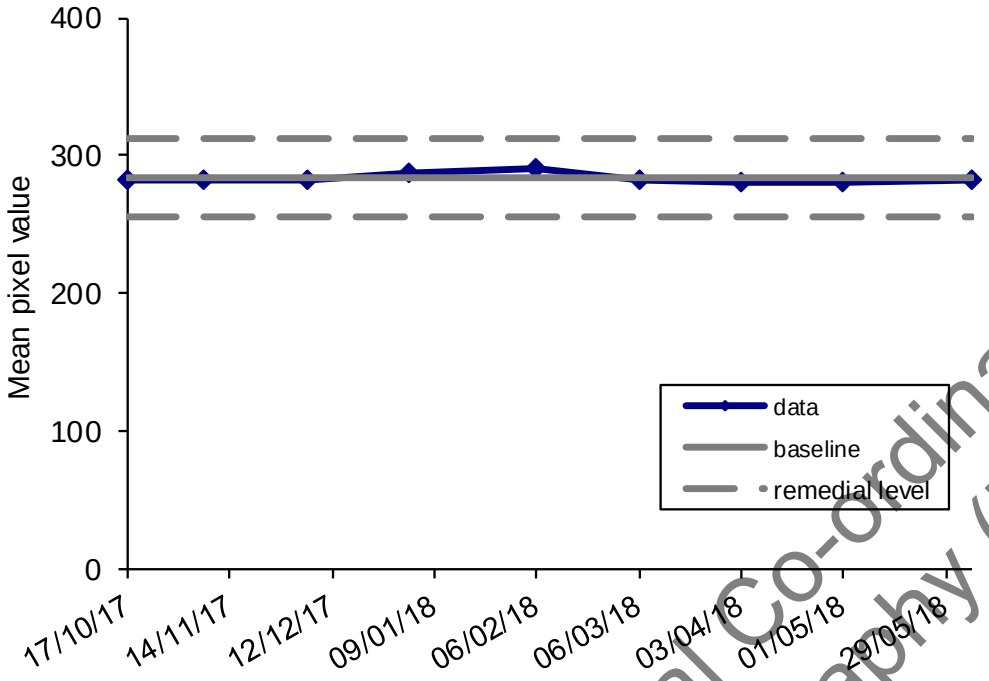

Figure 16. Mean pixel value recorded monthly for 20mm of Perspex

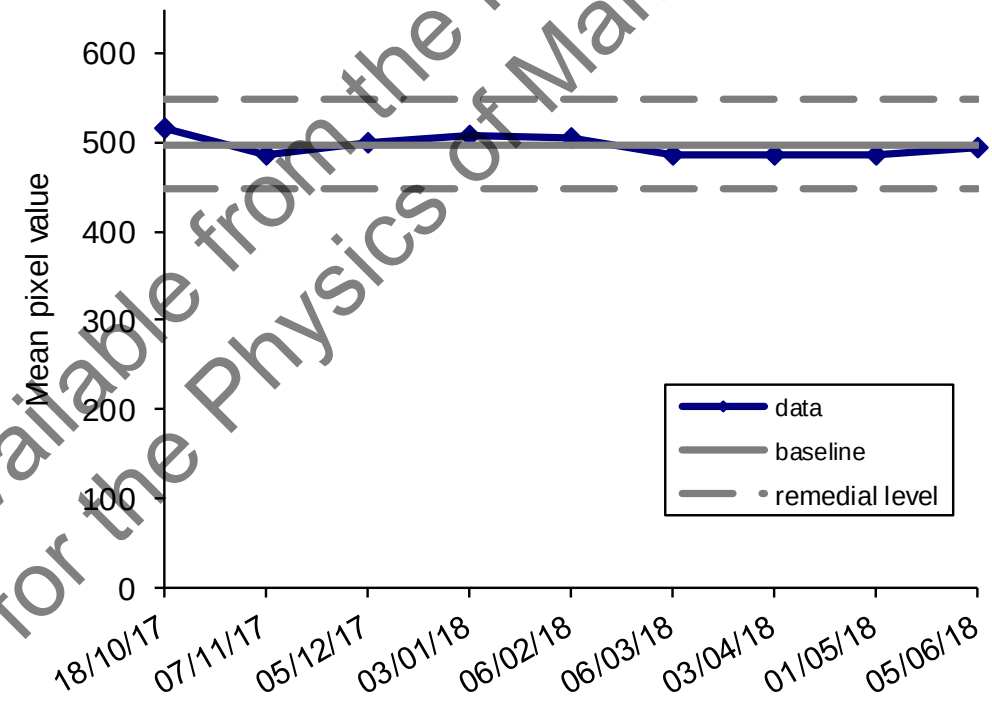

Figure 17. Mean pixel value recorded monthly for 70mm of Perspex

4. Data on screening carried out

4.1 Clinic throughput

Screening clinics are held at the centre mainly for complicated cases and as extra clinics to cover periods when any screening van is not available.

Screening clinics were scheduled for Wednesday mornings and afternoons during the evaluation. These were normally fully booked. Assessment clinics were held on other days, with additional screening clinics scheduled in as and when required.

Daily QC testing of X-ray equipment in the centre is performed in the morning. The system under evaluation was tested daily and was available for use from 09:00.

4.2 Clinical dose audit

Exposure details of 2D images were extracted from the DICOM headers for a dose survey of over 1,130 women. The details for both the flat paddles and the SmartCurve paddles relate to the period February 2018 to July 2018. The 18cm x 24cm SmartCurve paddle had been in use from the start of the evaluation in October 2017. However, because the paddle height was incorrectly calibrated during the installation, the average mean glandular dose (MGD) was found to be higher than intended for the earlier period (on average 2.3mGy for MLO views of 50-60mm thick breasts). Hologic corrected the calibration in February 2018. Only the data extracted after this correction was analysed in separate batches, to facilitate comparison of MGDs for flat and SmartCurve paddles.

Very small breasts were imaged using the small (8cm x 24cm) paddle, and MGDs for these were not included in the dose survey.

The dose calculator from NCCPM was used to calculate average MGDs. It is based on a model and data published by Dance et al.[6] The model assumes flat surfaces at the top and bottom of a breast under compression, and has not been modified to allow for SmartCurve paddles. Measurements with small Perspex blocks extending up into the curved space are presented in the technical evaluation report for the 3Dimensions in 2D mode[4]. These indicate that the exposure factors and MGDs are the same for flat and SmartCurve paddles, if the displayed compressed breast thicknesses (CBT) are the same. It has therefore been assumed that MGDs for breasts imaged with SmartCurve paddles could be calculated in the same way.

The MGD for the MLO view of 50-60mm thick breasts, averaged over both flat paddles, was 1.67mGy. This compares favourably with the national diagnostic reference level (DRL) of 2.5mGy.

Detailed results for the 4 dose surveys are presented in Appendix 2. The average MGDs and CBTs are summarised in Tables 1 and 2 for the different paddle sizes. All MGDs are below the national DRL.

For the 18cm x 24cm SmartCurve paddle, the average MGD for the MLO view was 1.76mGy, for 50-60mm thick breasts. While this is higher than for the 18cm x 24cm flat paddle(1.69mGy), the difference is not significant ($p = 0.075$).

For the 24cm x 29cm SmartCurve paddle, the average MGD for the MLO view of 50-60mm thick breasts was 1.99mGy, which is about 28% higher than for the corresponding flat paddle(1.55mGy). The difference is significant ($p < 0.001$).

Paddle	View	Group of women	Number of images	Average MGD (mGy)	Average CBT (mm)
Flat	CC	all	1109	1.65	52
	MLO	all	1064	1.72	53
	MLO	CBT 50-60mm	341	1.69	55
SmartCurve	CC	all	313	1.64	48
	MLO	all	309	1.74	50
	MLO	CBT 50-60mm	95	1.76	55

Table 1. Average values of MGD and CBT using 18cm x 24cm paddles

Paddle	View	Group of women	Number of images	Average MGD (mGy)	Average CBT (mm)
Flat	CC	all	459	2.14	52
	MLO	all	440	2.44	53
	MLO	CBT 50-60mm	60	1.55	55
SmartCurve	CC	all	223	2.21	61
	MLO	all	215	2.73	70
	MLO	CBT 50-60mm	45	1.99	56

Table 2. Average values of MGD and CBT using 24cm x 29cm paddles

The overall average MGD , for MLO views of 50-60mm thick breasts, was 1.71mGy.

4.3 Imaging times

Radiographers and assistant practitioners (APs) were asked to record the time taken for each screening examination for a small set of women. Times ranged from 5 to 18 minutes, the longer times being associated with the more complex cases.

Radiography staff were also asked to comment on delays experienced within the examination and if these could be attributed to equipment. Comments recorded with the

longer times were generally for women with more complex practical issues such as “wheelchair” or “positioning”.

No separate changing facilities were available, but the lower times for women with no complicated issues show that screening clinics with 6 minute appointments are possible with this system.

Figure 18 shows a histogram of timings recorded. These reflect the diversity of the client base seen in the screening clinics at the centre.

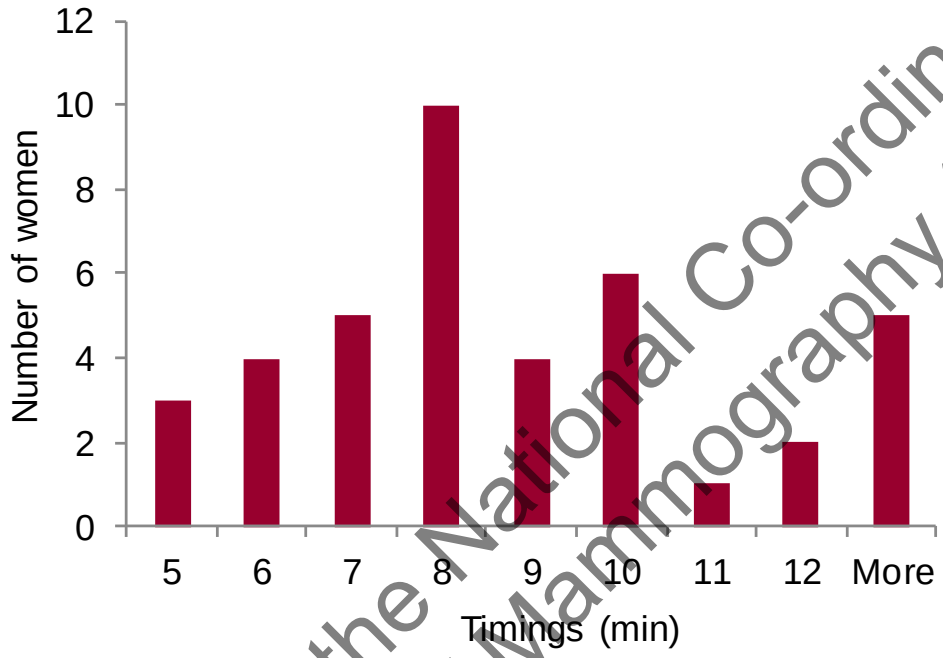

Figure 18. Imaging times

4.4 Image quality

During the evaluation period, an audit of image quality was undertaken by the film readers, for a total of 138 cases, all of which were double read. Both CC and MLO views were assessed and comments were recorded on NHSBSP Equipment Evaluation Form 8 for user assessment of digital image quality.

The readers were asked to make an estimate of the breast composition for each case within the dataset collected. These cases were classified as fatty, mixed or dense.

The proportions found in the 138 cases by double reading were:

- Fatty: 13%
- Mixed: 70%
- Dense: 17%

The breast density assessment is shown in Figure 19.

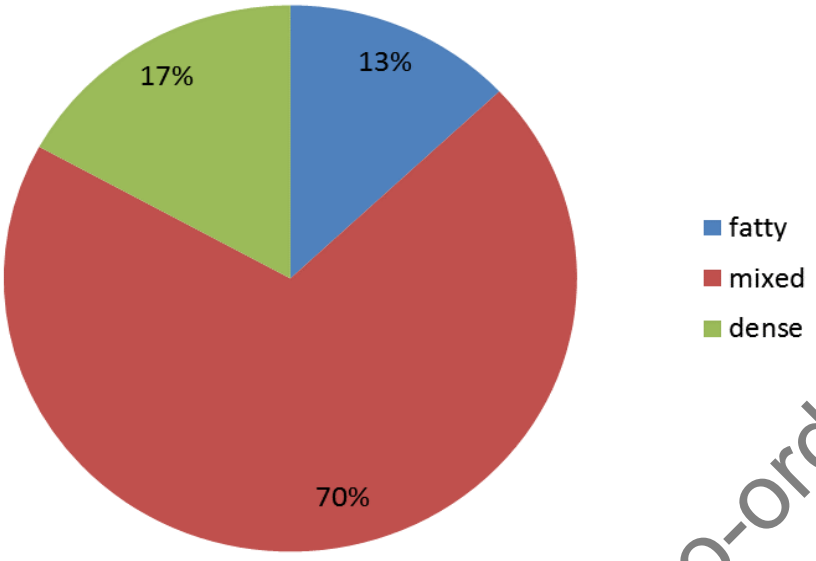

Figure 19. Readers' estimates of breast density

The audit also looked at image quality features for both CC and MLO views, using the same cases as for the breast density.

The readers assessed the overall contrast for these images and rated as satisfactory 70% of the cases. They also rated 26% as high or very high overall contrast and the rest as slightly low.

In the assessment of the suitability of image processing, the readers judged it good or excellent in 74% of the cases with the remaining 26% satisfactory. They considered that it was poor for a very few cases with none inadequate.

Overall diagnostic value was found to be excellent or good in 73% of cases, with most of the rest satisfactory. There were a few cases assessed as poor but none were found to be inadequate.

Diagnostic zoom was rated as excellent or good in 73% of cases with the rest as satisfactory.

Figures 20 to 23 show the results from these image quality assessments.

As a follow on to reports of noise affecting images elsewhere, an additional audit was carried out by a team of experienced radiologists. The team used a small dataset of 34

women with small breasts and 12 women with breast implants to specifically assess possible image degradation due to noise. The team concluded that none of the images were non-diagnostic or noisy on visual inspection.

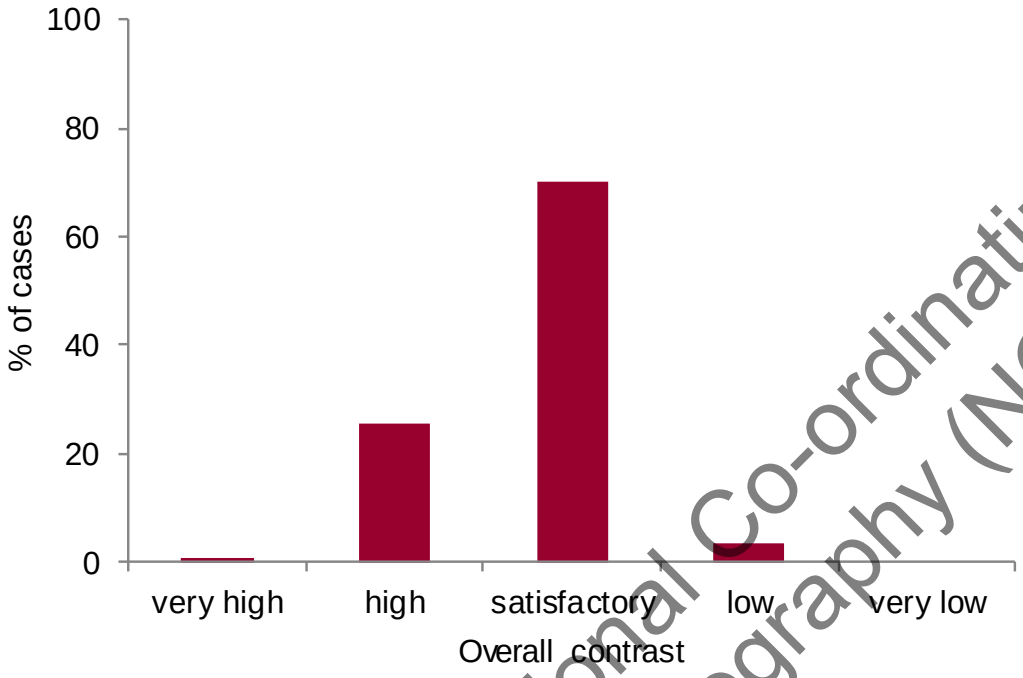

Figure 20. Readers' assessment of overall contrast

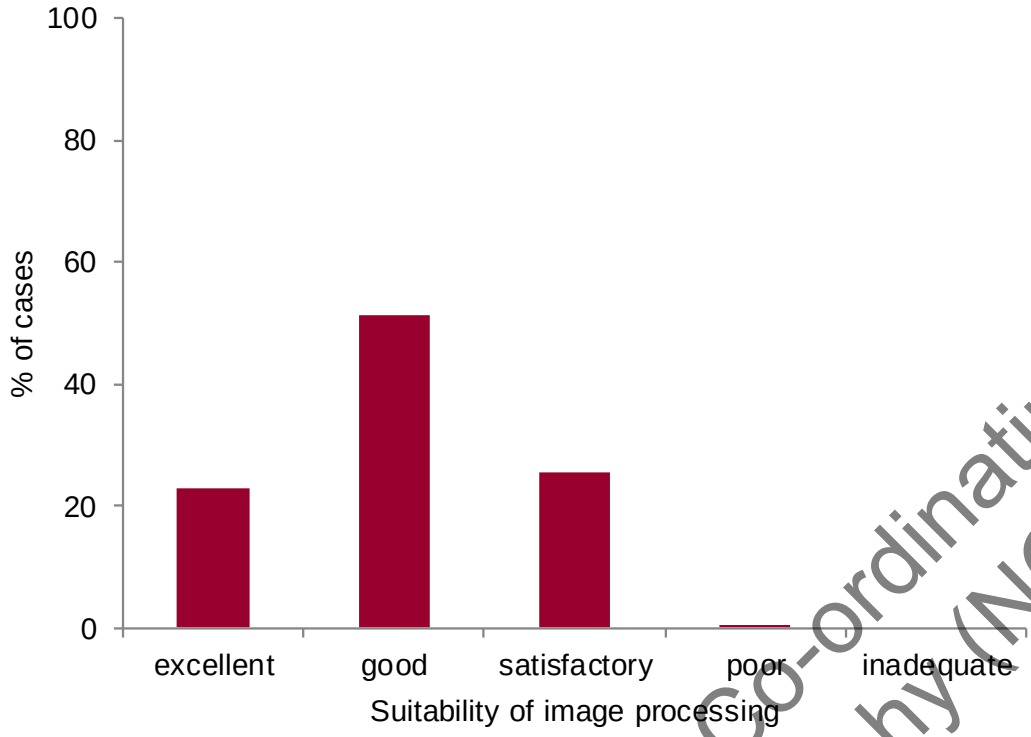

Figure 21. Readers' assessment of suitability of image processing

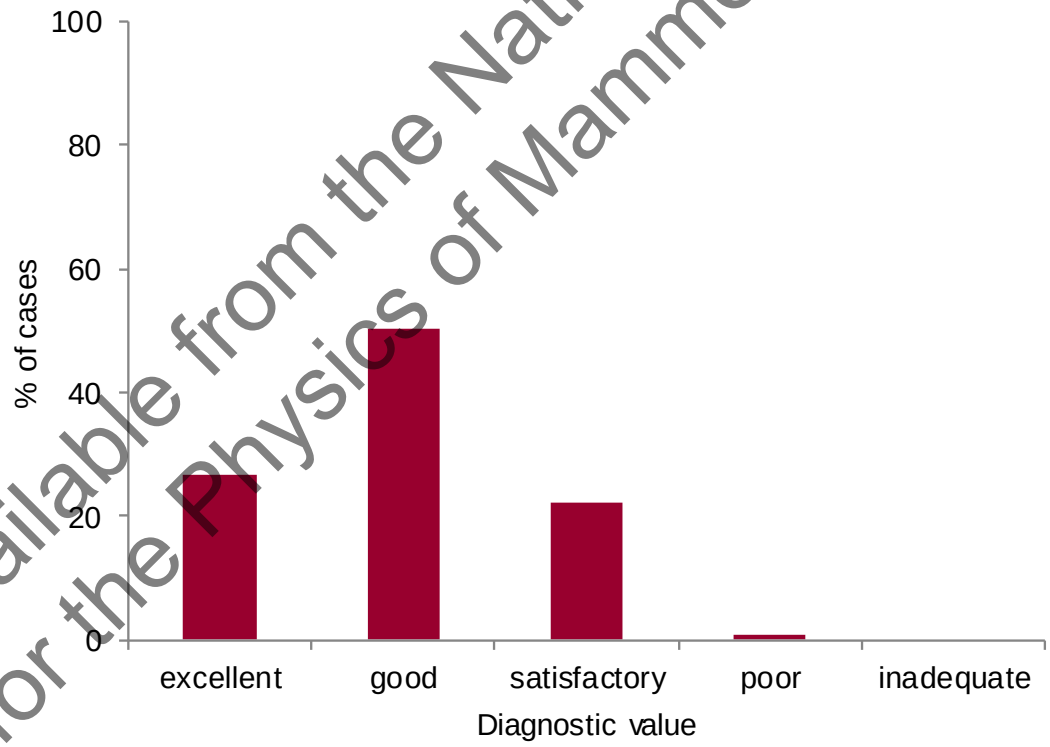

Figure 22. Readers' assessment of overall diagnostic value

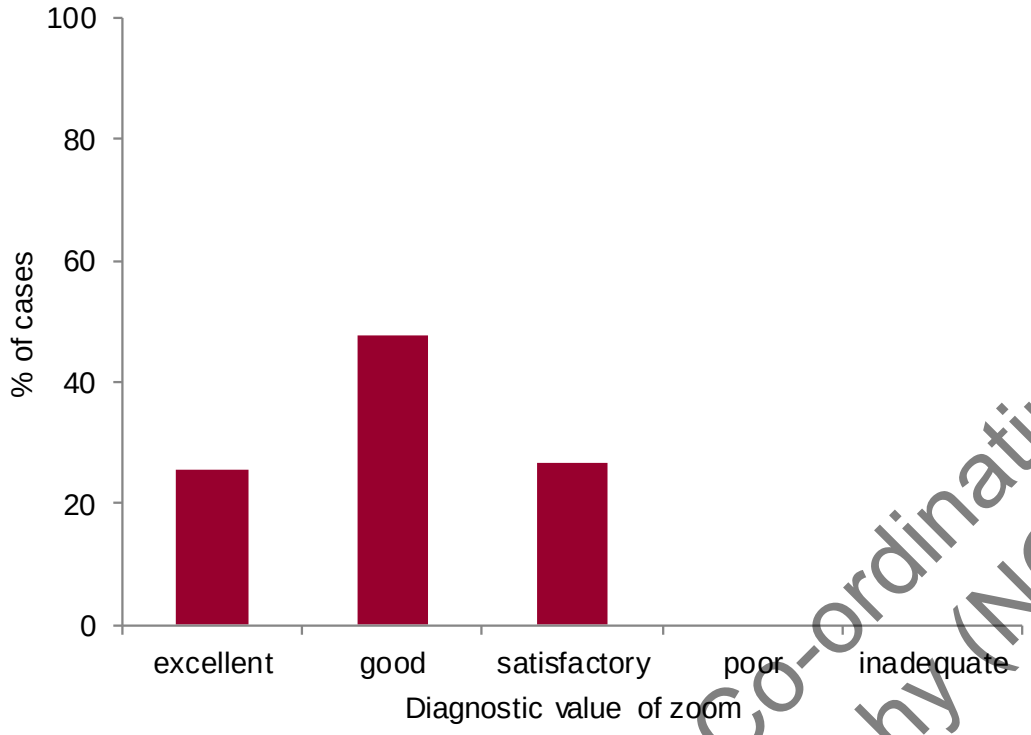

Figure 23. Readers' assessment of diagnostic value of zoom

5. Data on assessment conducted

Assessments were carried out in the weekly assessment clinics by radiologists and advanced practitioners. Women recalled to the assessment clinics were imaged according to both national and local protocols.

In the assessment clinics 2D imaging with the 3Dimensions comprised additional views and magnification views, which were used routinely for assessment of calcium. Biopsies were normally carried out in tomosynthesis mode, as described in a separate evaluation report[7].

The assessment images were reviewed by the reporting team.

During the period from February 2018 to June 2018, magnification images were acquired for 147 women using the 3Dimensions. The radiographers' comments on the practicalities of using the magnification table are presented in Section 8.26. The magnification facility on the local PACS reporting workstations was also used to review some images.

The magnification images were all assessed as good in quality.

6. Equipment reliability

The equipment performed reliably during the entire evaluation period. There was no unplanned downtime reported.

The faults recorded on the NHSBSP Equipment Fault Reporting System during this period are listed at Appendix 3.

7. Electrical and mechanical robustness

A record of all safety checks recommended in the evaluation guidelines was kept for the system during the evaluation period. There were no safety issues, and no electrical or mechanical problems were encountered during the evaluation period.

8. Radiographers' comments and observations

The radiographers and APs involved in the evaluation of the Hologic 3Dimensions were all asked to record their observations on the NHSBSP Equipment Evaluation Form 6. Because of the similarity of the 3Dimensions to the Dimensions, questions which looked at similar topics had an additional response option to indicate this equivalence.

Radiographers initially completed the questionnaires in February 2018, but on review it was seen that their experience to date had not been enough to reflect use in the longer term. They therefore completed the questionnaires again in October 2018, when they were more familiar with the system and experienced in its use. Views reported in this section have been taken mainly from the later set of responses, but some earlier responses have been included.

A total of 20 staff returned the first questionnaire in February. In October, 16 staff returned the second questionnaire. The main details from the answers and comments made on the questionnaires are given below.

A copy of the questionnaire is included at Appendix 3.

8.1 Operator manual

A user manual was provided by Hologic and radiographers were asked to give it a rating if they had used it. Two of the respondents qualified the operator manual as being the same as for the Dimensions, with 7 saying that it was good and another 2 rating it as average. The remaining 5 did not respond, with 2 of them commenting that they had not read it and 1 saying they had not seen it.

8.2 Training

6 of the respondents said that the training provided for the modality was excellent with 9 saying that it was good. One did not respond. There was one comment that sometimes a hand moving across the touch screen made the image jump.

7 of the respondents found the training for the AWS excellent with another 7 rating it as good. The remaining 2 did not respond.

8.3 Ease of use

Most of the respondents rated this as either excellent (9) or good (6). The remaining 1 said it was the same as for the Dimensions.

8.4 Exposure times

All 16 respondents said that the X-ray exposure times were acceptable.

8.5 Exposure controls

All the respondents found using the foot pedal for exposures either excellent (14) or good (2). 2 also commented that they preferred to use the foot pedal.

Use of the single exposure button, which is a new feature of the system, was also rated as excellent by 7 and good by 9 respondents. One comment was that the button was of a good size to use.

8.6 Setting radiographic views

The rotation of the support arm was rated as excellent (8) or good (6). The remaining 2 respondents found it to be the same as for the Dimensions.

A total of 2 respondents found the visibility for the set angle the same as for the Dimensions. The rest rated it as excellent (9) and good (4) with 1 saying it was average.

8.7 Setting the position of the breast support table

The respondents found there was no issue with the controls for positioning the height of the breast support table, with 10 finding them excellent and the remaining 6 saying they were good. One commented that they rarely had to use it.

8.8 Height adjustment of AWS

The adjustment of the height of the AWS is a new feature of this system. Most found it useful with 6 rating it excellent and 7 good. Of the remaining 3, one found it average and commented that they did not find it a useful effect. Another one found it satisfactory and commented that it was the same as before. There was also one very positive comment about it being beneficial to have variable height.

8.9 Angle of console surface

Another new feature of the system is that the console surface is horizontal instead of sloping. The majority (15) found it more convenient to have the console surface horizontal. There was one non-respondent who commented that it did not matter

whether it was horizontal or sloping. One found it useful to put paperwork on, like a large desk.

8.10 Use of touchpad

Respondents had an opportunity to comment on using the touchpad both before and after adjustment to its sensitivity. (see Section 1.2.1)

Before the adjustment, 2 found it excellent with 10 good, 2 average, and 1 poor. There was 1 non-respondent. One commented that they had not encountered any issues.

After the adjustment, the ratings improved slightly with 6 finding it excellent, 7 good and 2 satisfactory. There was no one saying that it was poor although one did say that it still occasionally jumped.

8.11 Use of mouse

7 of the respondents preferred to use the mouse while 7 said otherwise. Two did not respond. One preferred it sometimes, when her fingers were cold and it was more difficult to use the touchpad.

8.12 Range of movements

The range of movements was deemed more than adequate, and was rated as excellent(8) and good(6). One of the respondents said it was the same as for the Dimensions and there was 1 non-respondent.

8.13 Effectiveness of brakes and locks

Most of the respondents found that the brakes worked well, rating them as excellent (6) or good (5). A total of 3 of the remaining respondents said they were the same as for the Dimensions with the others giving no response.

8.14 Compression and paddles

The effectiveness of the compression system was rated as excellent (8), or good (6) with 1 finding it the same as for the Dimensions. There was 1 non-respondent who commented that it was “a bit sudden”. Another comment was that it was “quite fast”.

The visibility of the compression force from the breast support table was considered excellent(4), good (10) and average (1) with the last 1 saying it was the same as for the Dimensions.

The respondents were also asked how convenient it was to use the different paddles. The SmartCurve paddles were rated as excellent (2), good (4), average (7), satisfactory (1) and poor (1) with the last one a non-respondent. In the earlier survey, there had previously been several comments about how the operators' hands were getting caught under the SmartCurve paddle during compression. This was before the further training on use of SmartCurve paddles as described in Section 12. In the later survey, there was a comment about the SmartCurve paddles not being good for thin 'slim' breasts or very large ones.

Both the 18cm x 24cm flat paddle and the 24cm x 29cm flat paddle were rated as excellent (10) or good (4) while 2 said they were the same as for the Dimensions.

When using the skinny (8cm x 24cm) paddle, 9 rated it as excellent, 4 good and 1 average with 2 finding it the same as for the Dimensions.

8.15 Comfort level for women

The respondents were asked to report how comfortable the women were with the flat paddles and the SmartCurve paddles. When using the flat paddles, the system was rated as excellent (6), good (5), and average (2). The remaining 3 respondents said it was the same as for the Dimensions.

With the 18cm x 24cm SmartCurve paddle, the system was rated as excellent (3), good (7), average (2), satisfactory (2), with 2 non-respondents. There was a comment that it was too subjective to ask women to remember their level of comfort 3 years previously. One reported varying comments about comfort.

8.16 Range of controls and indicators

15 of the respondents said that all the expected controls were present with the last one saying it was the same as for the Dimensions. There were 2 comments about the fingerprint recognition not being there at the beginning.

All the respondents thought that the controls were easy to find and use. One earlier comment was that it was difficult to find the on/off switch if you do not know it is there.

With the controls positioned on the gantry column, 8 respondents found this excellent while 7 found it good and 1 average.

The facility for offsetting the tube head when positioning for MLO views was found to be excellent (2), good (6), average (2) and satisfactory (1). There were 4 non-respondents. Several said they had not used the tube offset facility, one because they were not tall

enough. One remarked that it may be good for wheelchair clients. An additional early comment was that it was used regularly by an operator with suspected back issues.

8.17 Choice of paddles/collimators for spot compression

Of the 13 respondents, 2 thought it was excellent with 6 saying it was good. 5 said it was the same as for the Dimensions. Three did not respond.

8.18 Time elapsed before the image appears on the AWS

This was rated as excellent (6) and good (6), average (1). One found it the same as for the Dimensions. Two did not respond. There was 1 comment that the time was now less important (compared to a Dimensions) as it was not necessary to accept the image before moving on.

8.19 Image handling and processing facilities at the AWS

The image handling and processing facilities at the AWS were rated as excellent (7), good (6) with 2 non-respondents. One thought it was the same as for the Dimensions.

8.20 Overall image quality at the AWS

The overall image quality at the AWS was rated excellent (8) or good (5) with the 1 rating it the same as for the Dimensions. Two did not respond.

8.21 Level of confidence in results

The respondents rated their level of confidence as excellent (10) or good (6).

8.22 Hazards

Most of the respondents (15) said there were no hazards to either themselves when using the system. One expressed a concern about a potential hazard, feeling that she might bump her head on the monitor. It was noted that the lead glass screen was quite narrow, which might be an issue when several staff were in the room for an assessment procedure. The possibility of trapping a hand under the edge of the SmartCurve paddle was mentioned once.

In the later survey, all agreed that there were no hazards to the women.

8.23 Equipment cleaning

Most of the respondents reported that the system was easy to clean, rating it as excellent (4) or good (8). The remaining 4 said that it was the same as for the Dimensions.

7 respondents said that cleaning instructions were in the manual while the other 9 did not respond. Several of the respondents said they did not know, or used the local instructions instead.

On whether the equipment cleaning met the local infection control requirements, 11 said yes with none saying no. The remaining 5 did not respond.

8.24 Patient and exposure data on images

14 of the respondents said that all the necessary patient and exposure data was available on the images. One said it was this was the same as for the Dimensions, and 1 did not respond.

8.25 Did the performance of the system limit patient throughput?

14 of the respondents said that the system did not restrict patient throughput, but 2 said it did. A comment that finishing and closing the examination takes too long may be due to the PACS being located at a site remote from the centre.

8.26 Magnification

There were 6 respondents who rated the ease with which the magnification equipment was attached and removed as good with another 4 describing it as excellent. The remaining 6 did not respond. 3 commented that it was better/easier to attach than with the Dimensions.

It was the same for the ease of use of the magnification breast support table with 3 excellent and 6 good. 1 respondent said it was the same as for the Dimensions while the other 6 did not respond. One commented that it was less clumsy to attach than for the Dimensions.

8.27 Additional comments on SmartCurve paddles

Further comments from radiographers were collated, towards the end of the evaluation period. These comments were generally not captured in the questionnaires.

Radiographers always followed the NHSBSP guidance[8] on positioning the breast, but often encountered difficulties when imaging breasts less than 50mm thick with SmartCurve paddles. This was because they initially used them on breasts of all

thicknesses. However, SmartCurve paddles were perceived as “great” for breasts of compressed thickness 60-70mm or more. It was noted that habitus and the type of breast (dense or fatty) would affect the choice of SmartCurve or flat paddle.

The difficulties often experienced with breasts less than 50mm thick were as follows. Many found that extending the breast forward in the CC view, and holding it there whilst compression was applied, caused their hands or wrists to be trapped by the lower part of the SmartCurve paddles. With the MLO views, supporting the breast fully until compression was sufficient to hold the breast and demonstrate the inframammary angle (IMA), could also result in their wrists or hands becoming trapped. Alternatively, they found that the inframammary fold was compromised, as they had to let go of the breast to get their hand out.

Towards the end of the evaluation, Hologic provided further training on use of the SmartCurve paddles, as described in Section 12. The SmartCurve paddles were thought to be most useful for selected assessment cases, rather than for screening.

The film readers reported no loss of tissue in images acquired with SmartCurve paddles, but the smooth curve of the IMA was not always clearly shown without any overlying or underlying tissue. It is expected that the IMA should always be shown clearly.

8.28 Additional comments on other aspects

There were a number of comments on aspects of the system that were not covered in the questionnaire, as follows:

- the position of the monitor on the AWS could have been on the other side, which would give the operators a clearer view and better access to the panel.

  The position of the AWS is customisable on the Hologic system. Typically at installation, Hologic will discuss the position of the monitor with the Superintendent or the Lead Radiographer to identify preferences.

- the area behind the AWS is too cramped

  The “cramped area” comment does not reflect on the 3Dimensions, but is due to the size of the room where it was installed.

- very quick and images are awesome, much preferred for screening
- excellent equipment, really enjoy using it and image quality is fantastic

9. Readers' comments and observations

9.1 Reporting workstation

A SecurView workstation was available for the evaluation, but was not used very much because it was located outside the reading room, and so was less convenient to use. No workstation assessment was carried out as part of this evaluation, as it was not new equipment.

The centre uses Eizo MX workstations as their main PACS reporting workstations. These were normally used by the radiologists and other film readers to report on mammograms from the centre's existing systems. They, therefore, decided to continue with the existing reporting facilities for the evaluation.

9.2 Image quality

The radiologists' and film readers' assessment of image quality is presented in Section 4.4.

9.3 Use in assessment

The assessment images were reviewed by the assessment team, of two or three clinicians. All images were double read. Images taken in the clinic were scored overall as good or excellent when assessing the sharpness and overall quality of the images. Images reviewed using the magnification facility on the reporting workstation were also satisfactory.

Very few blurred images were identified during the evaluation.

10. Confidentiality

The evaluation complied fully with the NHS Cancer Screening Programmes' Confidentiality and Disclosure Policy[9].

11. Security issues

There were no issues with security as the system was located within the centre.

All electronic patient data were stored within NBSS and PACS as well as the centre's other systems. Access to all these systems is restricted to authorised users by password protection.

Access to the AWS and to the reporting workstations was similarly restricted to authorised users with individual passwords.

12. Training

The centre already had a number of Hologic systems in operational use, including Dimensions. Staff were, therefore, already familiar with many aspects of the system.

The initial applications training was provided over a week by an applications specialist from Hologic. Most members of staff had the opportunity to spend some time with the applications specialist during that period. Those who were not available in that period were trained by colleagues. Advice was always available over the phone from the Hologic applications support team. Several additional visits were made by the applications team to sort out issues as they arose.

Because of the issues raised with the SmartCurve paddle, Hologic offered further training for the radiographers which was taken up in October 2018. The radiographers thought this was beneficial as a refresher. The training specifically covered use of SmartCurve paddles with assessment women, considering factors such as thickness of the breast, scarring and anxiety levels. In suitable cases the SmartCurve paddle was well received. A minimum breast thickness of 40mm was suggested, for radiographers not to get their hands trapped when using SmartCurve paddles.

13. Discussion

13.1 Equipment and practical considerations

The 3Dimensions has several new ergonomic features, which most users found beneficial. These included the exposure foot pedal and single exposure button, the flat AWS table, the height-adjustable AWS and movement control buttons on the gantry. The facility to offset the tube head, while positioning for MLO exposures, was also appreciated by the majority of users. Some users experienced difficulty in using the touchpad when it was newly installed, as it was found to be very sensitive and the wrong patient name could inadvertently be selected from the worklist. After adjustment of the sensitivity, the majority were satisfied and found it easy to use. For some, reflection of light from the touchscreen surface was an issue, but this was related to individuals' height and the overhead position of the room lighting.

Some users considered that the compression came down fast. This may be in comparison to older equipment in the centre, as Hologic staff confirmed that the speed was as normal.

Some users reported difficulty in positioning with the SmartCurve paddle, as their hand became trapped under the outer curved edge. This was more likely to occur with smaller breasts. It was reported that the paddle caused some discomfort at the axilla for a few women; this may depend on the body habitus. It would be best to avoid using the SmartCurve paddle for certain cases, such as very small breasts.

13.2 Physics testing and routine QC

Physics tests carried out at commissioning and again some months later found equipment performance to be satisfactory.

A large number of QC tests were carried out routinely during the evaluation, and extensive results are presented in Section 3. These were the standard tests required in the NHSBSP protocol except that CNR was measured daily. The test results, taken as a whole, showed that the performance of the system was consistent and satisfactory, and remained within the NHSBSP limits.

13.3 Dose surveys

Dose surveys for both flat and SmartCurve paddles, of both sizes, indicated that doses were higher for SmartCurve paddles, for MLO views of 50-60mm thick breasts. For the 18cm x 24cm paddles, the difference was not significant. These results are based on

the simplistic assumption of using the displayed CBT to calculate the MGD; however, this assumption has been verified by physics measurements[4].

13.4 Screening times

Although there were no separate changing facilities adjacent to the room, records of timing showed that some women could be screened in 5 or 6 minutes (total time in the room). Many longer times were recorded, as women normally attend for screening in the centre in more complex cases, such as having a disability. The timings showed that 6 minute appointment times are achievable with this system, meeting the requirement of the NHSBSP.

13.5 Clinical assessment

Over 100 sets of images were assessed by the readers. Overall, approximately 75% of images were judged to have good or excellent image quality with the rest almost all satisfactory.

No evidence was found of noise in images in small breasts or breasts with implants.

13.6 Radiographers' and readers' views

The radiographers found the 3Dimensions easy to use. Many practical aspects were similar to the Dimensions, with which all were familiar. The newer ergonomic features were generally appreciated.

Those who received applications training rated it highly. The few complaints were from those who missed the training when it was delivered because they were working on mobile vans.

The radiographers expressed a few concerns about the system:

- the lead glass screen was too small when several staff were in the room during assessment examinations
- some users would have preferred the display screen to be on the other side of the AWS – the decision was selected at installation by the team
- occasionally their hands would be trapped under the sides of the SmartCurve paddles
- it could be difficult in some cases to pull the breast forward when using the SmartCurve paddles

After further training and more experience, the conclusion was reached that the SmartCurve paddles were most suitable for use in selected assessment cases, rather than for screening. Avoiding their use on thinner breasts (less than 50mm thick)

alleviated entirely the problem of radiographers' hands becoming trapped under the sides of the paddles.

A minor change to the AEC software would be expected to resolve the rare occurrence of the mAs being too low with a SmartCurve paddle, causing a noisy image. Otherwise the radiologists and film readers were satisfied with all aspects of the 3Dimensions and its images.

14. Conclusions and recommendations

The 3Dimensions was reliable in use for screening and assessment during the evaluation period. A few engineer visits were required but there was no downtime recorded.

Radiographers and APs found it easy to use and appreciated the new ergonomic features. However, they found some practical difficulties in using the SmartCurve paddles with breasts of thickness less than 50mm.

Image quality was assessed as good or excellent in the majority of cases. The average MGD calculated for MLO views of 50-60mm breasts was 1.7mGy, well below the national DRL of 2.5mGy. However, the MGDs for the large SmartCurve paddle were slightly higher than the MGDs for the flat paddles. For this reason, and also due to some practical difficulties encountered during their use, the SmartCurve paddles are most appropriate for use in clients with breast thickness of more than 50mm.

Overall the 3Dimensions in 2D mode was found to be suitable for general use in the NHSBSP, when used with standard flat paddles. The SmartCurve paddles could be used in selected cases.

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Appendix 1 – Physics survey reports

A1.1 Commissioning Report

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Mammography Physics Commissioning Report – Version 2

Hologic 3Dimensions

Jarvis Breast Screening Centre – Room 3

1 Introduction

A commissioning survey was carried out on the 12th and 13th October 2017 for a Hologic 3Dimensions full-field digital mammography system with tomosynthesis installed in Room 3 at the Jarvis Breast Screening Centre. The X-ray equipment was tested in accordance with the requirements of the Ionising Radiations Regulations 1999 and NHS BSP 33, 'Quality Assurance Guidelines for Medical Physics Services'. Engineering controls, safety features and warning signals provided by the employer were also checked as part of the survey.

The performance of the X-ray equipment and displays were checked using procedures described in IPEM89 "The Commissioning and Routine Testing of Mammographic X-ray Systems" and NHSBSP publication 0604 "Commissioning and Routine Testing of Full Field Digital Mammography Systems". Performance was compared with NHSBSP standards and the Recommended Standards for the Routine Performance Testing of Diagnostic X-Ray Imaging Systems (IPEM91). Tomosynthesis imaging capabilities were tested in accordance with the NHSBSP Equipment Report 1407 "Routine quality control for breast tomosynthesis (Physicists)".

A new acquisition workstation monitor for the mammography unit and new 5MP tomosynthesis reporting workstations were also assessed in accordance with IPEM Report 91 and NHSBSP publication 0604 and the reports are attached.

A Critical Examination of the mammography system was completed on behalf of Hologic and will be reported separately.

This report has been updated to take into account new information provided by Hologic regarding the application of a geometric correction factor when performing the image size test. Changes have been highlighted in red.

2 Equipment

Mammography Unit:	Hologic 3Dimensions
System ID:	3DM160700101
Detector ID:	YM868135
Tube ID:	84518-P7
Acquisition Monitor:	Barco MDNC-3321 (3MP) SN: 2590087697
Reporting Workstation:	Barco MDMG-5221 (5MP) SN: 2590080575 (Left) / 2590075135 (Right)

3 Radiation Protection

The unit has been installed into an existing mammography room and the room layout has not been altered.

The following points were noted regarding radiation protection:

- Measurements of scattered doses were made using a 'combo' tomosynthesis + 2D exposure at the operator position, outside the door into the examination room and through the wall to the corridor opposite the gantry. These measurements were satisfactory and doses are not expected to exceed a constraint of 0.3 mSv/annum based on a workload of 250 patients/week.
- A new lead screen has been installed by Hologic at the control console and is labelled appropriately (0.5 mm Pb @ 35 kV).

Page 1

- A "Controlled Area X-Rays/Do Not Entrer" warning light is fitted to the left hand side of the door into the mammography room from the corridor. This was found to be functioning correctly.
- All emergency off buttons were tested and found to be operating satisfactory. The system is correctly re-armed when the start button positioned behind the operator screen is pressed.
- A prior risk assessment will need to be carried out for the new mammography installation.
- Area local rules are in place, but should be reviewed after carrying out the risk assessment.
- A fault reporting system is in place already.

4 Equipment Radiation Protection and Performance

Radiation protection and performance checks gave satisfactory results. This is the first system of its type installed in the UK, however results were compared with those from Hologic Dimensions systems previously tested. Mean Glandular Doses (MGDs) in both 2D and tomo modes were found to be comparable to those measured for Dimensions systems. Contrast to Noise Ratios (CNRs) in 2D mode were also found to be comparable, however CNRs for tomo images were found to be slightly lower. This may be due to an increase in image noise caused by the smaller reconstructed pixel size for tomosynthesis images (70µm for the 3Dimensions system compared with 110µm for the Dimensions system). It is not known what effect this will have on overall image quality. The CDMAM test object was used to assess threshold contrast detail detection in 2D and tomosynthesis modes and results were again comparable to those obtained from Dimensions systems. It is acknowledged that the CDMAM test object was not designed for assessing tomosynthesis image quality.

The detailed results are appended to this report.

5 Conclusions and Recommendations

Room protection was found to be satisfactory. The X-ray equipment was operating satisfactorily in line with specification. The performance in terms of image quality and dose is excellent.

Recommendations

Radiation Protection

Flag	Conclusions	Recommendations	Local Action Taken (where required)	Sign & Date
RA	A prior risk assessment should be carried out for the new equipment.	6.1 A prior risk assessment should be carried out.		
A	Area local rules were on display but require reviewing.	6.2 Area Local Rules should be reviewed for the new equipment.		
A	Local QC checks will need to be implemented on the new unit. These were discussed with users during the survey.	6.3 Local QC checks should be established as soon as possible. Baseline, remedial and suspension levels will need to be set in both 2D and tomosynthesis modes. A spreadsheet has been provided to record results.		
A	Examination protocols should be documented	6.4 Examinations protocols should be documented and should include the standard settings used for both 2D and tomosynthesis exposures.		
A	A patient dose survey will need to be undertaken.	6.5 A patient dose survey should be undertaken to establish an LDRL for the new mammography unit. At least 50 patients are required for both 2D and tomosynthesis modes.		

Conventional 2D Mode

Flag	Conclusions	Recommendations	Local Action Taken (where required)	Sign & Date
A/G	The X-ray beam overlaps the left side of the images in contact mode by slightly more than 5mm in some cases.	6.6 This will have no impact on the image quality, patient dose or radiation safety of the system and therefore no action is required.		

Tomosynthesis 3D Mode

Flag	Conclusions	Recommendations	Local Action Taken (where required)	Sign & Date
A/C	The system has an Enhanced Mode feature which can be selected for tomosynthesis. This gives an increase in CNR up to 48% depending on the PMMA thickness; however it should be noted that the Mean Glandular Doses may be up to twice those in Standard Mode. This varies depending on the thickness of PMMA and at 7cm (90mm breast equivalent) the results for Standard and Enhanced modes are the same.	6.7 Standard Mode is recommended as the default. Use of Enhanced Mode would need to be justified in terms of the increased dose to the patient.		
A	The stereo biopsy license was not installed at the time of testing.	6.8 AEC and QAS tests have been requested to be carried out by the service engineer and results reported to Physics.		
A/C	CNRs and MGDs are the same in Tomo and TomoHD modes, however a C-view synthetic 2D image is generated automatically in TomoHD mode. There is currently no recommended test for assessing image quality for C-view.	None.		

Monitors

Flag	Conclusions	Recommendations	Local Action Taken (where required)	Sign & Date
G	Both the acquisition monitor and the new 5MP monitors were found to be operating satisfactorily.	None.		

Emma Bolt — ***Principal Physicist***

Mary Kelly — ***Lead Physicist***

18th October 2017 (Updated 3rd August 2018)

Key

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

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Mammography Physics Commissioning Report

2D Results Summary

Location *Jarvis BSC* ***Survey Date*** *12-13 October 2017*

Equipment *X-ray Room 3*

X-ray Set	Hologic	3Dimensions
Detector	DR: Hologic	

Survey Results

1 Radiation Protection

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

2 Tube and Generator

Measurement	Criteria	Result	OK	Comments
Tube Voltage	Max error ±1kV	0.6 kV	✓	
Tube Output (µGy/mAs@50cm)				
28kV WRh BF	Baseline set	67.7	✓	
28kV WAg BF	Baseline set	80.9	✓	
28kV WRh FF	Baseline set	58.5	✓	
28kV WAg FF	Baseline set	71.4	✓	
Repeatability (%)	Max 5% dev from mean	0.1	✓	
Variation with mAs (%)	Max 10% dev from mean	1.9	✓	
Half Value Layer (mmAl)				
28kV WRh		0.497	✓	
28kV WAg		0.531	✓	
Focal Spot (mm)				
BF W	>150% of nominal (0.3)	0.28	✓	
FF W	>150% of nominal (0.1)	0.09	✓	
Tube leakage (mGy/hr)	Max 1 mGy/hr@1m	0.03 mGy/hr@1m	✓	

3 X-ray Set

Measurement	Criteria	Result	OK	Comments
Max (kg)	15 - 20 kg	19.5	✓	
Maximum error (kg)	2 kg	1.1	✓	
Change over 30s	Should be no change	No change	✓	
CBT indicator max error (mm)	±5 mm at 50 N	4	✓	
Edge of bucky alignment	Within 5 mm	4.5	✓	
Image Size	Ratio > 0.95 of specified	18x24: LR: 1.00 FB: 1.00 24x29: LR: 1.00 FB: 1.00	✓	
Grid Transmission Factor	N/A	0.72 @ 29kV W/Rh	✓	
Paddle Transmission Factor	N/A	0.81 @ 28kV W/Rh	✓	

4 Alignment							
Measurement	**Criteria**	**Result**				**OK**	**Comments**
X-ray to Light Alignment	±5mm at all edges	F	B	L	R		
24x30 BF W		0	0	1	2	✓	
18x24 BF W		-1	-2	0	1	✓	
18x24 (left shift) BF W		-1	-2	0	-1	✓	
18x24 (right shift) BF W		-1	-1	-2	2	✓	
Mag 10 cm FF W		1	-1	0	0	✓	
X-ray to Detector Align. (mm)	0-5mm overlap all sides	F	B	L	R		
24x30 BF W		4	1	4	3	✓	
18x24 BF W		3	4	6	4	✓	1
18x24 (left shift) BF W		3	4	3	5	✓	
18x24 (right shift) BF W		4	5	6	3	✓	1
Mag 10 cm FF W		2	2	2	1	✓	
5 Detector Performance							
Measurement	**Criteria**	**Result**				**OK**	**Comments**
Detector Response							
Air Kerma (µGy) at PV=300	Baselines set	97.7				✓	
Noise		4.60				✓	
SNR		54.4				✓	
Limiting Resolution (lp/mm)	>70% Nyquist freq. (>5 lp/mm)	6.3 lp/mm				✓	
SWCTF(perp) at 1, 4, 5.6lp/mm	Baselines set	0.365	0.252	0.206		✓	
SWCTF(para) at 1, 4, 5.6lp/mm		0.362	0.249	0.204		✓	
Spatial Discontinuity	None	None				✓	
Image Retention	Retention Factor < 0.3	0.02				✓	
Calliper accuracy	Error 2%	1.0%				✓	2
Distortion	Any Distortion	No distortion seen				✓	
Uniformity	<10% variation	1.0%				✓	
6 Image Quality							
Measurement	**Criteria**	**Result**				**OK**	**Comments**
CDMAM							
Threshold Gold Thickness	Min Achievable						
Detail Diameter 1mm	0.091 0.056	0.049				✓	
0.5mm	0.150 0.102	0.095				✓	
0.25mm	0.352 0.244	0.205				✓	
0.1mm	1.680 1.100	0.881				✓	
Tormam	Baseline set	Baseline set				✓	

7 AEC Performance								
Measurement	**Criteria**	**Result**					**OK**	**Comments**
AEC Repeatability (%)	5% max dev from	1.6					✓	
AEC variation with position	>10% variation in mAs	4.0					✓	
AEC variation with density (%)	Hologic specification 15% mAs change per step	16%					✓	
Back up Timer	Functioning	Functioning					✓	
24x30								
CNR - variation with PMMA	Baselines set	Settings		CNR				
2 cm		25 W Rh		9.41			✓	
3 cm		26 W Rh		8.52			✓	
4 cm		28 W Rh		7.76			✓	
4.5 cm		29 W Rh		7.24			✓	
5 cm		31 W Rh		7.26			✓	
6 cm		31 W Ag		7.01			✓	
7 cm		34 W Ag		5.71			✓	
Mag								
CNR - variation with PMMA	Baselines set	Settings		CNR				
2 cm		25 W Rh		11.48			✓	
3 cm		27 W Rh		9.67			✓	
4 cm		30 W Rh		8.02			✓	
4.5 cm		31 W Rh		7.30			✓	
5 cm		31 W Ag		6.20			✓	
6 cm		34 W Ag		5.06			✓	

8 Mean Glandular Dose								
Measurement	**Criteria**	**Result**					**OK**	**Comments**
24x30	Within 30% of displayed values and	Settings	mAs	MGD (mGy)				
MGD (mGy) at thickness				Disp	Calc	% diff		
2 cm	<1mGy	25 W Rh	55	0.59	0.62	-5%	✓	
3 cm	<1.5mGy	26 W Rh	85	0.85	0.86	-1%	✓	
4 cm	<2mGy	28 W Rh	107	1.17	1.14	3%	✓	
4.5 cm "Standard Breast"	<2.5mGy	29 W Rh	128	1.47	1.41	4%	✓	
5 cm	<3mGy	31 W Rh	157	2.06	1.92	7%	✓	
6 cm	<4.5mGy	31 W Ag	174	2.79	2.44	14%	✓	
7 cm	<6.5mGy	34 W Ag	174	3.36	2.76	22%	✓	

9 Stereotactic Unit						
Measurement	**Criteria**	**Result**			**OK**	**Comments**
Stereotactic error (mm)	X, Y: 1mm, Z: 3 mm	QAS needle – max deviation 0.2 mm			✓	
MGD (mGy) at thickness		Settings	mAs	MGD (disp.)		
2 cm	<1mGy	25 W Rh	61	0.71	✓	
3 cm	<1.5mGy	26 W Rh	92	0.95	✓	
4 cm	<2mGy	28 W Rh	126	1.38	✓	
4.5 cm "Standard Breast"	<2.5mGy	29 W Rh	155	1.79	✓	
5 cm	<3mGy	31 W Rh	169	2.21	✓	
6 cm	<4.5mGy	31 W Ag	188	3.01	✓	
7 cm	<6.5mGy	34 W Ag	208	4.03	✓	

Comments

1. *The x-ray to imaged field alignment error exceeds 5mm for the left edges of the 18x24 central and left shift fields.*
2. *Calliper accuracy was tested in both contact and magnification modes on both the acquisition monitor and SecurView workstation.*

Reported By:
Emma Bolt
Principal Physicist

18th October 2017 *(Updated 3rd August 2018)*

Regional Radiation Protection Service NHS
St. Luke's Wing Royal Surrey County Hospital Guildford Surrey GU2 7XX
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Mammography Physics Commissioning Report
Tomosynthesis Results Summary

Location *Jarvis Breast Screening - Room 3* ***Survey Date*** *13 October 2017*

Equipment *Hologic 3Dimensions*

X-ray Set	Hologic 3Dimensions
Detector	FFDM-SD

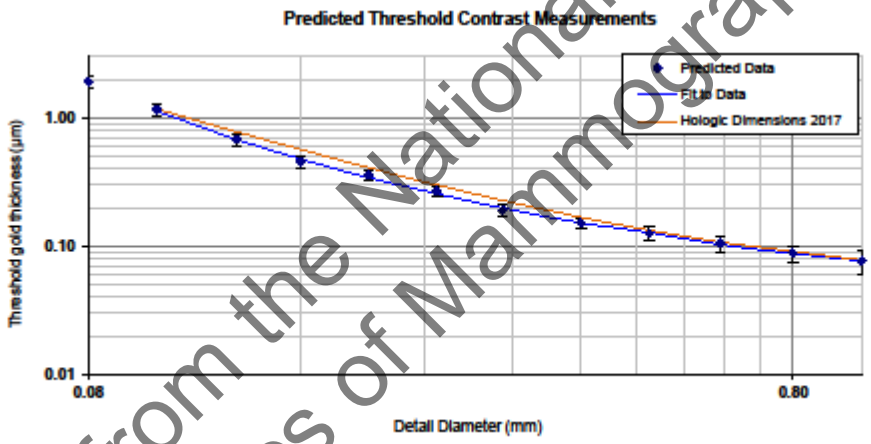
Survey Results

Measurement	Criteria or specification	Results	Satisfactory	Comments
Alignment				
X-ray field to reconstructed image alignment at chest wall	0-5mm	3 mm	✓	
Primary beam attenuation	Primary beam must be blocked by detector & surrounding structure	Confirmed satisfactory	✓	
Missed tissue at chest wall	< 5mm	4.5 mm	✓	
Target volume visualisation	All markers at top & bottom of target volume must be brought into focus	Yes	✓	
Tube output and HVL				
Tube Output (µGy/mAs@1m) and HVL (mm Al)	Baselines set	*kV/T/F* / *Output* / *HVL* 26 WAl / 22.3 / 0.433 28 WAl / 28.3 / 0.469 30 WAl / 34.4 / 0.506 31 WAl / 37.9 / 0.524 33 WAl / 44.4 / 0.560 36 WAl / 54.9 / 0.614 42 WAl / 77.4 / 0.723	✓	
Uniformity and artefacts	No clinically significant artefacts should be seen	Artefacts were seen	✓	1

Survey Results							
Measurement		**Criteria or specification**	**Results**			**Satisfactory**	**Comments**
Geometric distortion and artefact spread							
			Height of test object above table (mm)				
			7.5	*32.5*	*52.5*		
Height of best plane of focus		Baselines set	7.2	32.3	52.5	✓	
Distortion within focal plane – ratio of mean separations of balls in X and Y planes			1.00	1.00	1.00	✓	
Scaling accuracy (%)			0.36	0.47	0.43	✓	
FWHM perpendicular to detector (vertical or Z plane resolution), mm			11.4	10.7	10.4	✓	
Spread parallel to detector	X plane (parallel to tube axis)		0.04 mm	0.03 mm	0.02 mm	✓	
			0.6 pixels	0.5 pixels	0.4 pixels		
	Y plane (perpendicular to tube axis)		0.09 mm	0.09 mm	0.07 mm	✓	
			1.3 pixels	1.3 pixels	1.1 pixels		

Automatic Exposure Control (AEC Performance)						
AEC Repeatability	Max deviation in mAs or SNR from mean of >5%	mAs repeatability = 1.2 %			✓	
		SNR variation = 1.4 %			✓	
Contrast to Noise Ratios (CNRs)						
Image Size = 24x30 AEC mode = Auto Filter, Standard Processing = LCC Tomo						
Variation with PMMA	Baselines set	***kV/T/F***		***CNR***		
2 cm		26 WAl		7.0		
3 cm		28 WAl		5.2		
4 cm		30 WAl		4.5		
4.5 cm		31 WAl		4.6	✓	
5 cm		33 WAl		4.3		
6 cm		36 WAl		3.9		
7 cm		42 WAl		3.1		
Image Size = 24x30 AEC mode = Auto Filter, Enhanced Processing = LCC Tomo						
Variation with PMMA	Baselines set	***kV/T/F***	***CNR***	***% diff from Standard***		
2 cm		27 WAl	10.0	42%		
3 cm		29 WAl	7.8	48%		
4 cm		32 WAl	6.3	40%		
4.5 cm		33 WAl	6.1	33%	✓	2
5 cm		36 WAl	5.4	26%		
6 cm		41 WAl	2.6	-34% *		
7 cm		42 WAl	3.0	-4%		
* A processing artefact was present on this image which resulted in a lower CNR than expected. The artefact is not expected to affect clinical images.						

Survey Results					
Measurement	**Criteria or specification**	**Results**		**Satisfactory**	**Comments**
Image Quality					
AEC mode = Auto Filter, Standard					
Detail detection – threshold gold thickness, µm	Comparable with other units of same type	*Detail diameter, mm*	*Result*		
		0.08	1.910		
		0.1	1.152		
		0.13	0.678		
		0.16	0.455		
		0.2	0.357		
		0.25	0.268		
		0.31	0.190		
		0.4	0.151		
		0.5	0.125		
		0.63	0.105		
		0.8	0.087		
		1	0.076		
Best slice in focus (average):	21				



Survey Results

Measurement	Criteria or specification	Results	Satisfactory	Comments
Mean Glandular Dose (MGD)				

AEC mode = Standard

PMMA	Baselines set	kV/T/F	MGD (mGy)		% diff between displayed & calculated	Satisfactory	Comments
			Calculated	Displayed			
2 cm	Displayed values of MGD not > 30% different from calculated values	26 WAl	0.98	0.94	-3.7%	✓	
3 cm		28 WAl	1.07	1.08	0.5%	✓	
4 cm		30 WAl	1.40	1.44	3.2%	✓	
4.5 cm		31 WAl	1.85	1.93	4.3%	✓	
5 cm		33 WAl	2.20	2.35	6.8%	✓	
6 cm		36 WAl	3.39	3.66	7.9%	✓	
7 cm		42 WAl	4.57	4.89	7.0%	✓	

AEC mode = Enhanced

PMMA	Baselines set	kV/T/F	MGD (mGy)		% diff between displayed & calculated	% diff. from Standard	Satisfactory	Comments
			Calculated	Displayed				
2 cm	Displayed values of MGD not > 30% different from calculated values	27 WAl	1.90	1.89	0%	95%	✓	2
3 cm		29 WAl	2.15	2.16	0%	100%	✓	
4 cm		32 WAl	2.79	2.84	2%	100%	✓	
4.5 cm		33 WAl	3.56	3.75	5%	93%	✓	
5 cm		36 WAl	4.35	4.49	3%	98%	✓	
6 cm		41 WAl	5.02	5.20	4%	48%	✓	
7 cm		42 WAl	4.57	4.89	7%	0%	✓	

Comments

1. A subtle artefact was seen on the back edge of tomosynthesis slices. This is common for Hologic systems and is unlikely to impact on clinical image quality.
2. The system has an Enhanced mode which can be selected for tomosynthesis, however it should be noted that the Mean Glandular Dose measured are up to twice those in Standard mode with an average increase in CNR of 22% across the PMMA range of 2 cm - 7 cm.

Reported By: *Emma Bolt* *Principal Physicist* *Mary Kelly* *Principal Physicist* *18/10/2017*

Regional Radiation Protection Service

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Mammography Image Display Commissioning Report

Jarvis Breast Screening Centre - Room 3
October 2017

1. Background

A commissioning survey of the acquisition monitor for the mammography unit located in Room 3 at the Jarvis Breast Screening Centre was undertaken on 13th October 2017. The monitor was tested against the criteria given in the NHSBSP Report 0604, Commissioning and Routine Testing of Full Field Digital Mammography Systems. Tolerances for secondary monitors are less strict than for primary monitors which can be seen from the remedial levels given below.

2. Equipment

Workstation	
Type	Acquisition Monitor
Location	Room 3
Make & Model	Barco MD-3321
Pixels	3MP
Serial No.	2590087697

Test Pattern	
Type	SMPTE

3. Survey results

Physical parameter		Remedial Level	Results	OK?	Comment No.
General condition of unit		Satisfactory	Satisfactory	✓	
Luminance (cd/m^2)	100% White	< 200	517	✓	
	0% Black	> 1.0	0.4	✓	
	Ratio	< 100	1292	✓	
Max % diff from DICOM greyscale calibration		GSDF ± 20%	6.3	✓	
% Non-Uniformity		> 30%	5.5	✓	

4. Comments

None, satisfactory

Emma Bolt
Principal Physicist
18th October 2017

A1.2 Routine Physics Report

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Mammography Physics Routine Survey Report

Hologic Selenia 3Dimensions with Tomosynthesis

Jarvis Breast Screening Centre

1 Introduction

A routine radiation protection and performance survey of the Hologic 3Dimensions digital mammography equipment was undertaken on the 19th February 2018. The X-ray equipment was tested in accordance with the requirements of the The Ionising Radiation (Medical Exposure) Regulations 2017 and NHS BSP 33, 'Quality Assurance Guidelines for Medical Physics Services'. Engineering controls, safety features and warning signals provided by the employer were also checked as part of the survey.

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

The survey included performance testing of the tomosynthesis imaging capabilities in accordance with the NHSBSP Equipment Report 1407: Routine quality control tests for breast tomosynthesis (Physicists) (May 2015).

2 Equipment

Mammography Unit:	Hologic Selenia 3Dimensions
System ID:	3DM160700101

3 Conclusions and Recommendations

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

Tomosynthesis Mode

Flag	Conclusions	Recommendations	Local Action Taken (where required)	Sign & Date
G	None, satisfactory	None		

Conventional 2D Imaging

Flag	Conclusions	Recommendations	Local Action Taken (where required)	Sign & Date
A	1. The maximum compression force was measured to be slightly greater than 20 kg.	The service engineer should be asked to reduce the maximum compression force to be between 15-20 kg.		
A/G	2. The x-ray field was found to overlap the imaged area by slightly more than 5 mm for some fields. This will have no significant impact on image quality, patient dose or radiation safety and therefore no action is required.	None.		
A/G	3. The X-ray tube output and AEC post exposure mAs values were found to have decreased from baseline values, however Mean Glandular Doses (MGDs) remain within ±25% of the baseline value and no significant reduction in image quality was observed.	It is recommended that local QC is monitored closely to ensure that the mAs values remain within ±10% of remedial levels.		
A	4. For 7 cm PMMA, the variation between displayed and calculated MGD was found to be slightly outside the ± 30% remedial limit.	Hologic have been contacted and asked to comment on the method used for MGD calculation. RRPS will follow up in due course.		
A/G	5. The post exposure mAs values under AEC control in stereo mode were found to be comparable to previous values. Results are shown in table 1.	None.		

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

Table 1. Stereo AEC Test Results

	Baseline results October 2017			February 2018		
PMMA (cm)	CBT (cm)	kV / Target-Filter	mAs	CBT (cm)	kV / Target-Filter	mAs
2	2.2	25 W Rh	61	2.3	25 W Rh	60
4.5	5.3	29 W Rh	155	5.3	29 W Rh	156
7	9.0	34 W Ag	208	9.0	34 W Ag	204

Rebecca Hammond
Trainee Healthcare Scientist

Tom Jupp
Principal Physicist

23rd February 2018

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Mammography Routine Performance Report
Results Summary

Location Jarvis BSC
X-ray Room 3

Survey Date 19/02/2018

Equipment

X-ray Set	Hologic	3Dimensions
Detector	DR Hologic	 3Dimensions
Small Field Digital	n/a	n/a

Survey Results

1 Radiation Protection

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

2 Tube and Generator

Measurement	Criteria	Baseline	Result	OK	Comments
Tube Voltage (kV)	Max error ±1kV		1.0	☑	
Tube Output (uGy/mAs@50cm)					
28kV MoMo BF	>120 + 70% of baseline			☐	N/A
28kV MoRh BF				☐	N/A
28kV RhRh BF				☐	N/A
28kV WRh BF		67.7	64	☑	
28kV WAg BF		80.9	79	☑	
28kV MoMo FF				☐	N/A
28kV WRh FF		58/5	51	☑	
Output Rate (MoMo)	>7.5 mGy/sec			☐	N/A
Focal Spot (mm)					
BF Mo	150% of nominal value	Nominal BF 0.3		☐	N/A
BF Rh				☐	N/A
BF W			0.28	☑	
FF Mo		Nominal FF 0.1		☐	N/A
FF Rh				☐	N/A
FF W			No change from baseline	☑	

3 X-ray Set

Measurement	Criteria	Baseline	Result	OK	Comments
Patient Compression					
Max (kg)	15 - 20 kg		20.5	☐	1
Maximum error (kg)	2 kg		2.0	☑	
Change over 30s	Should be no change			☑	
CBT indicator max error (mm)	±5 mm at 100 N		4.0	☑	
Edge of bucky alignment (mm)	Within 5 mm			☑	

4 Alignment										
Measurement			Criteria	Baseline	Result				OK	Comments
X-ray to Light Alignment (mm)			±5mm at all edges		F	B	L	R	☑	
18x24 R	BF	W			1	-1	-3	1		
18x24 L	BF	W			1	-3	1	-1		
24x30	BF	W			0	-5	-1	-1		
18x24	BF	W			1	-3	0	0		
Mag	FF	W			0	-1	0	-1		
X-ray to Detector Alignment			0-5mm overlap all sides		F	B	L	R	☑	2
18x24 R	BF	W			2	4	4	2		
18x24 L	BF	W			2	3	6	5		
24x30	BF	W			5	0	4	0		
18x24	BF	W			2	4	5	3		
Mag	FF	W			1	3	2	1		

5 Detector Performance								
Measurement	Criteria	Baseline			Result			OK	Comments
Detector Response									
Air Kerma (µGy) at PV= 300	20% change frm baseline	97.74			97.2			☑	
Noise	10% change frm baseline	4.63			4.30			☑	
SNR	10% change frm baseline	54.43			58.2			☑	
Limiting Resolution (lp/mm)	<75% of baseline	6.3			6.3			☑	
SWCTF(perp) at 1lp/mm, 4lp/mm, 80% Nyquist	10% change frm baseline	0.365	0.252	0.206	0.35	0.23	0.19	☑	
SWCTF(para) at 1lp/mm, 4lp/mm, 80% Nyquist	10% change frm baseline	0.362	0.249	0.204	0.36	0.23	0.20		
Spatial Discontinuity	None							☑	
Image Retention	Retention factor <0.3				0.01			☑	
Uniformity	<10% variation				DR		1.0	☑	
					CR	Centre-side			
						Left-right			

6 Image Quality					
Measurement	Criteria		Result	OK	Comments
CDMAM					
Threshold gold thickness (µm)	Min	Achievable			
Detail Diameter 2mm			N/a		
1mm	0.091	0.056	0.06	☑	
0.5mm	0.150	0.103	0.10	☑	
0.25mm	0.352	0.244	0.20	☑	
0.1mm	1.690	1.100	0.83	☑	
TORMAX					
Perpendicular lp/mm	Significant difference			☐	n/m
Parallel lp/mm	from baseline				
Contrast (%) 1mm					
Contrast (%) 0.5mm					
Contrast (%) 0.25mm					
TORMAM	Significant difference				
Diff from Baseline	from baseline		Unchanged	☑	

7 AEC Performance

Measurement	Criteria	Baseline	Result	OK	Comments
AEC Repeatability (%)	5% max dev from mean		2.5	☑	
Back up Timer	Functioning		mAs BF: FF:	☑	

24x30								
CNR - variation with PMMA	10% change frm baseline	Settings		CNR	Settings		CNR	☑
2 cm		25	W Rh	9.41	25	W Rh	9.45	
3 cm		26	W Rh	8.52	26	W Rh	8.28	
4 cm		28	W Rh	7.76	28	W Rh	7.36	
4.5 cm		29	W Rh	7.24	29	W Rh	7.27	
5 cm		31	W Rh	7.26	31	W Rh	7.26	
6 cm		31	W Ag	7.01	31	W Ag	7.05	
7 cm		34	W Ag	5.71	34	W Ag	5.70	

Mag								
CNR - variation with PMMA	10% change frm baseline	Settings		CNR	Settings		CNR	☑
2 cm		25	W Rh	11.48	25	W Rh	10.89	
3 cm		27	W Rh	9.67				
4 cm		30	W Rh	8.02	30	W Rh	7.38	
4.5 cm		31	W Rh	7.30				
5 cm		31	W Rh	6.20				
6 cm		34	W Ag	5.06	34	W Ag	4.79	

8 Mean Glandular Dose

Measurement	Criteria	Baseline			Result			OK	Comments
24x30									
MGD (mGy) at thickness	25% change frm baseline	Settings		MGD	Settings		MGD		
2cm	<1mGy	25	W Rh	0.62	25	W Rh	0.58	☑	
3cm	<1.5mGy	26	W Rh	0.86	26	W Rh	0.74	☑	
4cm	<2mGy	28	W Rh	1.14	28	W Rh	0.95	☑	
"Standard breast" 4.5cm	<2.5mGy	29	W Rh	1.41	29	W Rh	1.24	☑	
5cm	<3mGy	31	W Rh	1.62	31	W Rh	1.70	☑	
6cm	<4.5mGy	31	W Ag	2.44	31	W Ag	2.21	☑	
7cm	<6.5mGy	34	W Ag	2.76	34	W Ag	2.49	☐	3

Comments

1 The maximum compression force was measured to be slightly greater than 20 kg.

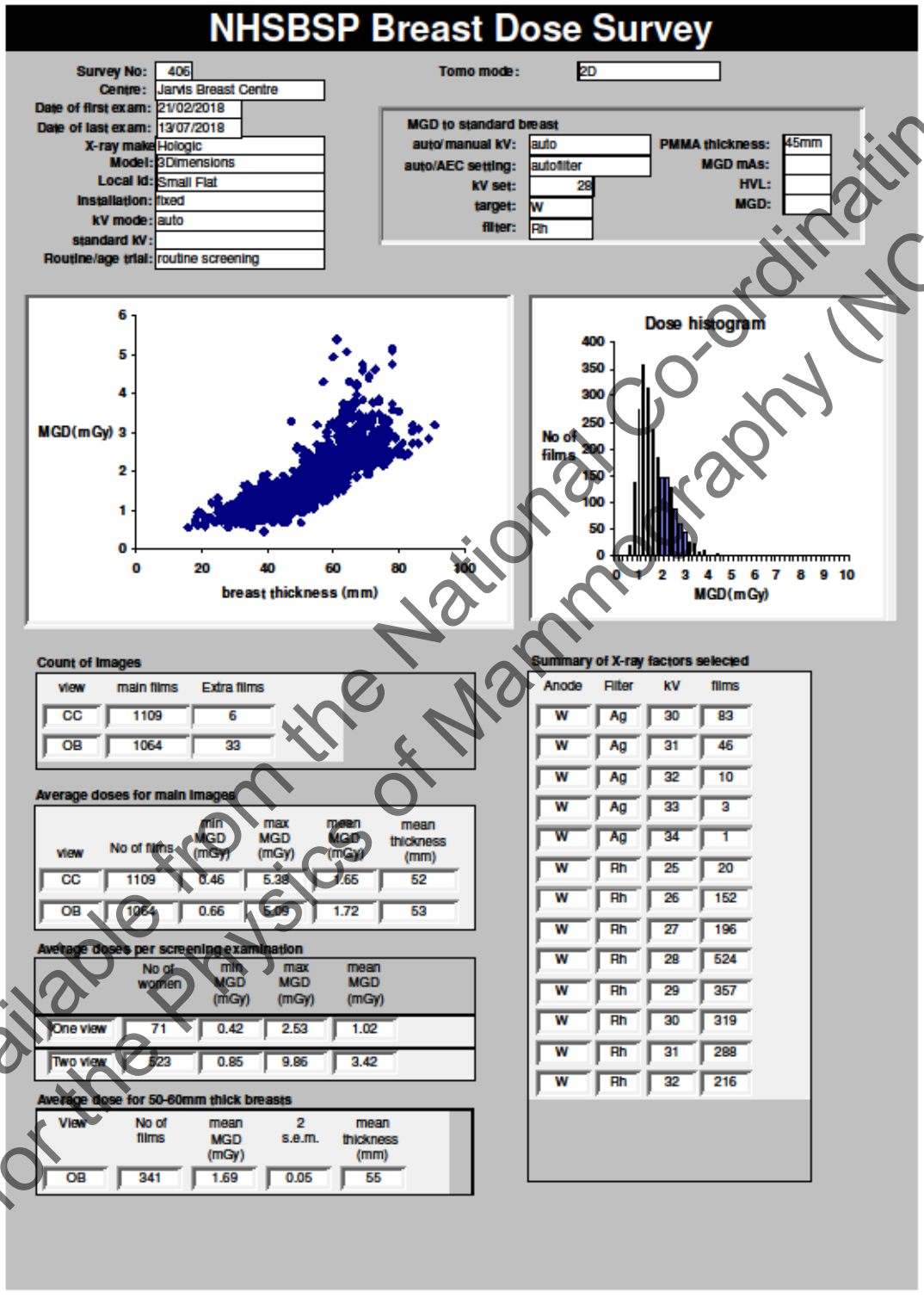
2 The x-ray field was found to overlap the imaged field by slightly more than 5 mm for some fields.

3 For 7 cm PMMA, the variation between displayed and calculated MGD was found to be slightly outside the ± 30% remedial limit.

Reported By: ***Tom Jupp***
Principal Physicist

Appendix 2: Clinical breast dose survey

A2.1 Dose survey for 18cm x 24cm flat paddle



NHSBSP Breast Dose Survey

Survey No: 406
Centre: Jarvis Breast Centre
Date of first exam: 21/02/2018
Date of last exam: 13/07/2018
X-ray make: Hologic
Model: 3Dimensions
Local Id: Small Flat
Installation: fixed
kV mode: auto
standard kV:
Routine/age trial: routine screening

Tomo mode: 2D

MGD to standard breast
auto/manual kV: auto
auto/AEC setting: auto/filter
kV set: 28
target: W
filter: Rh
PMMA thickness: 45mm
MGD mAs:
HVL:
MGD:

Count of Images

view	main films	Extra films
CC	1109	6
OB	1064	33

Summary of X-ray factors selected

Anode	Filter	kV	films
W	Ag	30	83
W	Ag	31	46
W	Ag	32	10
W	Ag	33	3
W	Ag	34	1
W	Rh	25	20
W	Rh	26	152
W	Rh	27	196
W	Rh	28	524
W	Rh	29	357
W	Rh	30	319
W	Rh	31	288
W	Rh	32	216

Average doses for main images

view	No of films	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	1109	0.46	5.38	1.65	52
OB	1064	0.66	5.09	1.72	53

Average doses per screening examination

	No of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
One view	71	0.42	2.53	1.02
Two view	523	0.85	9.86	3.42

Average dose for 50-60mm thick breasts

View	No of films	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
OB	341	1.69	0.05	55

A2.2 Dose survey for 24cm x 29cm flat paddle

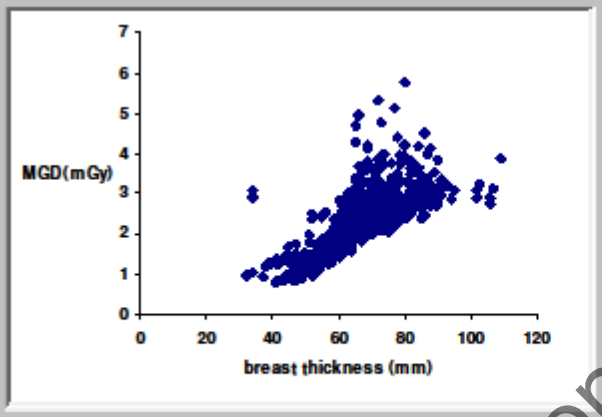
NHSBSP Breast Dose Survey

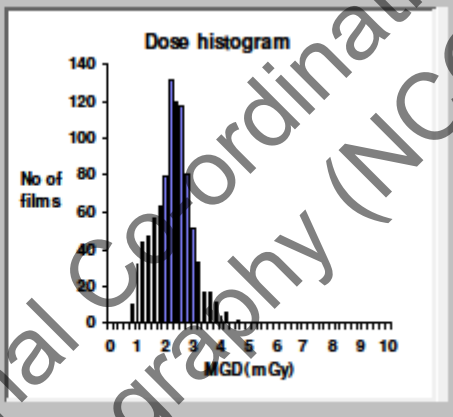
Survey No:	407
Centre:	Jarvis Breast Centre
Date of first exam:	21/02/2018
Date of last exam:	13/07/2018
X-ray make:	Hologic
Model:	3Dimensions
Local Id:	Large Flat
Installation:	fixed
kV mode:	auto
standard kV:	
Routine/age trial:	routine screening

Tomo mode: 2D

MGD to standard breast

auto/manual kV:	auto	PMMA thickness:	45mm
auto/AEC setting:	auto/filter	MGD mAs:	
kV set:	28	HVL:	
target:	W	MGD:	
filter:	Rh		





Count of Images

view	main films	Extra films
CC	459	9
OB	440	19

Summary of X-ray factors selected

Anode	Filter	kV	films
W	Ag	30	158
W	Ag	31	101
W	Ag	32	64
W	Ag	33	34
W	Ag	34	9
W	Ag	35	1
W	Ag	36	3
W	Ag	37	4
W	Rh	26	5
W	Rh	27	3
W	Rh	28	42
W	Rh	29	56
W	Rh	30	92
W	Rh	31	149
W	Rh	32	206

Average doses for main images

view	No of films	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	459	0.80	5.12	2.14	65
OB	440	0.86	5.79	2.44	70

Average doses per screening examination

	No of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
One view	14	0.74	2.10	1.39
Two view	225	1.74	10.50	4.63

Average dose for 50-60mm thick breasts

View	No of films	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
OB	60	1.55	0.09	56

A2.3 Dose survey for 18cm x 24cm SmartCurve paddle

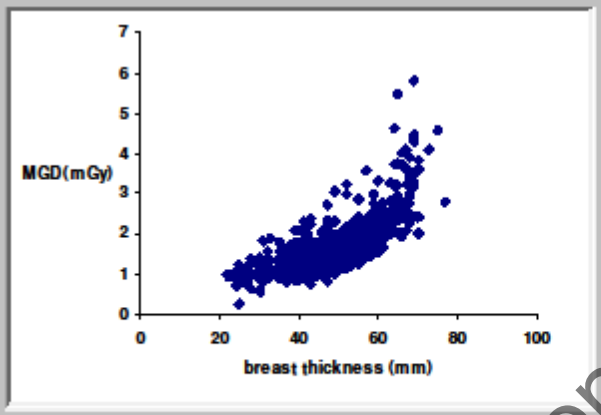
NHSBSP Breast Dose Survey

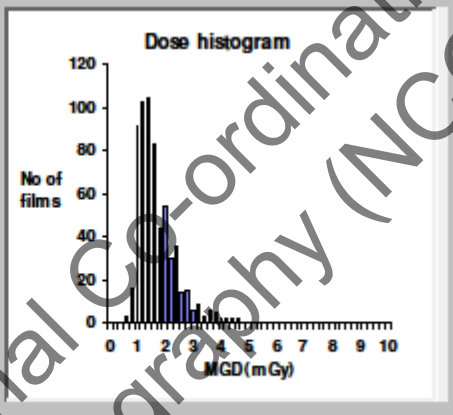
Survey No:	408
Centre:	Jarvis Breast Centre
Date of first exam:	21/02/2018
Date of last exam:	13/07/2018
X-ray make:	Hologic
Model:	3Dimensions
Local Id:	Small Curve
Installation:	fixed
kV mode:	auto
standard kV:	
Routine/age trial:	routine screening

Tomo mode: 2D

MGD to standard breast

auto/manual kV:	auto	PMMA thickness:	45mm
auto/AEC setting:	auto/filter	MGD mAs:	
kV set:	28	HVL:	
target:	W	MGD:	
filter:	Rh		





Count of Images

view	main films	Extra films
CC	313	2
OB	309	7

Summary of X-ray factors selected

Anode	Filter	kV	films
W	Ag	30	8
W	Ag	31	3
W	Rh	25	13
W	Rh	26	47
W	Rh	27	68
W	Rh	28	203
W	Rh	29	101
W	Rh	30	84
W	Rh	31	55
W	Rh	32	49

Average doses for main images

view	No of films	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	313	0.28	5.80	1.64	48
OB	309	0.62	5.47	1.74	50

Average doses per screening examination

	No of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
One view	5	0.57	0.92	0.74
Two view	166	1.06	9.22	3.39

Average dose for 50-60mm thick breasts

View	No of films	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
OB	95	1.76	0.09	55

A2.4 Dose survey for 24cm x 29cm SmartCurve paddle

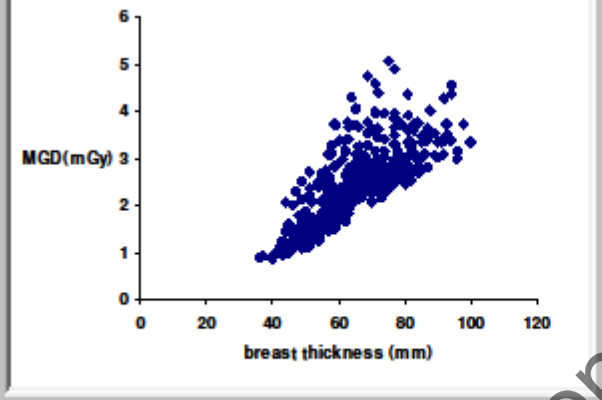
NHSBSP Breast Dose Survey

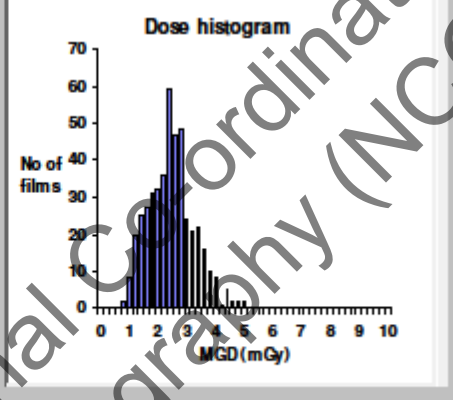
Survey No:	409
Centre:	Jarvis Breast Centre
Date of first exam:	21/02/2018
Date of last exam:	13/07/2018
X-ray make:	Hologic
Model:	3Dimensions
Local Id:	Large Curve
Installation:	fixed
kV mode:	auto
standard kV:	
Routine/age trial:	routine screening

Tomo mode: 2D

MGD to standard breast

auto/manual kV:	auto	PMMA thickness:	45mm
auto/AEC setting:	auto/filter	MGD mAs:	
kV set:	28	HVL:	
target:	W	MGD:	
filter:	Rh		





Count of images

view	main films	Extra films
CC	223	4
OB	215	6

Summary of X-ray factors selected

Anode	Filter	kV	films
W	Ag	30	51
W	Ag	31	42
W	Ag	32	26
W	Ag	33	16
W	Ag	34	13
W	Ag	35	3
W	Ag	36	1
W	Rh	27	2
W	Rh	28	37
W	Rh	29	36
W	Rh	30	74
W	Rh	31	68
W	Rh	32	79

Average doses for main images

view	No of films	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	223	0.87	4.81	2.21	61
OB	215	0.90	5.07	2.73	70

Average doses per screening examination

	No of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
One view	5	0.94	2.30	1.43
Two view	109	1.34	9.15	5.00

Average dose for 50-60mm thick breasts

View	No of films	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
OB	45	1.99	0.16	56

Appendix 3: Fault reports requiring engineer visit

Date	Fault	Solution
21/11/2017	Smudgy top and bottom line on tomosynthesis images	Engineer visit Adjusted left hand 24x30 collimator blade
05/12/2017	Grinding noise on compression	Engineer visit Loose cover on compression motor. Cover was fastened Engineer cleared
03/01/2018	Following power outage image taken of poor quality	Image repeated on another system. Apps specialist looked at image on site. Checked defaults had not reset. Paddle and compression not registering.
17/01/2018	2 CC's completed. Positioned for LMLO – no light on pressing button	Column off – no emergency switches appear to have been pushed. Rebooted system. Cleared
15/02/2018	VTA(29:17) call service PMC(38:24) Emergency gantry shutdown. VTA(38:23) call service GEN(25:17), also GEN(25:41) VTA(29:19), VTA(29:20)	System rebooted OK Reported to engineer on next visit
26/02/2018	Full gantry shutdown as moving from CC to MLO	System rebooted OK Engineer taken logs for further investigation

27/02/2018	On artefact evaluation, there is a white line 192mm long 1mm wide central along the far edge	Calibration and artefact evaluation repeated with same effect visible. Not visible on QA block images. Discussed with engineer, explained by the paddle attachment at 4cm overlapping the fields edge when field fully open. OK to use.
31/05/2018	Error occurred while making exposure. mAs too low. QA failing and unable to display ROI on uniformity images	Full recalibration of the system and completed weekly QA. System functioning normally - OK to use.

Appendix 4: Radiographers' questionnaire

NHSBSP 2D equipment evaluation form 6: Radiographers' observations and findings

A copy of this form should be completed by each operator, once comfortable with use and operation of the equipment.
For each question, please tick one of the "Excellent to Poor" columns, and/or delete from the alternatives (Yes/No, Better/Same/Worse etc.) as appropriate. "Same as Dimensions" column is for questions where there has been no change, in which case, there is no need to fill in other columns.

Equipment: Hologic 3Dimensions **Evaluation centre:** Jarvis Breast Centre

Name:

	Same as Dimensions	Excellent	Good	Average	Satis-factory	Poor	Comments
1. How good was the operator's manual?							
2. How good was the clinical applications training provided by supplier: a. modality?							
b. acquisition workstation?							

	Same as Dimensions	Excellent	Good	Average	Satis-factory	Poor	Comments
3. How do you rate the system's ease of use?							
4. Were the X-ray exposure times acceptable?		Yes/No					Explain if no
5. How convenient was it for making the exposures with a. foot pedal?							
b. single button?							
6. Setting for radiographic views: 6.1 How do you rate the rotation of the support arm?							
6.2 How do you rate the visibility of the set angle?							
7. How do you rate the facility for positioning the height of the breast support table?							

	Same as Dimensions	Excellent	Good	Average	Satis-factory	Poor	Comments
8. How useful was the height of adjustment of the acquisition work station/console?							
9. Was it more convenient to have the console surface horizontal (rather than sloping)		Yes/No					
10. How convenient was the use of the touchpad? a. initially							
b. after adjustment to make less sensitive							
11. Did you prefer to use the mouse?		Yes/No					
12. How adequate was the range of movements offered by the system?							
13. Effectiveness of brakes/locks: How well did the brakes work? (was there any backlash or movement, for example)							

	Same as Dimensions	Excellent	Good	Average	Satis-factory	Poor	Comments
14. Compression 14.1 How effective was the compression system?							
14.2 Visibility of compression force from breast support table?							
14.3 How convenient were the paddles in use: a. SmartCurve							
b. flat (18 x 24)							
c. flat (24 x 30)							
d. skinny							
15. How comfortable was the system for women with: a. flat paddle?							Enter any informative comments made by women
b. SmartCurve paddle?							

	Same as Dimensions	Excellent	Good	Average	Satis-factory	Poor	Comments
16. Range of controls and indicators:							
16.1 Were all the expected controls present?		Yes/No					Explain if no
16.2 Were they easy to find and use?		Yes/No					
16.3 How useful were the controls on the gantry column?							
16.4 How useful is the facility for offsetting the tube head for MLO views?							
17. How do you rate the choice of paddles/ collimators supplied for spot compression?							
18. How do you rate the time for an image to appear at the acquisition workstation?							

	Same as Dimensions	Excellent	Good	Average	Satis-factory	Poor	Comments
19. How do you rate the image handling and processing facilities at the acquisition workstation?							
20. How would you rate the overall image quality at the acquisition workstation?							
21. What was your level of confidence in good results from the machine?							
22. Were there any potentially hazardous areas accessible to: a. you?		Yes/No					Explain if yes
b. the woman?		Yes/No					
23. Equipment cleaning 23.1 Ease of cleaning the machine?							

	Same as Dimensions	Excellent	Good	Average	Satis-factory	Poor	Comments
23.2 Were there instructions in the manual?		Yes/No					
23.3 Does this meet the local Infection Control requirements?		Yes/No					
24. Was all necessary patient and exposure data available on the images?		Yes/No					
25. Did the system performance limit patient throughput?		Yes/No					If no, explain (for example, wait between exposures too long)
26. Any additional comments on general or imaging performance							

Magnification

	Same as Dimensions	Excellent	Good	Average	Satis-factory	Poor	Comments
1. Rate the ease with which the magnification equipment may be attached and removed with the push button system.							
2. Rate the ease of use of the magnification breast support table							

Appendix 5: Manufacturer's comments

A5.1 SmartCurve™ Breast Stabilization System

A5.1.1 Practical Considerations

Hologic appreciates the feedback on the use of the SmartCurve™ Breast Stabilization System. We are pleased that the images were found to be clinically acceptable. With regards to the comments about the practical difficulties with the system we realize that it may be better suitable for use in lower throughput screening clinics, because the paddles may not be suitable for all breast sizes and types. More training and guidance from Hologic on positioning in the future might help with the slight modification in technique which is required when using the system in comparison with the conventional flat paddle. For the majority of women, the system has been proven to increase comfort during the mammography procedure[1].

Another comment was made regarding the fact that some women found the small SmartCurve Breast Stabilization System uncomfortable in the MLO position. Hologic has provided proper positioning guidance in response to these comments (specifically instructions on how to roll the humeral head forward before positioning the breast). These instructions will be included in applications training.

A5.1.2 Radiation Dose

The results in this report showed higher doses with the SmartCurve Breast Stabilization System when using the larger paddle. The dose values recorded differ slightly from our experience. The average values over the population studied by Hologic and the NCCPM team were identical when using the 18x24 standard paddle and the 18x24 SmartCurve paddle, but for the larger SmartCurve system the Jarvis team recorded doses were 8% higher than the flat paddle, whereas for Hologic this increase was 3%.

In the Hologic US clinical trial, the same women were compressed with both flat and SmartCurve paddles, using the same radiographer[1]. Doses were similar and the recorded values are given in Table 1. The doses reported are averaged over all breast sizes. The clients were representative of asymptomatic women presenting for screening in the US.

Table 1: Doses recorded in US clinical trial

	Mean glandular dose (mGy)		Dose Ratio
Paddle size	Flat Paddle	SmartCurve	SmartCurve/Flat
18x24	1.58	1.58	1.00
24x29	2.16	2.23	1.03

A5.2 Compression

A5.2.1 Practical Considerations

Some users commented that the compression on the 3Dimensions™ Mammography System came down *"quite fast".* In response to this it is possible to modify the pre-force value and release height in the system. This does not change the speed of the compression however starting the compression with the paddle adjusted to a lower position might change the perception of the compression speed. This is something Hologic covers during applications training.

References

1. Smith, Andrew Ph.D. Improving Patient Comfort in Mammography. WP-00119 Rev 001. July 2017.