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NHS Breast Screening Programme Equipment Report

Practical evaluation of Hologic® 3Dimensions™ Mammography System in digital breast tomosynthesis mode

July 2020

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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 tomosynthesis mode. The evaluation was carried out between October 2017 and August 2018.

The system was reliable and the quality control test results were stable, remaining 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 in the majority of cases. Almost all lesions were seen, in a detailed study of different types of lesion viewed in 2D, tomosynthesis and synthesized 2D.

Both standard flat paddles and curved paddles (SmartCurve™ Breast Stabilisation System) were used in the evaluation. The average mean glandular dose (MGD) calculated for MLO views of 50 to 60mm thick breasts was 2.0mGy, well below the national dose reference level (DRL) of 2.5mGy.

The Hologic 3Dimensions™ mammography system was found suitable for use in tomosynthesis mode for assessment in the NHSBSP, for imaging and for tomosynthesis biopsy.

1. Introduction

1.1 Evaluation centre and timeline

The evaluation was carried out at the Jarvis Breast Centre in Guildford, Surrey, a breast screening unit which is run as a standalone unit with women being referred to local hospitals for further procedures when necessary. The centre meets the relevant national quality standards[1] for breast screening and meets the criteria for evaluation centres outlined in the NHSBSP Guidance Notes for Equipment Evaluation[2].

The centre serves the population of Surrey and North East Hampshire for women of normal screening age and for the age extension trial. 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 1200 biopsies were performed during that period.

The evaluation of the Hologic 3Dimensions system, took place over the period of October 2017 to August 2018. Both the 2D and tomosynthesis modes of the system were under evaluation in the centre during that period. The 18cm x 24cm SmartCurve paddle was installed in October 2017, while the 24cm x 29cm SmartCurve paddle was made available in February 2018.

1.2 Equipment evaluated

1.2.1 3Dimensions Mammography system and workstation

The 3Dimensions system 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. The system uses rhodium and silver filters in 2D mode, and a aluminium filter. when operating in tomosynthesis mode. The pixel size for tomosynthesis images in high resolution mode is 0.07mm; this mode was used for the evaluation.

The acquisition workstation (AWS) has a single 3megapixel 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 mammography system

1.2.2 Other equipment available for the evaluation

1.2.2.1 Paddles

Three standard-size compression flat paddles and 2 curved 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 breast paddle (8cm x 24cm) used for women with small breasts. Specialist paddles such as the 5cm x 5cm and 6cm x 7cm stereo paddles were used in assessment, as required.

18cm x 24cm and 24cm x 29cm SmartCurve paddles were in routine use as well as the flat paddles. Figure 2 shows a 24cm x 29cm SmartCurve™ Breast Stabilisation System (SmartCurve paddle). The shape of the 18cm x 24cm paddle is similar. The choice of using flat or SmartCurve paddles was made by the radiographer.

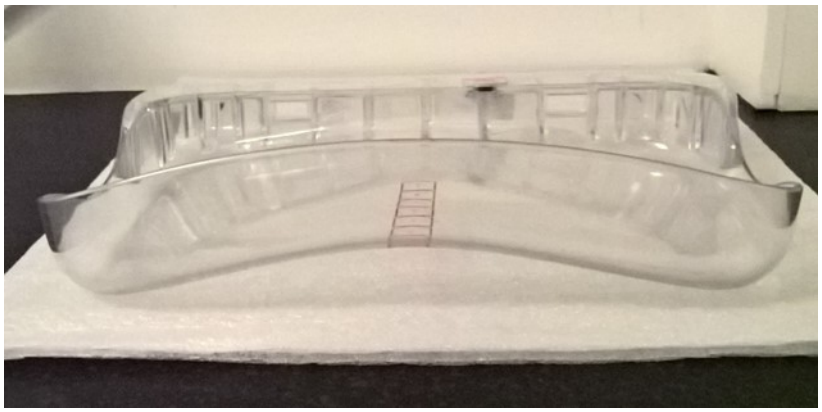

Figure 2. SmartCurve paddle, 24cm x 29cm version

1.2.2.2 SecurView Reporting Workstation

A SecurView® reporting workstation was available for viewing images and to enable the smart mapping feature of Intelligent 2D™ (synthetic) images derived from the tomosynthesis images. Smart mapping is a feature by which a mouse click on a suspicious area of the Intelligent 2D image automatically displays the corresponding tomosynthesis slice on the adjacent monitor.

1.2.2.3 Hologic Affirm™ Breast Biopsy System

A Hologic Affirm™ Biopsy system was provided and was used for tomosynthesis biopsy procedures. The Affirm has already been evaluated as described in an earlier practical evaluation report[3].

1.2.3 Image Reading

All images from the 3Dimensions were transferred automatically to the PACS and the SecurView workstation. Clinical images were principally read on the PACS reporting workstations.

1.3 Practical considerations

At the time of the evaluation, users were already familiar with Hologic systems having previously worked with the Dimensions. However, users found that the space behind the lead glass shield of the 3Dimensions was limited. They would have preferred a wider lead glass screen to give more space behind it for all 3 staff usually present during a biopsy procedure.

1.4 Objectives of the evaluation

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

The detailed objectives were:

- to assess the reliability and user-friendliness of the equipment in an assessment environment
- to assess dose against national standards
- to assess the image quality and diagnostic value of tomosynthesis and synthesized images

2. Acceptance testing, commissioning and performance testing

2.1 Acceptance testing and commissioning

The 3Dimensions was installed in October 2017 in one of the imaging rooms in the Jarvis Breast Centre. The system was used in place of one of the existing Hologic Dimensions mammography machines, which was mothballed for the duration of evaluation.

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

The acceptance and commissioning tests[4] were carried out by the local medical physics service and the physics reports are included at Appendix 1. This followed a technical evaluation[5] 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.

2.2 Performance testing

The local medical physics team carried out their first six monthly routine performance survey[6] on the system in February 2018. The report from this survey is included at Appendix 1. In August 2018, they carried out a second six monthly routine performance survey and the survey report is also included in Appendix 1.

3. Routine quality control

Routine quality control (QC) was carried out as detailed in the NHSBSP guidelines.[4] 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 for the 2D mode during the evaluation period:

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

The results for these are presented in Figures 3 to 6. Although measurements of CNR are only required weekly, these were recorded daily and the daily CNR is shown in Figure 6.

For the tomosynthesis mode, the mAs and the mean pixel value as the detector dose indicator (DDI), were recorded daily. These are the only quantities required by the QC guidance for tomosynthesis[7]. The results are shown in Figures 7 and 8.

No artefacts were recorded during the evaluation period.

3.1.1 Daily tests – 2D exposure

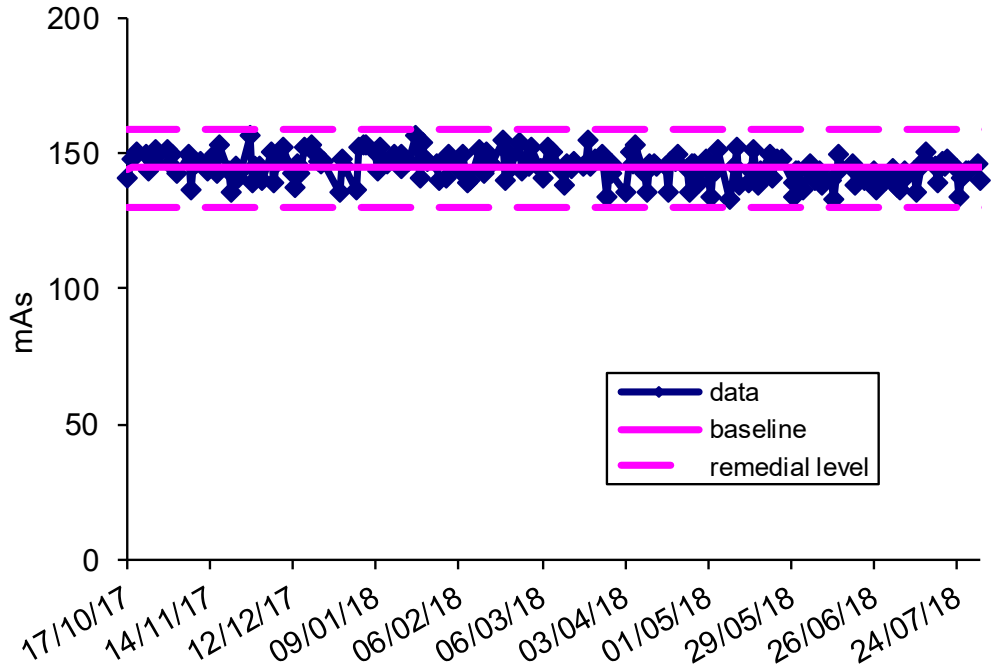

Figure 3. mAs recorded daily for 45mm of Perspex (2D)

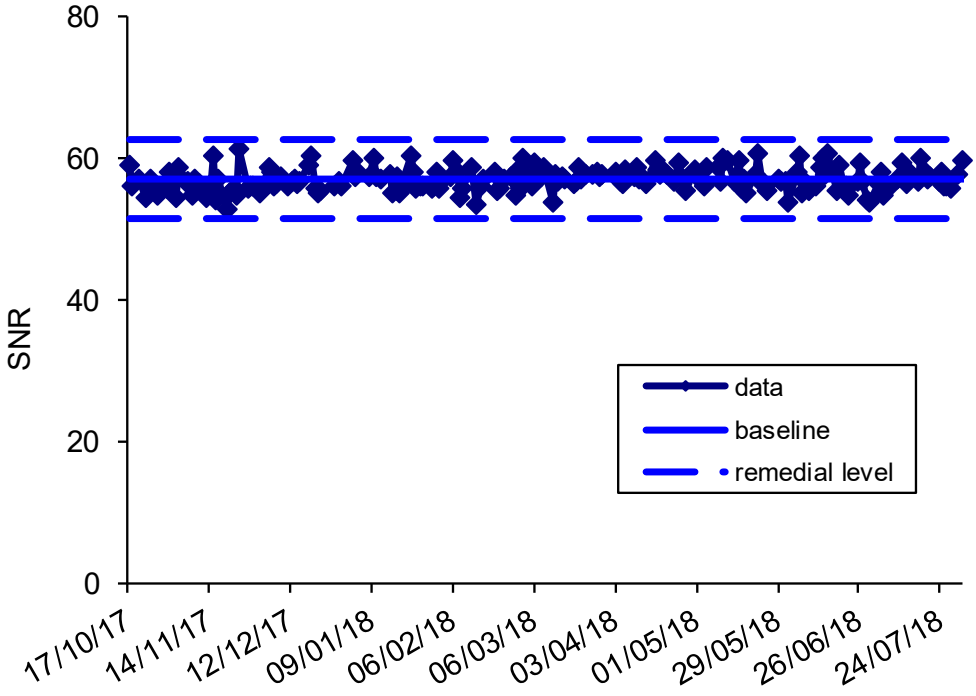

Figure 4. SNR recorded daily for 45mm of Perspex (2D)

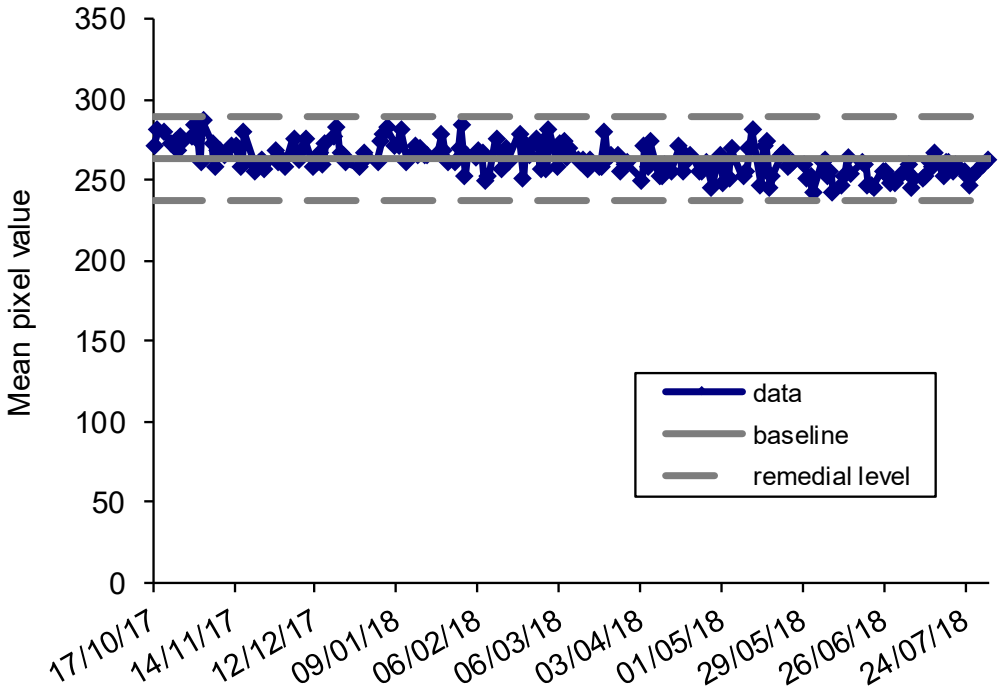

Figure 5. Pixel value recorded daily for 45mm of Perspex (2D)

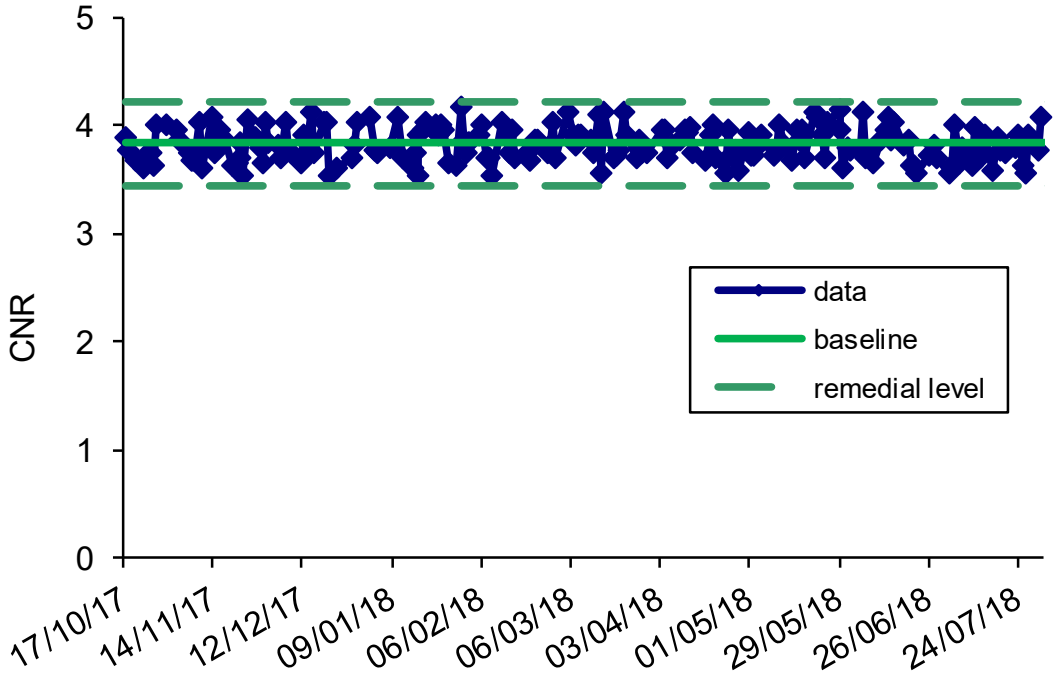

Figure 6. CNR recorded daily for 45mm of Perspex (2D)

3.1.2 Daily tests – tomosynthesis exposure and artefacts

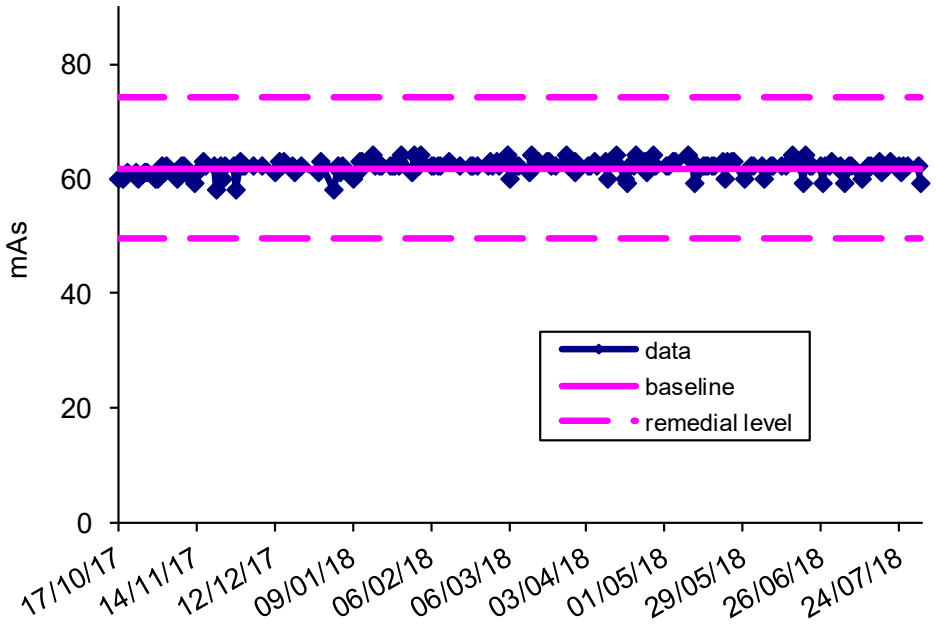

Figure 7. mAs recorded daily for 45mm of Perspex (tomosynthesis)

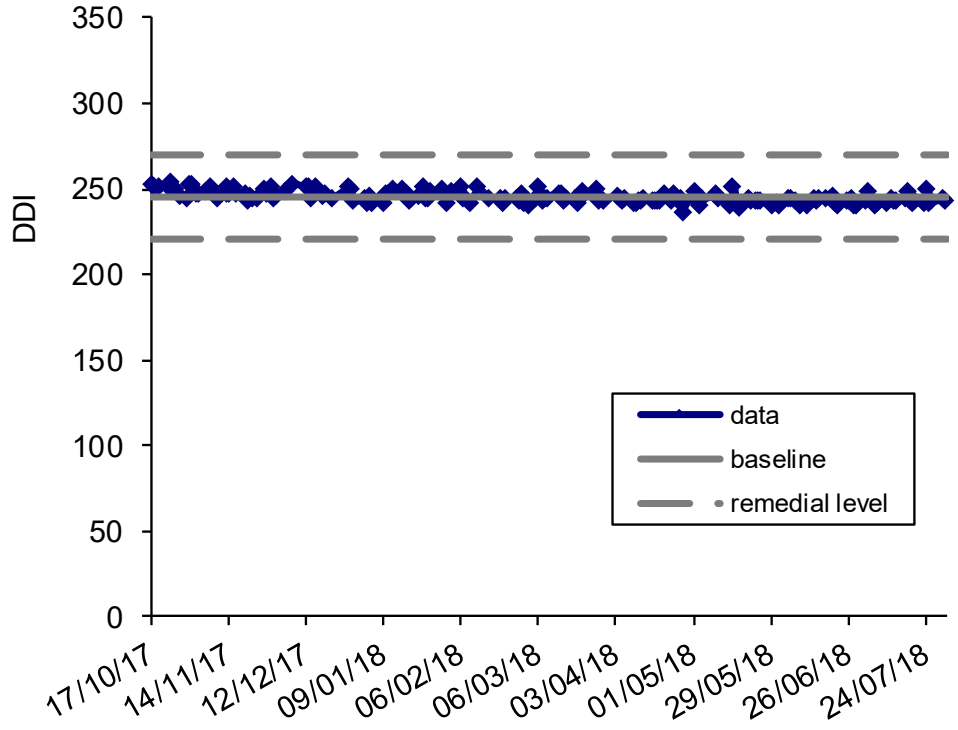

Figure 8. Detector Dose Indicator recorded daily for 45mm of Perspex (tomosynthesis)

3.2 Weekly QC tests

The results for the following tests in 2D mode were recorded weekly for the duration of the evaluation:

- CNR
- uniformity
- image quality measured with a TORMAM

They are presented in Figures 9 to 11.

For the tomosynthesis mode, only the image quality was recorded. This is shown in Figure 12.

3.2.1 Weekly tests – 2D

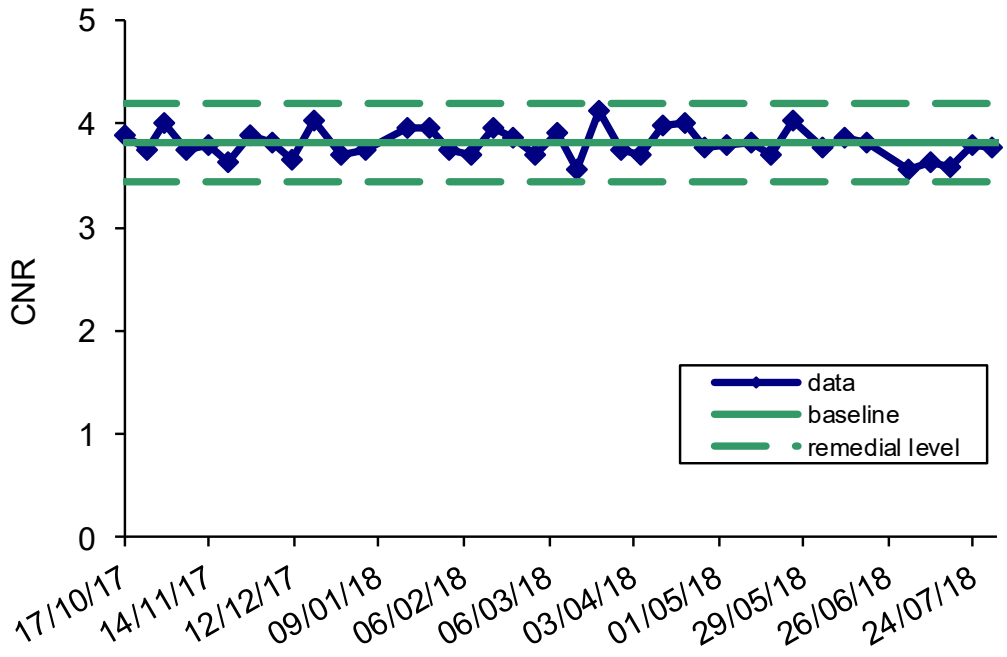

Figure 9. Weekly CNR measurements for 45mm Perspex (2D)

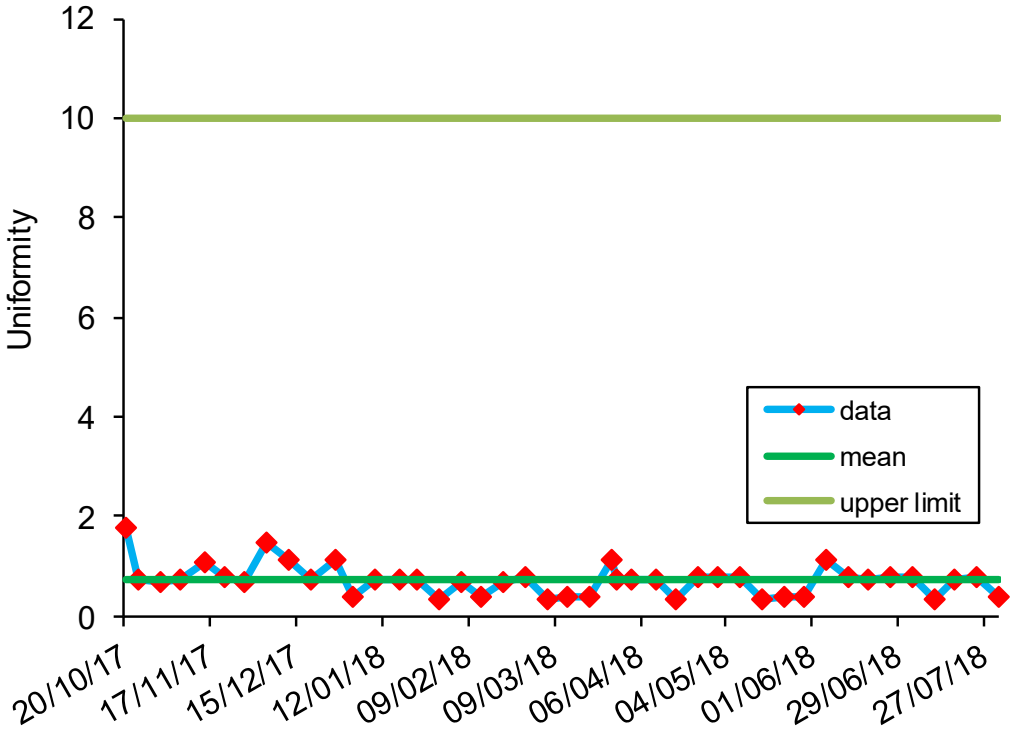

Figure 10. Weekly uniformity measurements for 45mm Perspex (2D)

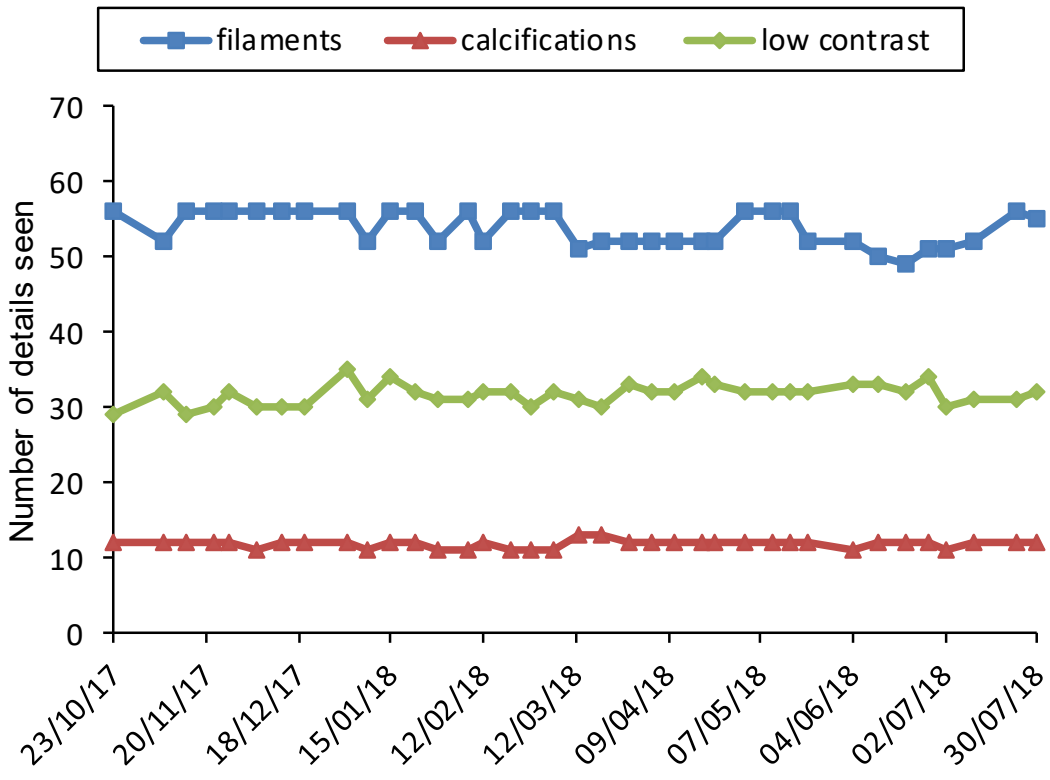

Figure 11. Weekly tests of image quality measured with TORMAM test object (2D)

3.2.1 Weekly tests – tomosynthesis

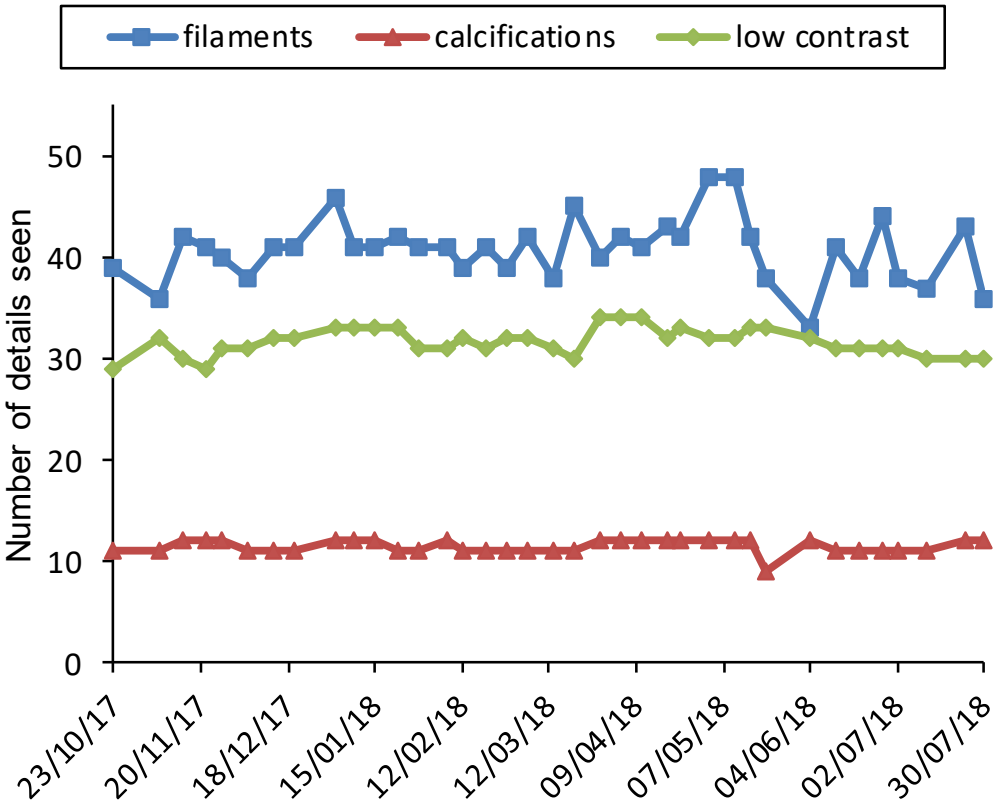

Figure 12. Weekly tests of image quality measured with TORMAM test object (tomosynthesis)

3.3 Monthly QC tests

The results for the following were recorded in 2D mode monthly for the duration of the evaluation:

- 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 13 to 20.

For the tomosynthesis monthly tests, the following results were recorded during the evaluation:

- mAs for 20mm and 70mm Perspex
- DDI for 20mm and 70mm Perspex

These are shown in Figures 21 to 24.

3.3.1 Monthly tests – 2D

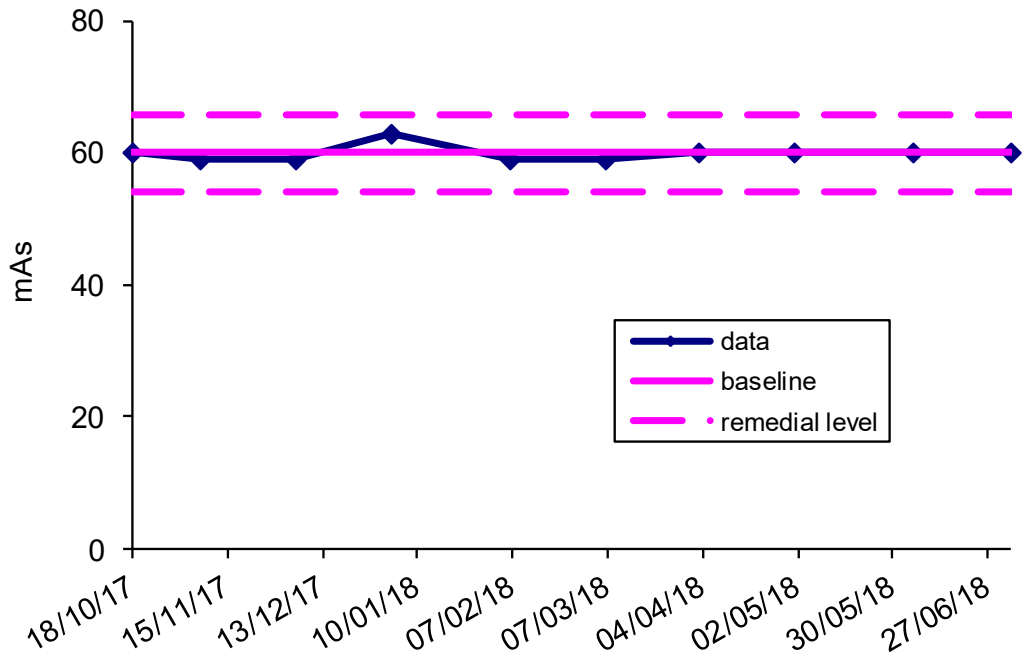

Figure 13. mAs recorded monthly for 20mm Perspex (2D)

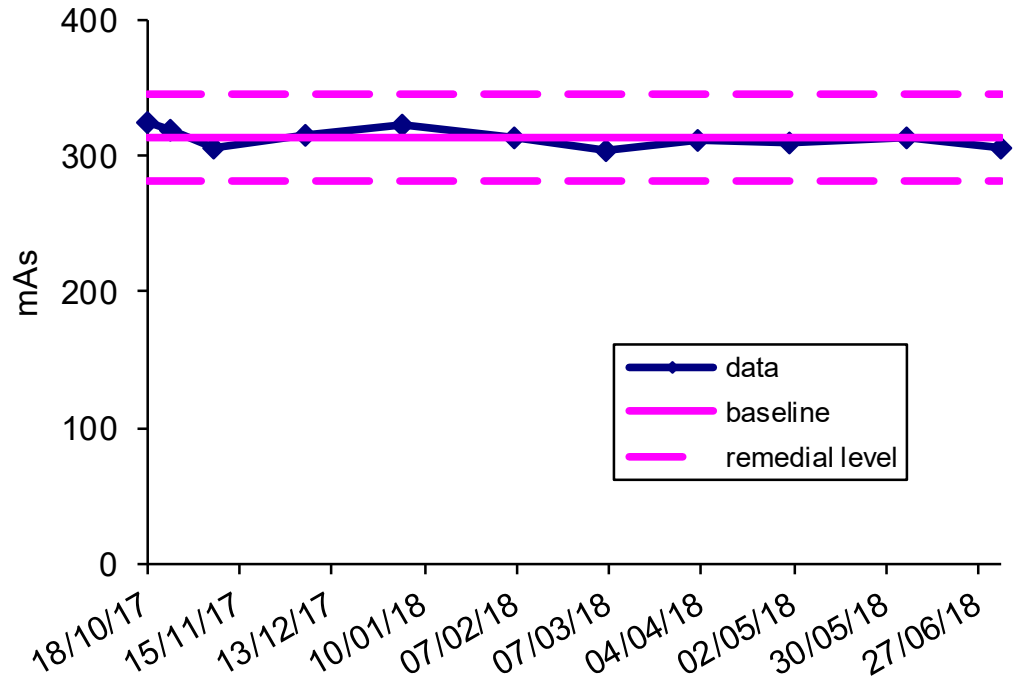

Figure 14. mAs recorded monthly for 70mm Perspex (2D)

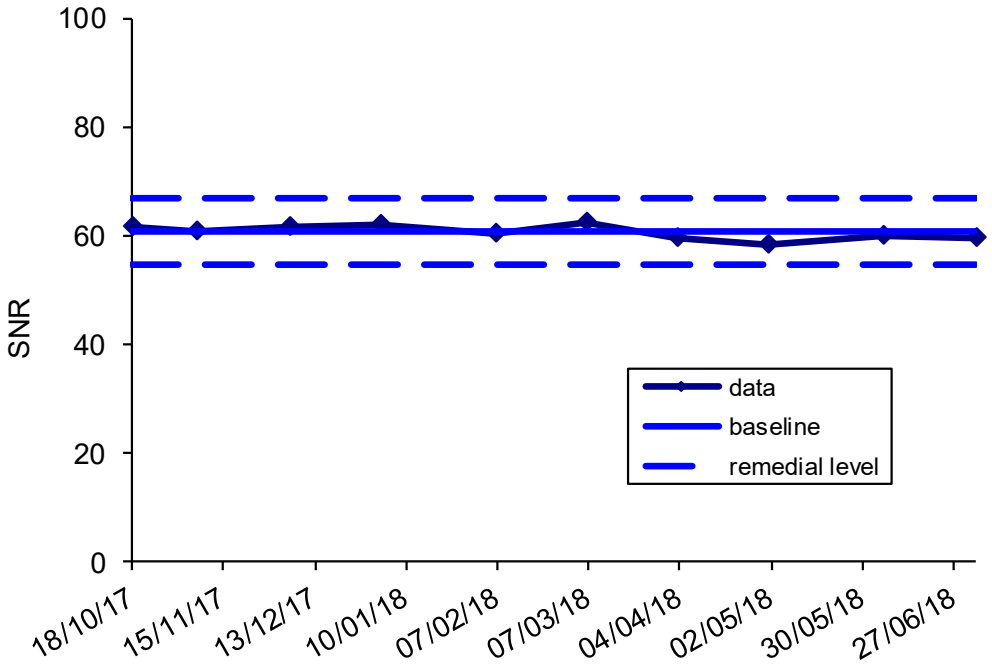

Figure 15. SNR recorded monthly for 20mm Perspex (2D)

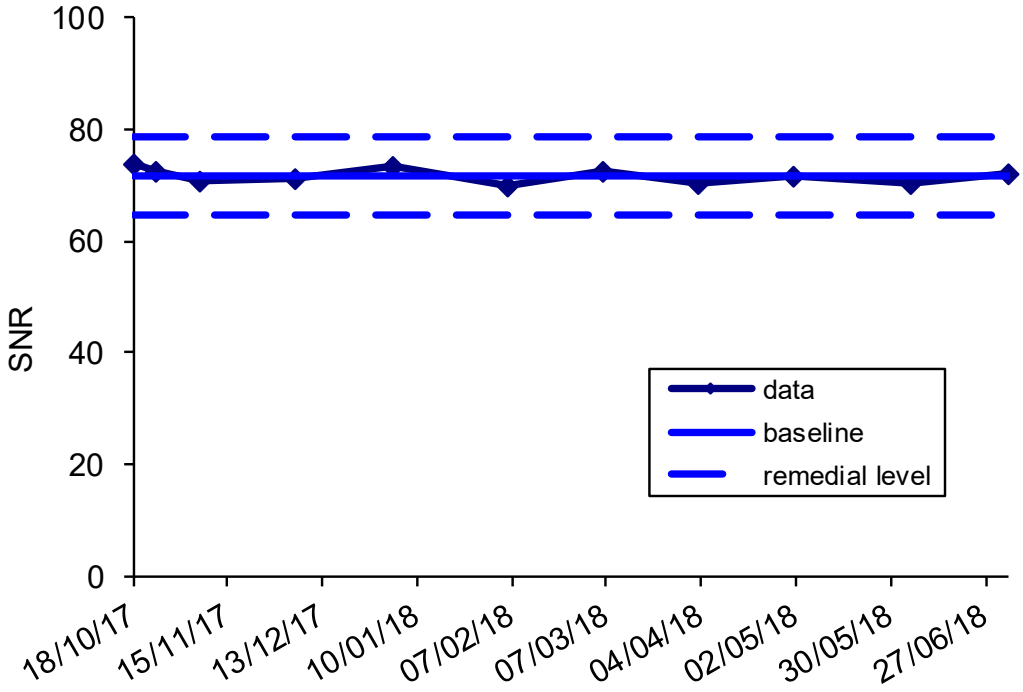

Figure 16. SNR recorded monthly for 70mm Perspex (2D)

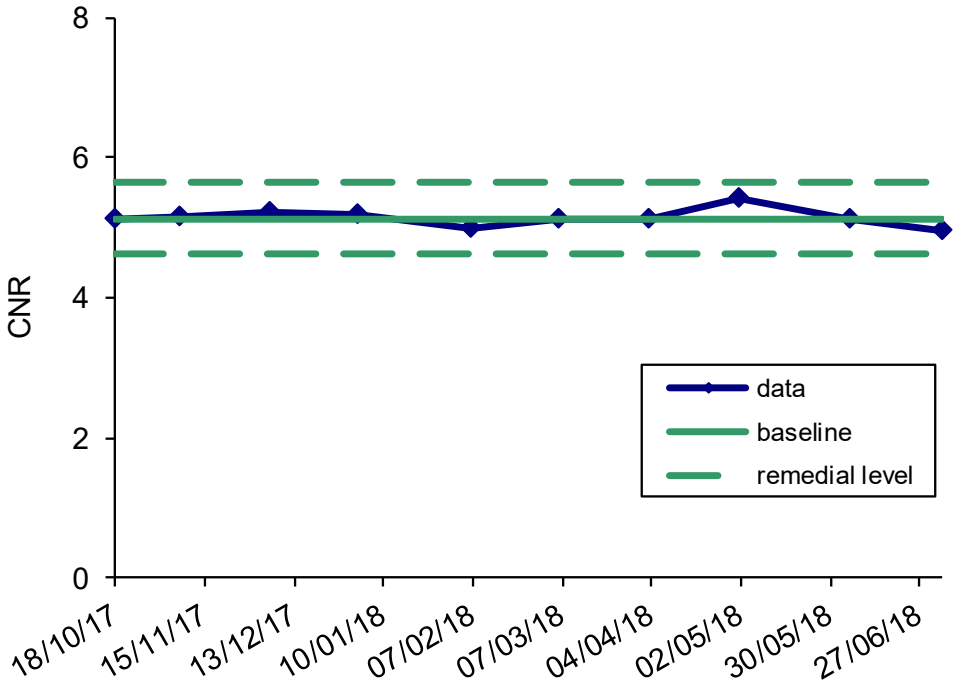

Figure 17. CNR recorded monthly for 20mm Perspex (2D)

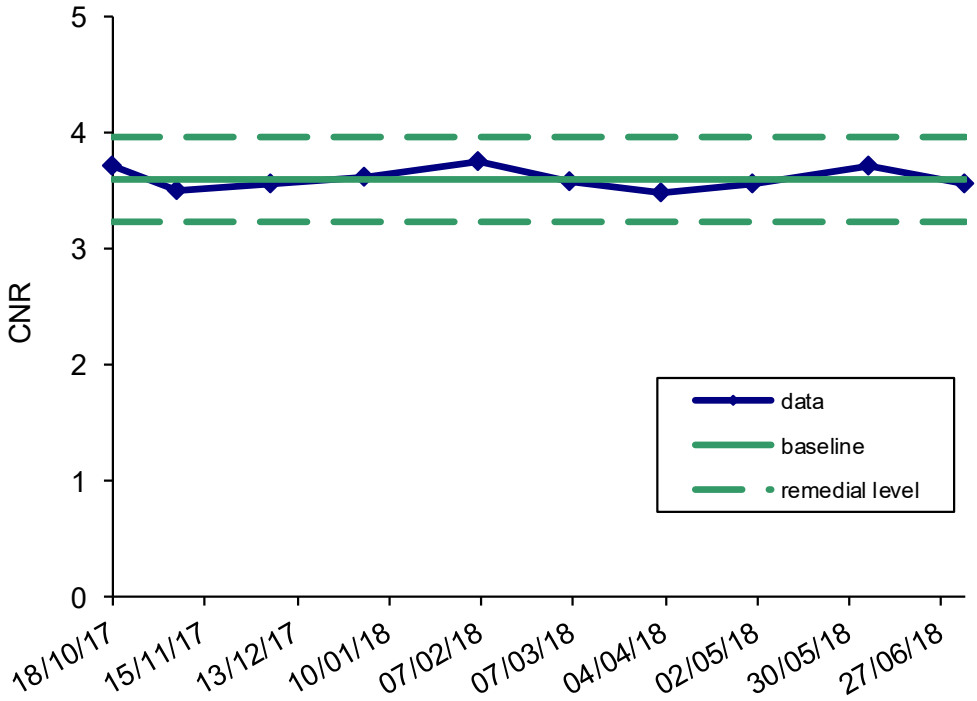

Figure 18. CNR recorded monthly for 70mm Perspex (2D)

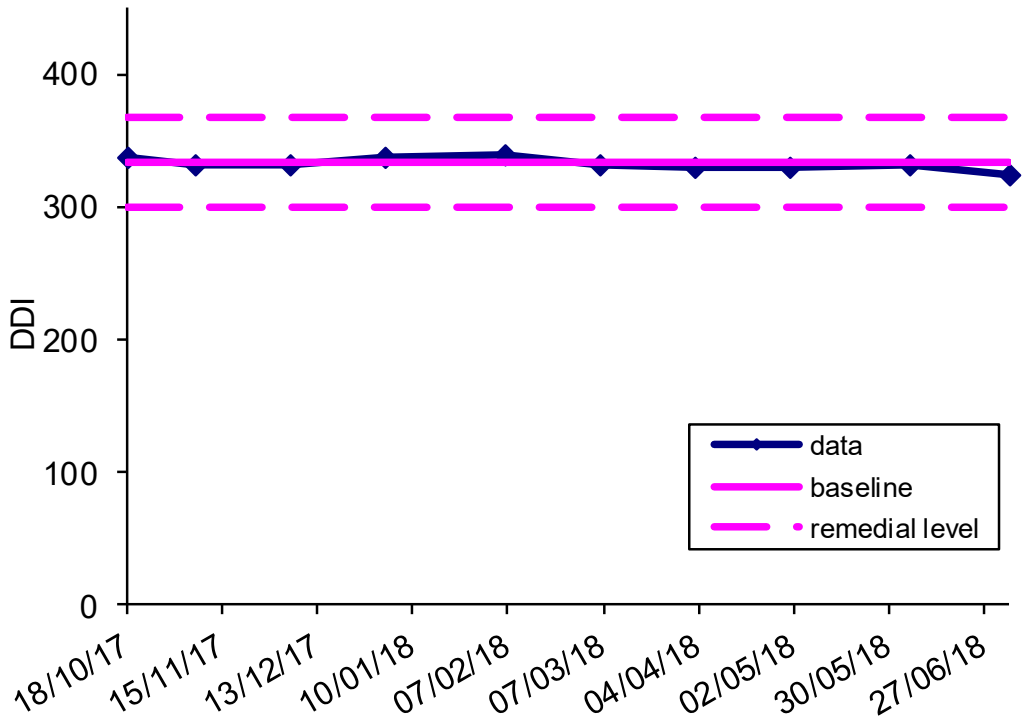

Figure 19. Detector Dose Indicator for 20mm Perspex (2D)

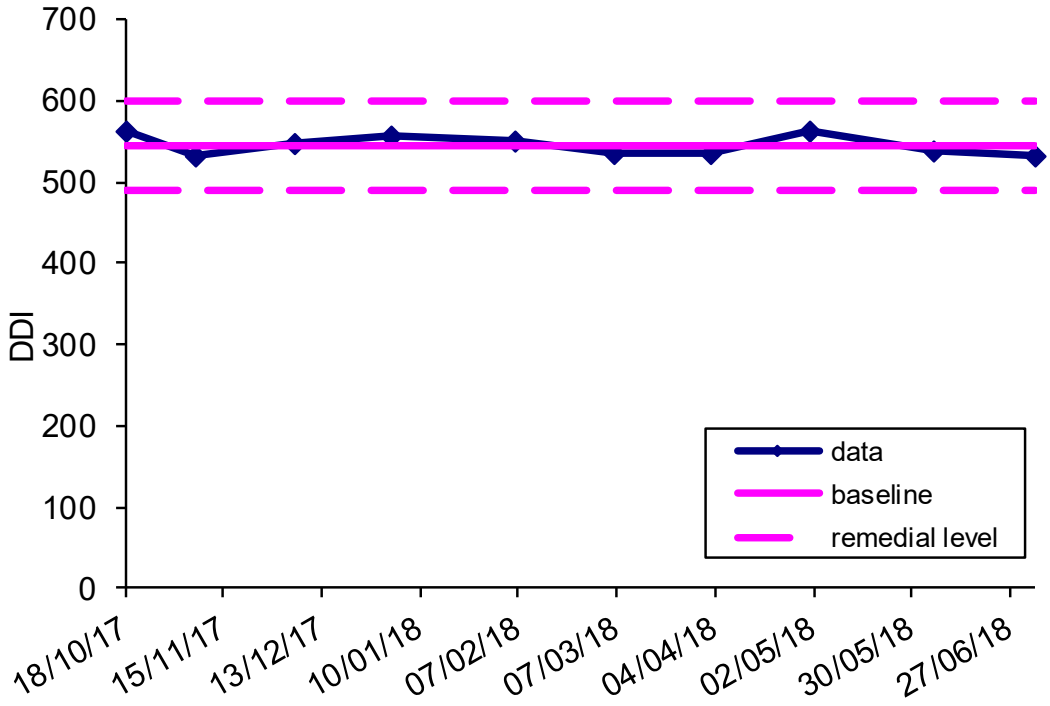

Figure 20. Detector Dose Indicator for 70mm Perspex (2D)

3.3.2 Monthly tests – tomosynthesis

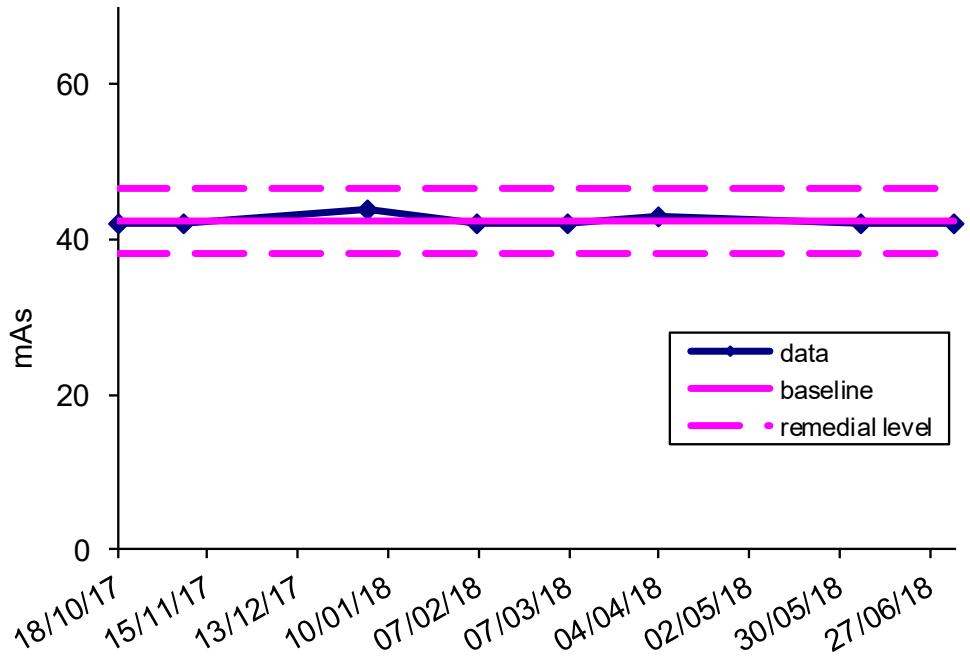

Figure 21. mAs recorded monthly for 20mm Perspex (tomosynthesis)

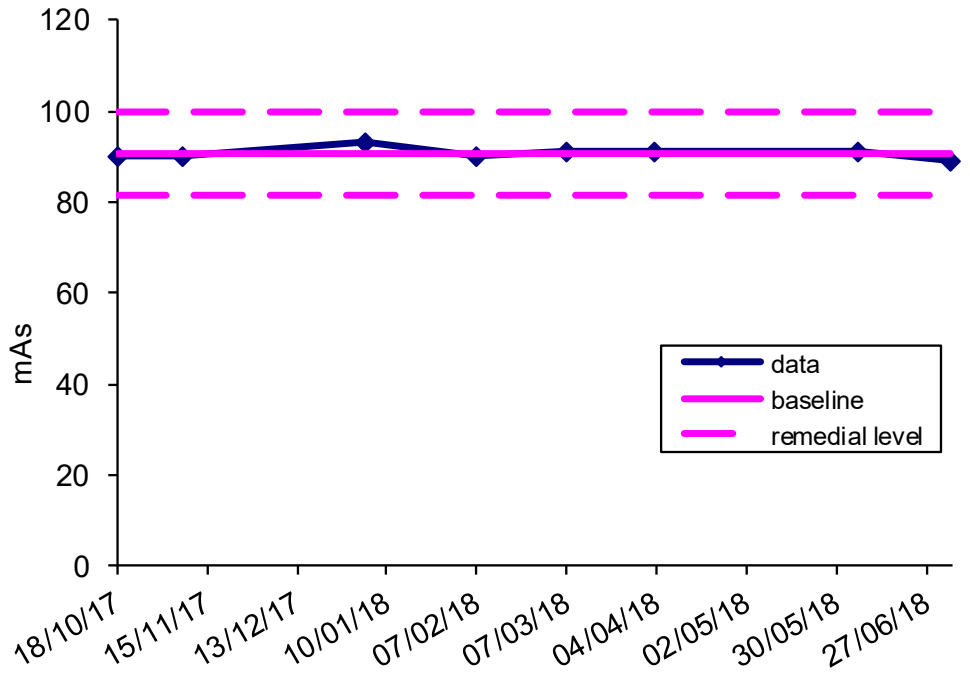

Figure 22. mAs recorded monthly for 70mm Perspex (tomosynthesis)

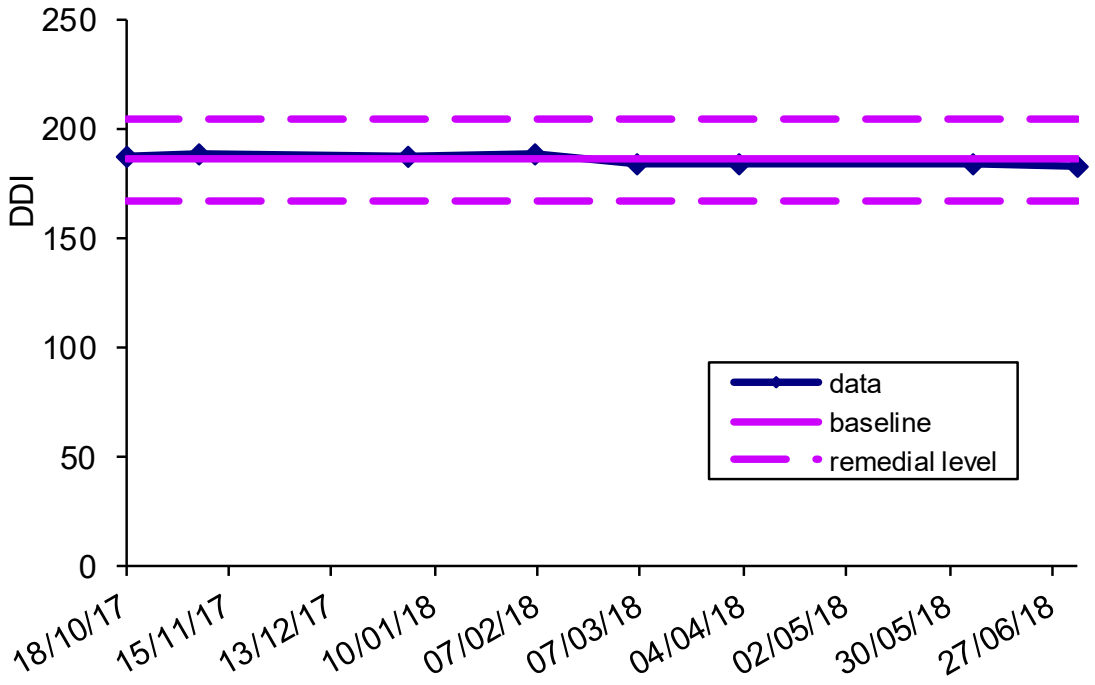

Figure 23. Detector Dose Indicator for 20mm Perspex (tomosynthesis)

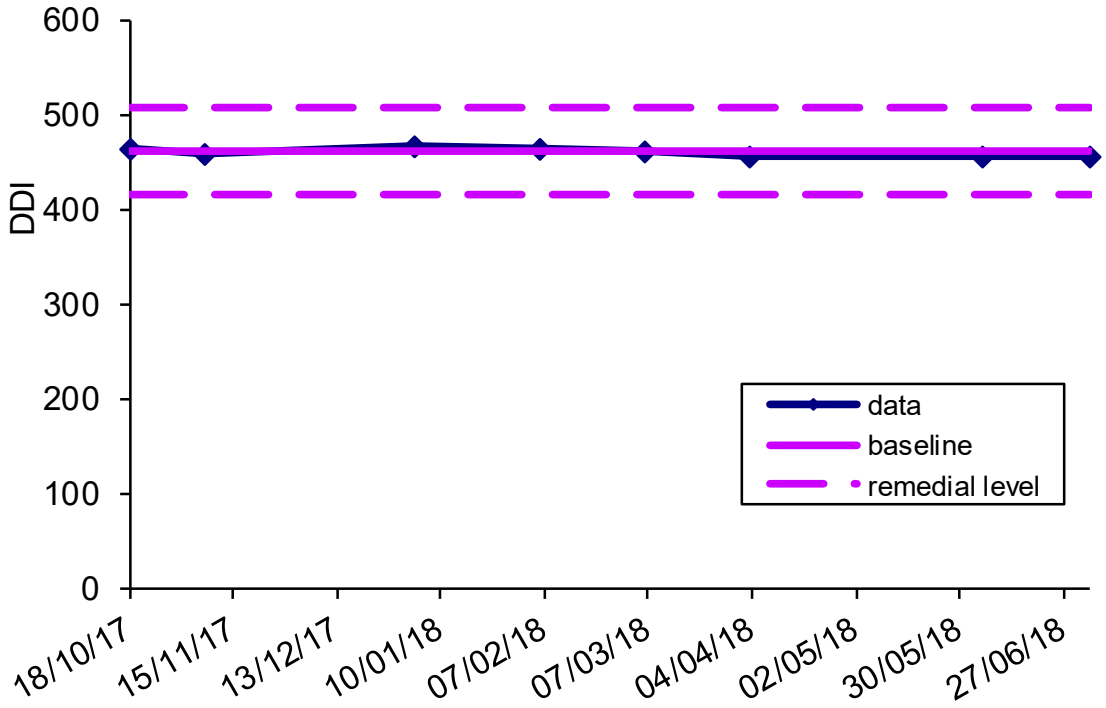

Figure 24. Detector Dose Indicator for 70mm Perspex (tomosynthesis)

4. Data on assessments conducted

4.1 Clinical Dose Audit

Exposure details of tomosynthesis images were extracted from the DICOM headers for a dose survey of 980 images (CC and MLO). Details for both the flat paddles and the SmartCurve Breast Stabilization System relate to the period February 2018 to July 2018. Incorrect calibration of the paddle height for the 18cm x 24cm SmartCurve paddle meant that data from earlier than February 2018 had to be discarded.

The dose calculator from NCCPM was used to calculate average MGDs. It is based on a model and data published by Dance et al.[8, 9] The model assumes flat surfaces at the top and bottom of a breast under compression, and has not been modified for curved paddles.

Detailed results for the 4 dose surveys are presented in Appendix 2. The average MGDs and compressed breast thicknesses (CBTs) are summarised in Tables 1 and 2 for the different paddle sizes. All the MGDs for the MLO view of 50-60mm thick breasts compare favourably with the national diagnostic reference level (DRL) of 2.5mGy for 2D imaging.

For the 18cm x 24cm SmartCurve paddle, the average MGD for the MLO view was 1.95mGy, for 50 to 60mm thick breasts. It is very close to that for the 18cm x 24cm flat paddle (1.96mGy).

For the 24cm x 29cm SmartCurve paddle, the average MGD for the MLO view of 50 to 60mm thick breasts was 1.88mGy, which is slightly (7.5%) lower than for the corresponding flat paddle (2.02mGy). The value of 1.88mGy is, however, the mean of only 3 values that fell in the 50 to 60mm thickness range, and so no definitive conclusion can be drawn from this result.

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	293	2.07	55
	MLO	All	336	2.02	54
	MLO	CBT 50 to 60mm	114	1.96	55
SmartCurve	CC	All	37	1.82	48
	MLO	All	40	1.89	50
	MLO	CBT 50 to 60mm	16	1.95	55

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

Paddle	View	Group of women	Number of images	Average MGD (mGy)	Average CBT (mm)
Flat	CC	All	98	2.64	65
	MLO	all	105	3.02	70
	MLO	CBT 50 to 60mm	18	2.02	56
SmartCurve	CC	all	36	2.29	59
	MLO	all	35	2.93	68
	MLO	CBT 50 to 60mm	3	1.88	54

The overall average MGD, for MLO views of 50 to 60mm thick breasts, was 1.96mGy.

4.2 Comparison of displayed dose with calculated MGD

The doses displayed on the acquisition workstation are stored in the DICOM headers of the images. These are calculated by the 3Dimensions, using stored values of X-ray output and half value layer (HVL). The MGDs that were used for the dose surveys were obtained by calculation, using data and equations published by Dance et al.[6,7]. The output and HVL values were derived from physics measurements made by NCCPM at the Jarvis Centre.

The displayed dose is plotted against the calculated dose in Figure 25. The slope of the trendline is 14% higher than equality (slope = 1), and this reflects the differences in the output and HVL values used in the calculations.

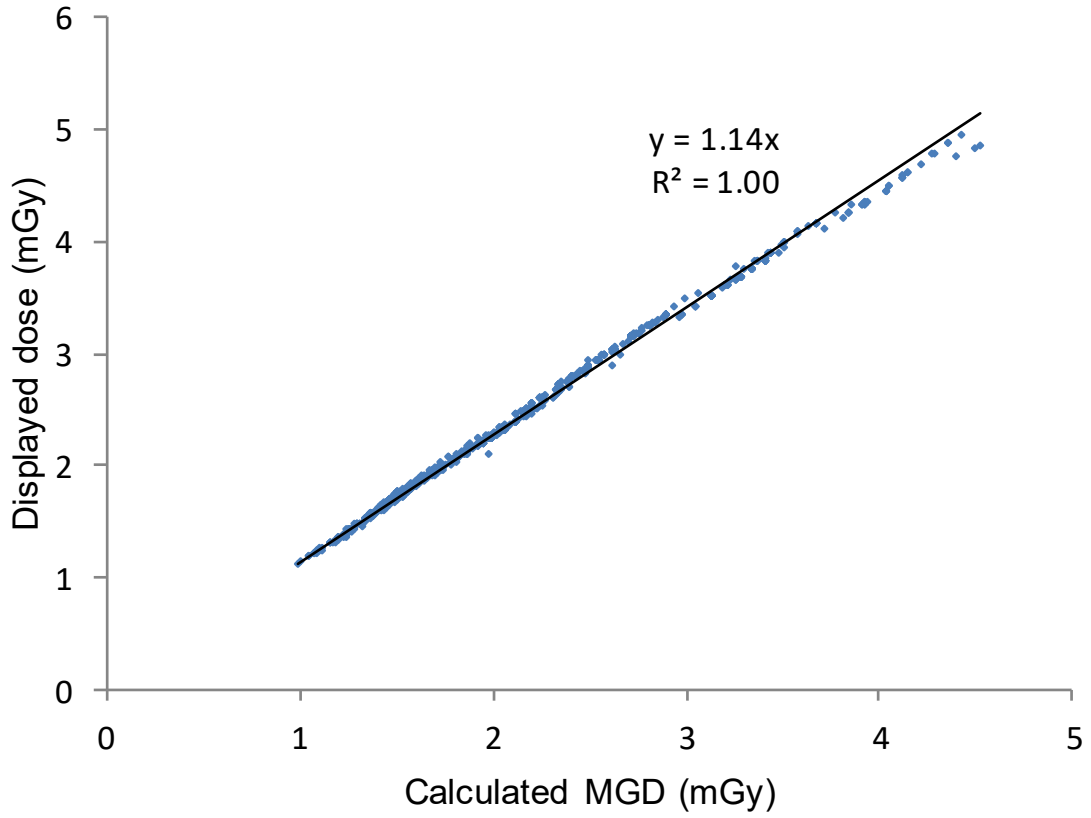

Figure 25. Displayed dose versus calculated dose (tomosynthesis)

4.3 Imaging times

Imaging times were found to be acceptable in clinical use. To provide illustrative figures, a 45mm thick block of Perspex was imaged in both tomosynthesis mode and combo mode, and timings from pressing the exposure button noted with a stopwatch. However, only tomosynthesis mode was used during the evaluation. The results are shown in Table 3. The times shown are cumulative, for example the first reconstructed slice is seen 6s after the end of exposure.

Table 3. Stopwatch timings for exposures of a 45mm Perspex phantom from the beginning of acquisition

Exposure stage	Tomosynthesis time in seconds	Combo time in seconds
End of exposure / decompression	10	17
First reconstructed slice seen on screen	16	16
System ready for next exposure (cycle time)	31	42

4.4 Timings for image reading by readers

Image reading was carried out on the PACS workstations normally in use within the centre. There was a standalone SecurView provided for the purposes of the evaluation.

Although images loaded more quickly on the SecurView than on the PACS workstations, the readers preferred to use the PACS workstations as they were more familiar with the equipment.

All readers were radiologists with a number of years' experience in reading tomosynthesis images. They found that image reading was mostly limited by the time taken for the images to load on the PACS workstations.

Although the smart mapping tool available on the SecurView was not widely used, readers found it useful to confirm the position of lesions. They also found that the presence of calcium was confirmed more quickly with the smart mapping tool, as discussed in Section 8.15.

4.5 Clinic workflow

Normally, tomosynthesis imaging and tomosynthesis biopsy is carried out in the centre in a single room. However, during the evaluation, assessment cases were shared between the 3Dimensions and the existing Dimensions system located in another room. Workflow was found to be the same in all cases, as no delays or problems were experienced when using the 3Dimensions.

4.6 Image quality assessment

4.6.1 Breast density

As part of the image quality assessment, readers were asked to make an estimate of the percentage breast density for each case within a sample dataset. Comments were recorded using a modified version of NHSBSP Equipment Evaluation Form 8 for user assessment of digital image quality. These cases have been classified as fatty (0 to 33% density), mixed (34 to 66% density) and dense (67 to 100% density). The density information was taken from 98 cases and the proportions found were:

- fatty: 21%
- mixed: 69%
- dense: 10%

The results are shown in Figure 26.

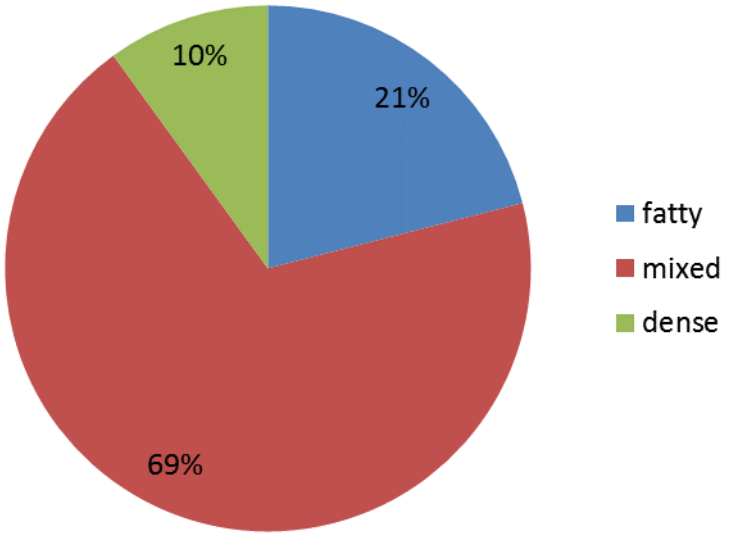

Figure 26. Reader estimates of breast density

4.6.2 Image quality

The readers also assessed the image quality for these cases with the results for a total of 267 image views shown in Figures 27 to 31. Image view refers to a reader reading either a CC or MLO view for a single case.

82% of the image views were rated as satisfactory for overall contrast. The rest were assessed as either high or very high.

In the assessment of the suitability of image processing, the readers judged it good or excellent in just under 80% of image views with the rest satisfactory. There was no poor or inadequate.

Overall diagnostic value was found to be excellent or good in more than 85% of the image views. 2% were judged poor with the rest satisfactory. No image views were assessed as inadequate.

Diagnostic zoom was rated as good or excellent for more than 80%. There was one image view judged poor with the rest satisfactory.

Diagnostic value of the Intelligent 2D images was also assessed. More than 76% of the image views were rated good or excellent. 16% were satisfactory with the rest, 8%, judged to be poor.

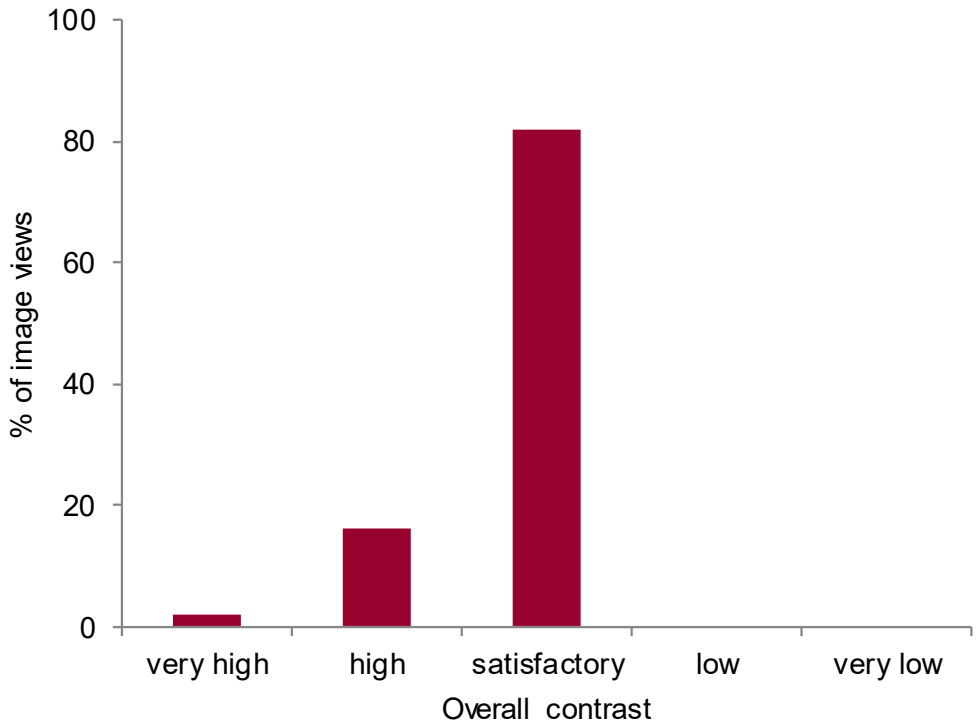

Figure 27. Readers' assessment of overall contrast

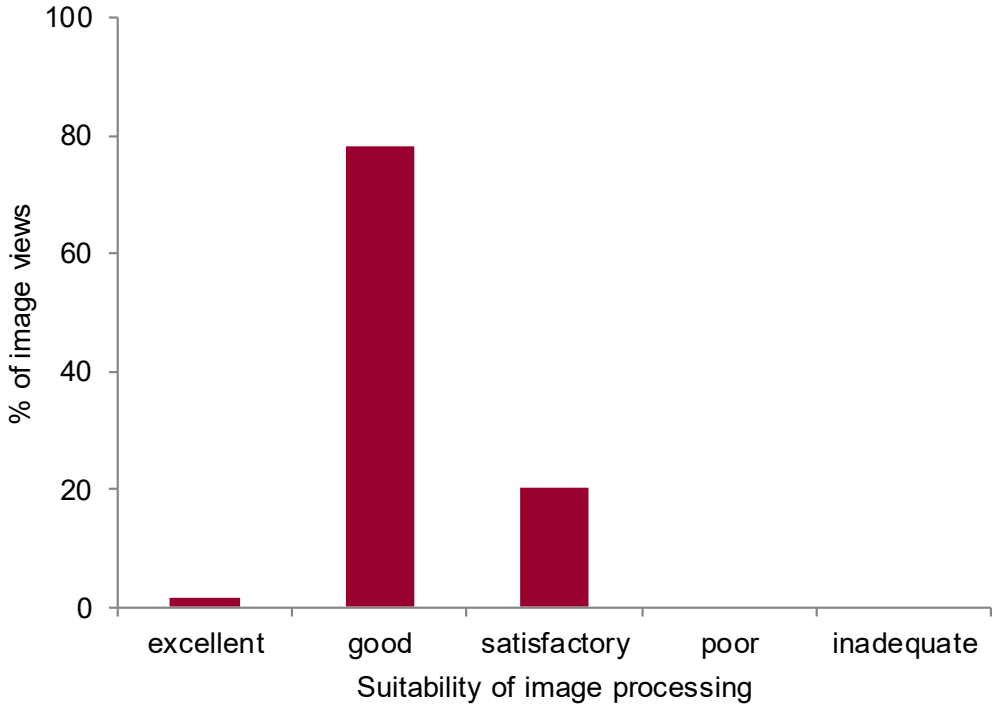

Figure 28. Readers' assessment of suitability of image processing

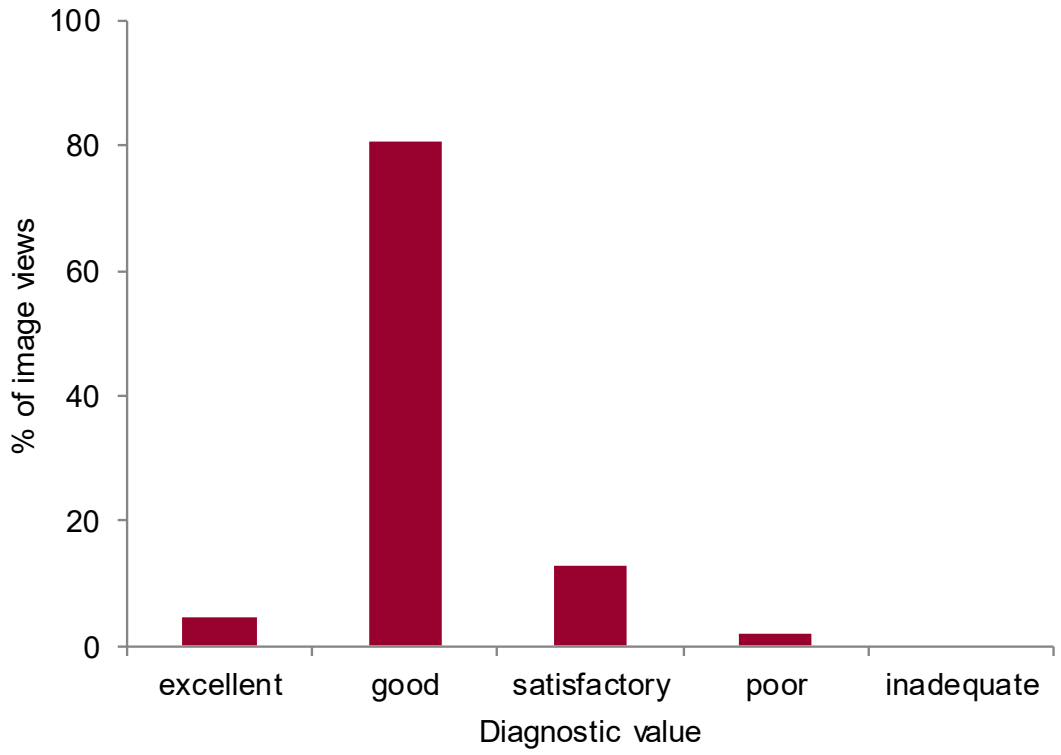

Figure 29. Readers' assessment of overall diagnostic value

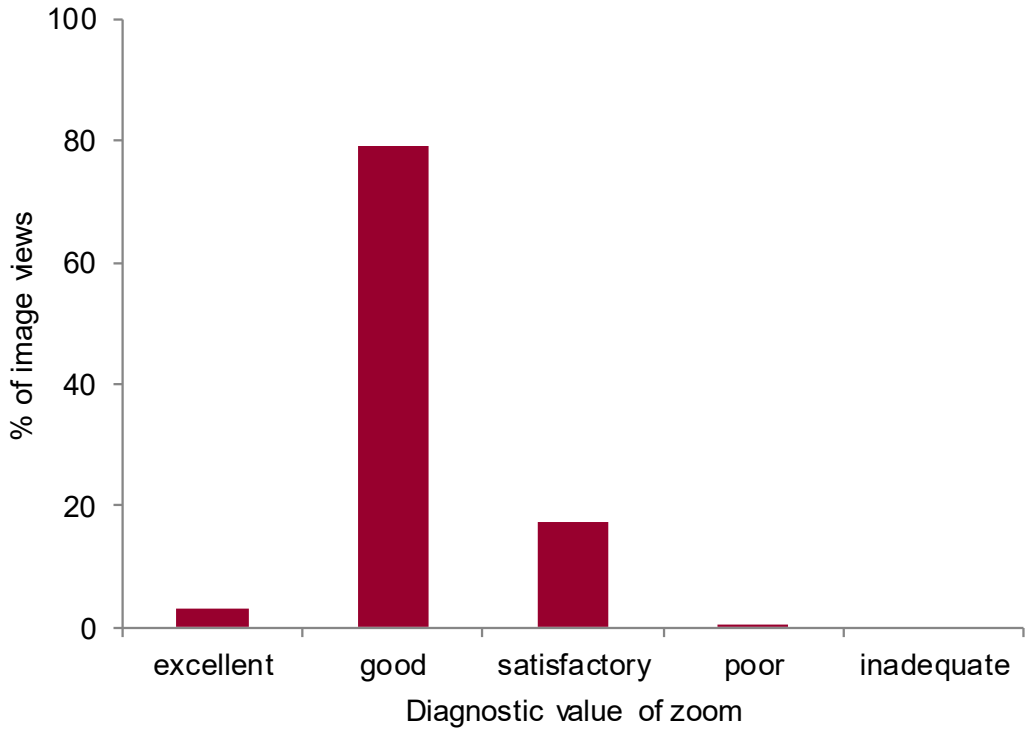

Figure 30. Readers' assessment of diagnostic value of zoom

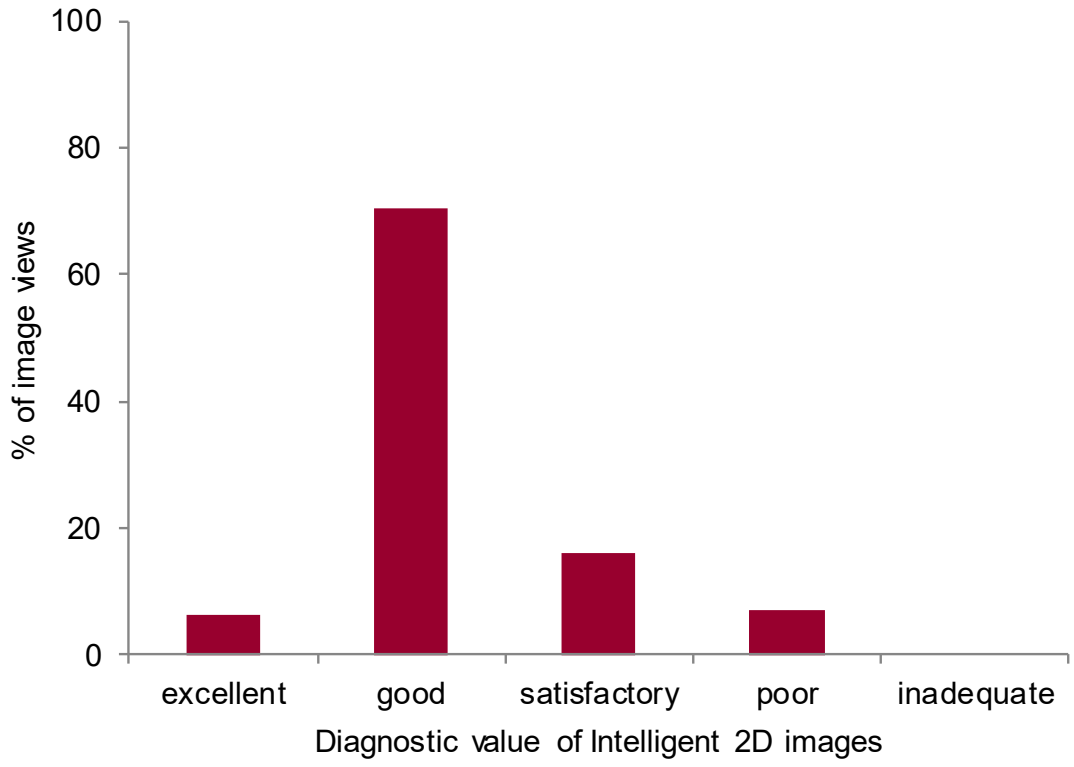

Figure 31. Readers' assessment of diagnostic value of Intelligent 2D images

4.7 Radiologists' commentary

One of the radiologists made the following comments as part of this study:

- intelligent 2D makes the calcium particles appear coarser and more benign looking whilst often the finer particles are not seen at all
- tomosynthesis always gives added value with calcifications, which enables ruling out an associated mass (see manufacturers comment)
- with round masses, both 2D and Intelligent 2D appear the same, but tomosynthesis is better as the entire margin is more clearly seen
- ASDs may be less visible in Intelligent 2D than in 2D images, however that does not necessarily mean that it is of less diagnostic value, because tomosynthesis makes it look normal or benign, which paradoxically increases diagnostic value, as less visibility on Intelligent 2D means that the lesion is not real.

4.8 Using the 3Dimensions system for biopsy

Tomosynthesis biopsies were carried out on a total of 43 women during the evaluation period. Four of these were diagnostic vacuum biopsies with 1 vacuum excision, while the rest were core needle biopsies. All the biopsies were carried out by the radiologists.

Use of the Affirm biopsy system with the 3Dimensions was the same as its use with a Dimensions[3]. Radiographers' comments on the practicalities of using tomosynthesis biopsy with the 3Dimensions are summarised in Sections 7.18 to 7.20.

5. 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.

6. 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.

7. Radiographers' comments and observations

The views of radiographers were sought on the use of the 3Dimensions system in tomosynthesis mode for assessment. The questionnaire was based on standard form 11 from the NHSBSP guidelines. Because of the similarity of the 3Dimensions to the Dimensions, questions which looked at similar topics had an additional response option to indicate this similarity.

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 familiar with the system and experienced in its use. Views reported in this section are mainly from the later set of responses, but some earlier responses are included.

A total of 20 staff returned the first questionnaire, and 18 the second. The main details from the answers and comments made on the questionnaires are given below. A copy of the questionnaire is included at Appendix 4.

7.1 Operator manual

Hologic provided a user manual and radiographers were asked to give it a rating if they had used it. Responses were good (5) or satisfactory (1), while 1 rated it the same as the Dimensions. The others did not use it.

A shorter set of instructions, developed in-house, was in use and was preferred by most users (14), while 1 did not prefer it and 3 had no preference.

7.2 Training

The applications training for tomosynthesis was delivered by Hologic applications staff to some radiographers who then trained the others, as described in Section 12.1.

The training was considered excellent (6) or good (6) by those who responded. Several commented on missing the training and having to learn from colleagues.

The training for the acquisition workstation was also regarded as excellent (6) or good (6) by those who responded.

7.3 Ease of use

Respondents initially rated this as excellent (8) or good (7), and later as excellent (12) or good (4). All staff were familiar with the Dimensions systems in use at the centre, and so the others simply rated ease of use as “same as Dimensions”.

7.4 Ease of fitting the tomosynthesis faceplate

This was rated by most as excellent (10) or good (5), while 2 said it was the same as for the Dimensions.

7.5 Exposure controls

The 3Dimensions has 2 options for initiating exposures, a foot pedal and a single exposure button on the top of the AWS. Both were generally liked, with the foot pedal rated as excellent (14) or good (4). The exposure button was initially rated excellent (3), good (12), average (2) or satisfactory (1), while 2 did not use it. In the later responses, the exposure button was rated more highly, as excellent (9), good (8), or satisfactory (1).

Several comments indicated a preference for using the foot pedal rather than the exposure button.

7.6 Tomosynthesis QA tests and calibration

QA testing is carried out by different radiographers in turn, but a few had not yet carried out these tests on the 3Dimensions. Those who had done so rated the tests as easy (4), average (12) or difficult (1). The respondent who found the QA tests difficult said that the QA instructions were not ready at first, and not clear enough. With regards to weekly calibration, respondents rated this as easy (5) or average (12).

7.7 Exposure times

When asked whether the compression time was acceptable, all 18 said it was.

7.8 System performance and throughput

All 18 respondents said that system performance did not limit patient throughput.

7.9 Comfort level of women

Four rated comfort during tomosynthesis exposures as excellent and 8 good. One commented that most women do not seem to notice the difference. In the earlier responses, one respondent said the curved paddle was uncomfortable, as it dug into

the shoulder, and another that the curved paddle was less comfortable. Body habitus and sensitivity of the client also play an important role in addition to equipment design.

7.10 Range of controls and indicators

Asked whether all the expected controls were present, all respondents said that they were. The biometric login was made available 2 months after the start of the evaluation period.

All respondents said the controls and on-screen icons were easy to find and use.

7.11 Image appearing at the acquisition workstation

The time for the image to appear at the acquisition workstation was rated excellent (11) or good (3). Two said it was slightly slower than the Dimensions and two did not respond.

7.12 Image handling and processing at the AWS

When rating the image handling at the AWS, scrolling through the image levels was rated as excellent (6), good (5), average (1) or satisfactory (1). Three assessed it as the same as for the Dimensions. One would have preferred to use a rollerball for scrolling.

Radiographers rated the image processing facilities at the AWS as excellent (1), good (7) or average (1). Three considered the image processing to be the same as for the Dimensions.

Only 10 of the respondents had used query/retrieve at the workstation, to bring back prior images, and they rated it as excellent (4), good (3), average (2) or satisfactory (1). Two also said it was the same as with the Dimensions.

7.13 Ease of use of human interface facilities at the AWS

Most respondents had no issue with using the keyboard, rating its ease of use as excellent (7), good (5) or average (2). Two rated it the same as for a Dimensions.

Fourteen respondents commented positively about the touchscreen, rating its ease of use as excellent (6), good (4), average (3) or satisfactory (1). At the earlier stage, comments were that it seemed slow to respond, but this was not reflected in the later responses. The sensitivity was reduced after a few months, on request from the centre, because users found it over-sensitive initially. All respondents were satisfied with the sensitivity after this.

Use of the mouse was rated positively by most respondents, saying it was excellent (4), good (9), average (1) or satisfactory (1). There were 3 non-respondents. Five initially

had difficulty using the mouse to move the cursor, especially between the 2 screens, but this was no longer a problem after the longer period of use. One had initially found it over-sensitive, which sometimes caused the wrong client to be highlighted on the screen.

Ease of scrolling through the tomosynthesis slices was rated as excellent (4), good (9), or satisfactory (2). One said it was the same as on a Dimensions with 2 non-respondents. There 2 comments about preferring to use a roller ball, which they felt made this task easier than with a mouse.

7.14 Image quality for tomosynthesis

The overall quality of tomosynthesis images, viewed at the AWS, was rated positively by all the respondents, who assessed it as excellent (10) or good (7). One thought it was the same as for a Dimensions.

Visibility of fine calcifications was rated as excellent (6), good (8) or average (2). One said it was the same as on the Dimensions, while one did not answer because they had not noticed, or considered it a matter for the readers to judge.

7.15 Level of confidence in the system

All respondents expressed confidence in the system, giving ratings of excellent (11) or good (6). One said their confidence was the same as for a Dimensions.

7.16 Hazards

Seventeen respondents said there were no potential hazards to themselves, while 1 said it was the same as for a Dimensions. Two identified minor hazards in the earlier responses. One was the repeated trapping of her hand under a curved paddle while positioning, while the other considered the position of the monitor to be a potential hazard. This has been discussed in detail in the 2D practical evaluation report.[10]

Respondents did not perceive any hazard to the woman, with 15 saying no hazard and one saying it was the same as for a Dimensions.

7.17 General comments

A number of general or further comments were made by the radiographers. These were:

- really great
- fantastic equipment, excellent clarity
- HD is a winning feature

- the position of the monitor screen obstructed the view of the client, limited space to reposition without hindering movement for the mammographer – this should have been identified at room design stage and amended
- it would be desirable to have a management system, so that images acquired on other systems would be visible on the 3Dimensions, which would be useful for biopsy, and sometimes essential (see manufacturers comment)
- the moveable faceguard is a good addition, but needs careful positioning not to cut off the chest wall edge of the image

7.18 Fitting and removing biopsy equipment

Fitting and removing the Affirm biopsy attachment was rated as excellent (1), good (6) or average (3). Three found it to be the same as for a Dimensions, while the others did not comment because they had no experience of doing this.

7.19 Ease of use of system for tomosynthesis biopsy

Twelve respondents had experience of biopsy with the 3Dimensions, and rated its ease of use as excellent (1), good (4), average (3) or satisfactory (2). Two said it was the same as for a Dimensions. One commented that there was some play in the needle.

7.20 Additional comments on tomosynthesis biopsy

One said that QAS testing indicated great accuracy for both 2D and tomosynthesis biopsy. One said that the round pointer for needle testing tilts with compression, preferring a square or rectangular one. One warned that needle guides are specific to the individual X-ray set, so they need careful identification.

Needle guides for Hologic equipment have an ‘L’ on the package and clear identification of compatibility is also on the package

8. Readers' comments and observations

The views of radiologists on the use of the 3Dimensions in tomosynthesis mode for assessment were collected using standard evaluation form 12 from the NHSBSP guidelines[1]. The questionnaires were completed by 6 experienced radiologists who have been working with tomosynthesis images for a number of years. The answers to the questionnaires are given below with the main comments from the respondents included. A copy of the questionnaire is included at Appendix 5.

The Jarvis Breast Centre's PACS is located at a remote site. Some reports of slow image handling in the following sections are likely to reflect PACS and network issues, rather than properties of the 3Dimensions tomosynthesis images.

8.1 Operator manual

The operator manual which was provided by the manufacturer was not used by the radiologists during this evaluation as they were already familiar with using the Dimensions previously.

8.2 Applications training for tomosynthesis

Only one of the respondents said that the applications training was good while the remaining 5 did not respond.

8.3 Use of reporting station controls for tomosynthesis

Most of the respondents rated the mouse, keyboard and keypad as excellent, good or average. It should be noted that most image-reading was done on the PACS workstations, which readers preferred to use. The SecurView was mainly used in evaluation of the smart mapping tool, reported in section 8.15.

One respondent said that they had not been told how to use the keyboard or keypad for image reading.

8.4 Image handling tools for tomosynthesis

The rating of image handling tools including zoom and cine was excellent (1), good (3) and average (2). One commented that the tools were the same as those used in everyday image reading.

8.5 Visibility and usability of on-screen icons for tomosynthesis

The on-screen icons were scored as excellent (1), good (4) and average (1).

8.6 Slab thickness change when reviewing tomosynthesis images

Only 2 of the respondents had changed the slab thickness, with one making use of it on rare occasions. The other one who commented that they were unable to change to 2mm thickness slabs, but only to larger thicknesses. There was also a comment from another respondent that they had not been shown how to do it.

8.7 Reading and reporting flow pattern in tomosynthesis mode

The response about the reading and reporting workflow was varied. One respondent rated it as excellent with another as good. Of the others, 3 rated it as poor with the last respondent rating it as satisfactory. A majority of respondents commented that the workflow was slow, very slow or too slow, but acknowledged. This may be due to the use of PACS amd it not being located within the evaluation centre.

8.8 Time for image to appear on reporting workstation in tomosynthesis mode

For the selection of each new patient, the time was judged as either satisfactory (2) or poor (4). One respondent also commented that it was too slow.

The in-examination change was marked as satisfactory (1) and poor (3). The remaining 2 did not respond. One commented that it was slow.

For biopsies, one said it was good with 2 rating it as average. The remaining readers did not respond.

8.9 Adjustment of reporting monitors to suit the user

Two respondents found this easy and 2 average, while the remaining 2 did not respond.

8.10 Navigating between tomosynthesis slices

Five respondents found it easy to navigate between the tomosynthesis slices. The last one found it average and also commented that it was slow.

8.11 Image quality of tomosynthesis images

The majority of readers considered image quality to be excellent (2) or good (3) for image contrast. One did not respond.

For image sharpness, 4 found it good and one average. There was one non-respondent.

8.12 Visibility of fine calcifications

When looking for fine calcifications, the respondents rated tomosynthesis as good (2), average (2) and poor (2).

Two rated the visibility of fine calcifications in Intelligent 2D images as excellent, 2 good, one average and one satisfactory.

One of those who gave the poor rating for tomosynthesis images also commented that viewing an Intelligent 2D image can also underestimate the number of particles in a cluster, when compared to viewing a magnification table image.

8.13 Value and quality of Intelligent 2D images

The value and quality of Intelligent 2D images was rated as excellent (1), good (1) and average (3). The one non-respondent commented instead that it was useful in most cases.

8.14 Comparison of Intelligent 2D™ images

8.14.1 Intelligent 2D compared with 2D

When comparing Intelligent 2D images with 2D images, one respondent said it was the same while 3 respondents said it was poorer and the other 2 did not respond.

One commented that some small masses were difficult to see. Another comment was that Intelligent 2D seemed to smooth features making cancers less obvious, although calcifications were seen better. Another reader said that asymmetry and low density masses were not well seen.

Of the 2 who did not give a rating, one commented that it was variable and they still relied on looking at the 2D images. Raw data tomo images are always read in conjunction with synthesized images. They also said that on occasion, the Intelligent 2D did not show calcifications. The other one commented that they wanted to have a more formal comparison using batches of images to be able to answer.

8.14.2 Intelligent 2D compared with C-view

When comparing Intelligent 2D with previous experience of viewing C-view images, one respondent said it was the same and 2 said it was poorer while the other 3 did not respond.

One of those who said it was poorer commented that Intelligent 2D “gets rid” of more lesions and makes them appear as lower density.

8.15 Usefulness of smart mapping tool on SecurView reporting workstation

Two respondents rated the usefulness of the smart mapping tool as good and 3 said it was average, while the last one said it was poor.

There was one comment that the mapping tool was useful to find calcification on tomosynthesis images, and for double-checking and speeding up checking of areas of calcium. Another comment was that it was hard to go from one workstation to another and keep to the first-time view but this may be due to the use of additional PACS workstations.

8.16 Acceptability of images acquired with SmartCurve Breast Stabilization System

Three respondents said the images acquired with curved paddles were acceptable, 2 said they did not know, while the last did not respond.

8.17 Recording findings on NBSS for tomosynthesis images

This function is not currently available on NBSS.

8.18 Overall impression of image quality

Most of the readers thought that image quality was good (5) with one saying that image quality was excellent.

8.19 Overall satisfaction in use for assessment

The overall opinion from respondents was that the 3Dimensions system was excellent (1), good (3), average (1). There was one respondent who thought it was poor and commented that the slow loading of images on the reporting workstation severely detracted from its benefits. This comment relates to the local PACS/IT infrastructure and not directly to the system under evaluation.

8.20 General comments

One respondent commented that loading and saving the tomosynthesis images to the PACS was slow and time-consuming but relates to the IT infrastructure, not the system.

Another responded that the system seemed very good and was certainly equivalent to or better than any other systems they had seen. They also commented that the slow

loading of tomosynthesis images were hindered by the PACS speediness. This might not be the case for an on-site PACS, or if images had been viewed primarily on the SecurView, as images were sent directly to it.

9. Information Systems

9.1 Workflow configuration

The 3Dimensions system was integrated into the local network of the centre as shown in Figure 31. The PACS was located at a site remote to the centre.

The clinic worklist was sent from the NBSS system to the 3Dimensions, which was connected to both the PACS and to a SecurView reporting workstation.

Images were sent to both when the examinations were closed. Prior images were available on the SecurView workstation as well as on the PACS workstations for comparative image reading.

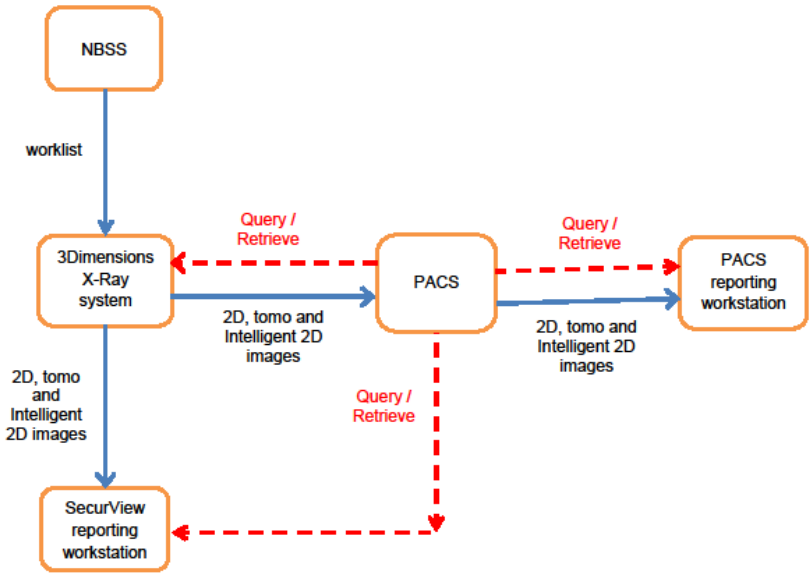

Figure 31. Image workflow example

9.2 Reporting workstations

As described in Section 1.2.2.2, a SecurView workstation was available for the evaluation. However, the SecurView was only used as a secondary reporting workstation as the readers viewed the clinical images on the PACS MX workstations. Its main use was to enable the smart mapping feature of Intelligent 2D (synthesized) images derived from the tomosynthesis images. Smart mapping is a feature by which a mouse click on a suspicious area of the Intelligent 2D image automatically displays the corresponding tomosynthesis slice on the adjacent monitor.

9.3 Image sizes

The 3Dimensions is capable of producing tomosynthesis images in two different formats: standard with 100 micron pixel size and high resolution with 70 micron pixel size. High resolution images were used in the evaluation.

Table 3 shows the sizes of images produced by the 3Dimensions. The size of a tomosynthesis image depends on the field size and the CBT. The range of values given reflects the extremes that have been imaged in the centre, from the thinnest breast (18cm x 24cm image) to the thickest (24cm x 29cm image).

Table 3. Image file sizes in megabytes (MB)- no compression applied

Image type	18cm x 24cm (thinnest breast)	24cm x 29cm (thickest breast)
2D image	16.6	26.6
2D synthesized (Intelligent 2D) image	25.0	40.0
tomosynthesis projections	13.5	65.9
tomosynthesis HD image	477.1	2835.4

10. Confidentiality and security issues

The evaluation complied fully with the NHS Cancer Screening Programmes' Confidentiality and Disclosure Policy[11].

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

12.1 Radiographer training

The applications training for tomosynthesis use was delivered by an applications specialist to the radiographers who were present in the centre at the time. The training was cascaded from these to the others, as is the usual practice.

All radiographers were experienced in the use of tomosynthesis imaging, and some also had experience in tomosynthesis biopsy.

12.2 Reader training

All 6 readers were experienced radiologists who had previously attended approved tomosynthesis image reading courses at either Kings College Hospital or St George's Hospital. They also had several years' experience of reading tomosynthesis images.

13. Discussion

13.1 Equipment and practical considerations

The 3Dimensions has a number of new features, which were mostly well received by the users, although some problems were reported with use of the SmartCurve paddles. Use of the SmartCurve paddles and the new ergonomic features of the 3Dimensions are described in detail in the practical evaluation (2D) report[10] and only mentioned incidentally in comments in this report. Of more consequence for the tomosynthesis evaluation are the 70 micron pixels for tomosynthesis and synthesized images, the new type of synthesized images (Intelligent 2D) and the smart mapping feature. These are discussed in Section 13.4.

13.2 Physics testing and routine QC

Physics tests carried out at commissioning and again at approximately 6-monthly intervals later found equipment performance to be satisfactory.

QC tests for tomosynthesis were carried out routinely during the evaluation, and results are presented in Section 3. These were the standard tests required in the NHSBSP protocol7. The test results showed that the performance of the system was consistent and satisfactory, and remained within the NHSBSP limits.

13.3 Dose surveys

Dose surveys were carried out for both flat and curved paddles, of both sizes. The standard value for comparison is the dose (MGD) for MLO views of 50 to 60mm thick compressed breasts. The doses for curved paddles 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].

For the 18cm x 24cm paddles, the doses were practically the same, 1.96mGy for the flat paddle and 1.95mGy for the SmartCurve paddle. For 24cm x 29cm paddles, the dose was lower for the SmartCurve paddle than for the flat one, 1.88mGy compared with 2.10mGy, but the 1.88mGy is the average of only 3 values, so no firm conclusion can be drawn from the limited data. Still, the results seem to differ from those found in the 2D practical evaluation[11], where doses were found to be higher when using the SmartCurve paddles. A possible explanation is that breasts are compressed to a different extent in tomosynthesis imaging for assessment. Not enough is known about how breast tissue distributes itself when compressed under a curved paddle, with different degrees of compression.

13.4 Clinical assessment

First the readers evaluated image quality in a general way, for a set of 98 cases. The great majority of ratings given were “good”, for suitability of image processing, diagnostic value of tomosynthesis and Intelligent 2D images, and diagnostic value of zoom. Overall contrast was rated by most as satisfactory.

An image quality study of 68 assessment cases gave more detailed results for different types of lesions, viewed in 2D, tomosynthesis and Intelligent 2D. For microcalcifications, round and spiculated masses and ASDs, the clear majority view was that lesions were clearly seen in most cases, with only a few or none not seen at all. Only distortions showed a different picture, as they were clearly seen in almost all cases in tomosynthesis images, but less well on the whole in 2D and Intelligent 2D.

Comparing the diagnostic value of tomosynthesis to 2D images, tomosynthesis was perceived as much better for all types of lesions except microcalcifications. For these, results were more mixed with some better, some worse than 2D images, and the majority the same.

Comparing the diagnostic value of tomosynthesis to Intelligent 2D images yielded more mixed results. Intelligent 2D images were generally judged as better than or the same as 2D. Only for microcalcifications were Intelligent 2D images perceived as worse, in about 20% of cases.

13.5 Radiographers’ views

The radiographers found the 3Dimensions generally easy to use and liked the quality of the images on the AWS. Most of the practical aspects were similar to the Dimensions, with which all were familiar. The newer ergonomic features were generally appreciated, as detailed in the 2D practical evaluation report[10]. The foot pedal for exposures was much liked, with all of the 18 radiographers rating it excellent or good.

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:

- some had difficulty using the mouse to scroll through tomosynthesis slices on the AWS screen, and expressed a preference for the rollerball (on the Dimensions) for this task; this was less of a problem after some months of use
- some had initial difficulty using the touchscreen, but this was resolved after the sensitivity was reduced and they had more experience with it
- occasionally their hands would be trapped under the sides of the curved paddles when positioning, and it was reported that they sometimes caused

discomfort to women; avoiding the use of curved paddles on thinner breasts resolved this issue
- some expressed concern about play in the needle, when performing tomosynthesis biopsy

13.6 Readers' views

The readers were generally satisfied with practical aspects of reading 3Dimensions images, except for repeated comments about slowness affecting workflow, such as in image transfer or bringing the next image onto the screen. It was suggested that this might be due to the Jarvis Centre being connected to a PACS at a remote site, although this idea could only be tested by installation elsewhere, at a site where the PACS is local. It is possible that the PACS workstations they used, and the large size of the tomosynthesis images, were also contributory factors. More use of the SecurView might have alleviated this problem.

The readers made thoughtful comments on the visibility of different types of lesions. These are found in Sections 4.7 and 8.12 to 8.14, and are difficult to summarise; there were some differences of opinion, even though readers viewed the same set of images. In practice, different types of image (2D, tomosynthesis and Intelligent 2D) might be the most useful for viewing, depending on the type of lesion.

The smart mapping tool was not much used, as it was available on the SecurView and the preference for reading was the PACS workstations. Its usefulness was rated good or average by most, and one commented on the time saving it offered when finding or checking areas of calcification.

14. Conclusions and recommendations

The 3Dimensions was reliable in use in tomosynthesis mode. It was used for imaging and for tomosynthesis biopsy. Practical aspects of its use were liked, after some initial adjustments were made and users gained experience with new features such as the touch screen. The remote location of the centre's PACS probably contributed to some reported slowness in sending or retrieving images.

The average MGD calculated for MLO views of 50-60mm thick breasts was 2.0mGy, well below the national DRL (for 2D images) of 2.5mGy.

The overall assessment of image quality and diagnostic value was that they were good, although a slightly more complex picture emerged when viewing different types of lesions. The majority of lesions were clearly seen, while only very small numbers were not seen in some types of image (2D, tomosynthesis and Intelligent 2D). I2D is recommended to be used in combination with tomosynthesis and not alone – this may change the results.

The 3Dimensions was found to be suitable for use in assessment in the NHSBSP, for tomosynthesis imaging and tomosynthesis biopsy.

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Appendix 1: Physics survey reports

A1.1 Commissioning Report

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 – 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*
R/A	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/G	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/G	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/G 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	0.61 @ 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				✓	
Caliper 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
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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

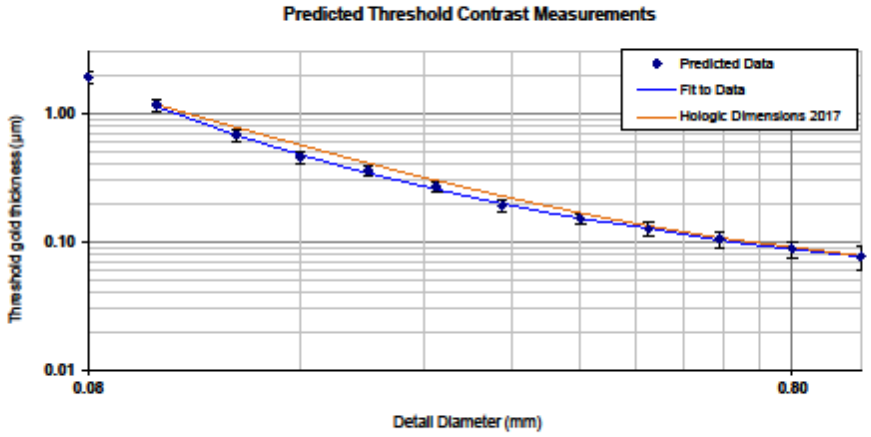
Survey Results

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%	✓	2
3 cm		29 WAl	7.8	48%		
4 cm		32 WAl	6.3	40%		
4.5 cm		33 WAl	6.1	33%		
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

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Mammography Image Display Commissioning Report
Jarvis Breast Screening - October 2017

1. Background

A commissioning survey of the primary image display monitors was undertaken at Jarvis Breast Screening on 13th October 2017. The monitors were tested against the criteria given in the NHSBSP Report 0604, Commissioning and Routine Testing of Full Field Digital Mammography Systems.

2. Equipment

Workstation		
Type		Mammography
Location		Clinic Area
Make & Model		Barco MDMG-5221
Pixels		5M
Serial No.	Left	2590080575
	Right	2590075135

Test Pattern	
Type	TG18-LN

3. Survey results

Physical parameter		Remedial Level	Results		OK?	Comment No.
			Left Monitor	Right Monitor		
General condition of unit		Satisfactory			✓	
Luminance (cd/m^2)	100% White	< 450	1006	971.5	✓	
	0% Black	> 1.5	1.12	1.04	✓	
	Ratio	< 300	898	934	✓	
Max % diff from DICOM greyscale calibration		GSDF ± 10%	2.2	0.5	✓	
% Non-Uniformity		> 30%	2.2	1.9	✓	
% variation between 100% luminance of paired monitors		> 5%	3.6		✓	
Room Illumination (lux)		> 10	8.5 lux - Main lights off, small lamps on		✓	

4. Comments

Satisfactory

Emma Bolt
Senior Physicist
18th October 2017

NEW DRAFT DAT 3 2 03B monitor QA mammo. MK Vs 1

A1.2 Routine Physics Report – February 2018

Regional Radiation Protection Service NHS
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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 NA 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 (µGy/mAs@50cm)					
28kV MoMo BF	>120 + 70% of baseline			☐	N/A
28kV MoRh BF				☐	N/A
28kV RhRh BF				☐	N/A
28kV WRh BF		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	1.680	1.100	0.83	☑	
TORMAX					
Perpendicular lp/mm	Significant difference			☐	n/m
Parallel lp/mm	from baseline				
Contrast (%) 6mm					
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	1.92	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.

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Mammography Physics Report

Routine Six-Monthly Testing

Tomosynthesis Results Summary

Location *Jarvis Breast Screening Centre - Clara* ***Survey Date*** *19 February 2018*

Equipment *Hologic 3Dimensions*

Survey Results

Measurement	Criteria or specification	Baseline(s)	Results	% Diff from Baseline	Satisfactory	Comments
Alignment						
X-ray field to reconstructed image alignment at chest wall	0-5mm	-	4 mm	-	✓	
Primary beam attenuation	Primary beam must be blocked by detector & surrounding structure	-	Confirmed satisfactory	-	✓	
Missed tissue at chest wall	< 5mm	-	5 mm	-	✓	
Target volume visualisation	All markers at top & bottom of target volume must be brought into focus	-	Yes	-	✓	

Measurement	Criteria or specification	Baseline(s)		Results		% Diff from Baseline	Satisfactory	Comments
Automatic Exposure Control (AEC Performance)								
Contrast to Noise Ratios (CNRs)								
		Image Size = 24x30	*AEC mode = Autofilter*		*Processing = LCC*			
Variation with PMMA		kV/T/F	*CNR*	kV/T/F	*CNR*			
2 cm	< 20% change from baseline	26 WAl	7.0	26 WAl	7.3	3.8%	✓	
3 cm		28 WAl	5.2	28 WAl	5.6	8.4%	✓	
4 cm		30 WAl	4.5	30 WAl	4.5	0.7%	✓	
4.5 cm		31 WAl	4.6	31 WAl	4.5	-2.7%	✓	
5 cm		33 WAl	4.3	33 WAl	4.1	-5.2%	✓	
6 cm		36 WAl	3.9	36 WAl	3.6	-7.5%	✓	
7 cm		42 WAl	3.1	42 WAl	3.0	-3.9%	✓	
Image Quality								
CDMAM								
		Image Size = 18x24	*AEC mode = Autofilter*		*Processing = LCC*			
CDMAM Detail detection – threshold gold thickness, µm	Comparable with other units of same type. No significant change from baseline.	*Detail diameter, mm*	*Threshold gold thickness µm*	*Detail diameter, mm*	*Threshold gold thickness µm*			
		0.08	1.910	0.08	1.618		✓	
		0.10	1.152	0.10	1.063	-8%		
		0.13	0.678	0.13	0.672	-1%		
		0.16	0.455	0.16	0.471	3%		
		0.20	0.357	0.20	0.359	1%		
		0.25	0.268	0.25	0.265	-1%		
		0.31	0.190	0.31	0.196	3%		
		0.40	0.151	0.40	0.151	0%		
		0.50	0.125	0.50	0.126	1%		
		0.63	0.105	0.63	0.102	-3%		
		0.80	0.087	0.80	0.086	-2%		
		1.00	0.076	1.00	0.078	2%		
Best slice in focus (average):		21						

A1.3 Routine Physics Report – August 2018

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Mammography Physics Routine Survey Report

Hologic Selenia 3Dimensions with Tomosynthesis

Jarvis Breast Screening Centre – Room 3

1 Introduction

A routine radiation protection and performance survey of the Hologic 3Dimensions digital mammography equipment was undertaken on the 14th August 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.

Flag	*Recommendations*	*Local Action Taken (where required)*	*Sign & Date*
	Tomosynthesis Mode:		
G	The routine 6-monthly physics QA tests were found to be satisfactory.		
	Conventional 2D Imaging:		
A	1. The max kV error was found to be just outside tolerance when using the MAG mode. This should be checked by the engineer at the next routine service.		
A/G	2. The X-ray beam was found to overlap the left hand sides of contact mode images by more than 5mm. This will have no impact on image quality, patient dose or radiation safety of the system and therefore no action is required.		
A/G	3. 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.		

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

Key:

R Immediate action required
RNA To be resolved as soon as practicable
A To be addressed
AIG Points to note
G Satisfactory

Table 1. Stereo AEC Test Results

2D:

	Baseline results October 2017			August 2018		
PMMA (cm)	CBT (cm)	kV / Target-Filter	mAs	CBT (cm)	kV / Target-Filter	mAs
2	2.2	25 W Rh	61	2.1	25 W Rh	65
4.5	5.3	29 W Rh	155	5.3	29 W Rh	155
7	9.0	34 W Ag	208	9.0	34 W Ag	212

Tomo:

	Baseline results October 2017			August 2018		
PMMA (cm)	kV	Target-Filter	mAs	kV	Target-Filter	mAs
2	26	W Al	39	26	W Al	40
4.5	31	W Al	62	31	W Al	62
7	42	W Al	74	42	W Al	74

Mandeep Rai
Trainee Healthcare Scientist
16th August 2018

Mary Kelly
Principal Physicist

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Mammography Routine Performance Report
Results Summary

Location	Jarvis BSC X-ray Room 3	**Survey Date**	14/08/2018

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		1.4	☐	1
Tube Output (µGy/mAs@50cm)					
28kV MoMo BF	>120 + 70% of baseline			☐	N/A
28kV MoRh BF				☐	N/A
28kV RhRh BF				☐	N/A
28kV WRh BF		67.7	65	☑	
28kV WAg BF		80.9	78	☑	
28kV MoMo FF				☐	N/A
28kV WRh FF		58.5	49	☑	
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			0.29	☑	
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		20.0	☑	
Maximum error (kg)	2 kg		0.3	☑	
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			☐	N/A

4 Alignment					
Measurement	Criteria	Baseline	Result	OK	Comments
X-ray to Light Alignment (mm)	±5mm at all edges		F B L R	☑	
18x24(L) BF W			1 0 1 -1		
24x30 BF W			2 0 1 0		
18x24 BF W			1 0 0 0		
18x24(R) BF W			1 -1 -2 2		
Mag FF W			1 0 -1 -1		
X-ray to Detector Alignment	0-5mm overlap all sides		F B L R	☐	2
18x24(L) BF W			2 5 6 5		
24x30 BF W			5 4 6 3		
18x24 BF W			2 5 6 4		
18x24(R) BF W			2 4 7 2		
Mag FF W			2 4 1 1		

5 Detector Performance								
Measurement	Criteria	Baseline			Result			OK	Comments
Detector Response									
Air Kerma (µGy) at PV= 300	20% change frm baseline	97.74			99.2			☑	
Noise	10% change frm baseline	4.63			4.30			☑	
SNR	10% change frm baseline	54.43			58.4			☑	
Limiting Resolution (lp/mm)	<75% of baseline	6.3			7.1			☑	
SWCTF(perp) at 1lp/mm, 4lp/mm, 80% Nyquist	10% change frm baseline	0.365	0.252	0.206	0.35	0.23	0.21	☑	
SWCTF(para) at 1lp/mm, 4lp/mm, 80% Nyquist	10% change frm baseline	0.362	0.249	0.204	0.35	0.24	0.20		
Spatial Discontinuity	None							☑	
Image Retention	Retention factor <0.3				0.03			☑	
Uniformity	<10% variation				DR 0.9 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	0.05	☑	
0.5mm	0.150	0.103	0.09	☑	
0.25mm	0.352	0.244	0.20	☑	
0.1mm	1.680	1.100	0.84	☑	
TORMAX					
Perpendicular lp/mm	Significant difference			☐	N/M
Parallel lp/mm	from baseline				
Contrast (%) 6mm					
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		1.0	☑	
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	9.63		
3 cm		26	W	Rh	8.52	26	W Rh	8.84		
4 cm		28	W	Rh	7.76	28	W Rh	7.95		
4.5 cm		29	W	Rh	7.24	29	W Rh	7.68		
5 cm		31	W	Rh	7.26	31	W Rh	7.60		
6 cm		31	W	Ag	7.01	31	W Ag	7.49		
7 cm		34	W	Ag	5.71	34	W Ag	6.12		

Mag								
CNR - variation with PMMA	10% change frm baseline	Settings			CNR	Settings		CNR	☑	
2 cm		25	W	Rh	11.48	25	W Rh	11.28		
3 cm										
4 cm		30	W	Rh	7.38	30	W Rh	7.19		
4.5 cm										
5 cm										
6 cm		34	W	Ag	4.79	34	W Ag	4.71		

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	0.63	☑	
3cm	<1.5mGy	26	W	Rh	0.86	26	W Rh	0.83	☑	
4cm	<2mGy	28	W	Rh	1.14	28	W Rh	1.11	☑	
"Standard breast" 4.5cm	<2.5mGy	29	W	Rh	1.41	29	W Rh	1.38	☑	
5cm	<3mGy	31	W	Rh	1.92	31	W Rh	1.90	☑	
6cm	<4.5mGy	31	W	Ag	2.44	31	W Ag	2.41	☑	
7cm	<6.5mGy	34	W	Ag	2.76	34	W Ag	2.75	☑	

Comments

1 The kV in mag mode was found to be outside the tolerance of 1kV. The contact mode was found to be within limits.

2 The x-ray to detector alignment was found to be greater than 5mm on the left hand side for all contact mode field sizes.

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Mammography Physics Report

Routine Six-Monthly Testing

Tomosynthesis Results Summary

Location *Jarvis Breast Screening Centre - Clara* ***Survey Date*** *14 August 2018*

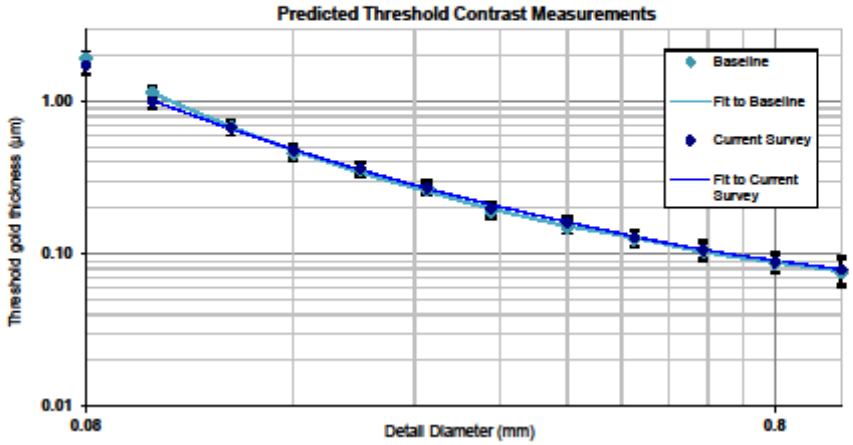
Equipment *Hologic 3Dimensions*

Survey Results						
Measurement	**Criteria or specification**	**Baseline(s)**	**Results**	**% Diff from Baseline**	**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	-	5 mm	-	✓	
Target volume visualisation	All markers at top & bottom of target volume must be brought into focus	-	Yes	-	✓	

Measurement		Criteria or specification	Baseline(s)			Results			% Diff from Baseline	Satisfactory	Comments
Tube Output											
Tube Output (µGy/mAs@1m)		Significant change from baseline	*kV/T/F*	*Output*		*Output*					
			26 WAl	22.3		21.8			-2.3%	✓	
			28 WAl	28.3		27.7			-2.1%	✓	
			30 WAl	34.6		33.7			-2.5%	✓	
			31 WAl	37.8		37.2			-1.7%	✓	
			33 WAl	44.4		43.8			-1.2%	✓	
			36 WAl	54.8		54.1			-1.2%	✓	
			42 WAl	77.4		76.9			-0.7%	✓	
Uniformity and Artefacts											
Uniformity and artefacts		No clinically significant artefacts should be seen	-			No artefacts seen				✓	
Geometric Distortion and Artefact Spread											
			Height of test object above table (mm)			*Height of test object above table (mm)*					
			7.5	*32.5*	*52.5*	*7.5*	*32.5*	*52.5*			
Height of best plane of focus		< 2mm change from baseline*	7.2	32.3	52.5	7.2	32.4	52.5	0.1 mm	✓	
Distortion within focal plane – ratio of mean separations of balls in X and Y planes		< 5% change from baseline*	1.00	1.00	1.00	1.00	1.00	1.00	0.1%	✓	
Scaling accuracy (%)		< 5% change from baseline or absolute error < 1 %*	0.36	0.47	0.43	0.36	0.45	0.41	5.8%	✓	
FWHM perpendicular to detector (vertical or Z plane resolution), mm		< 20% change from baseline*	11.4	10.7	10.4	11.2	10.7	10.3	1.6%	✓	
Spread parallel to detector	X plane (parallel to tube axis)	< 2 pixels or 50% change from baseline*	0.04 mm	0.03 mm	0.02 mm	0.03 mm	0.03 mm	0.01 mm	0.2 pixels	✓	
			0.61 pixels	0.53 pixels	0.37 pixels	0.46 pixels	0.53 pixels	0.21 pixels			
	Y plane (perpendicular to tube axis)		0.09 mm	0.09 mm	0.07 mm	0.07 mm	0.07 mm	0.06 mm	0.3 pixels	✓	
			1.34 pixels	1.34 pixels	1.08 pixels	1.04 pixels	1.16 pixels	1.00 pixels			

**These are proposed as investigation levels not remedial limits*

CDMAM continued



Measurement	Criteria or specification	Baseline(s)	Results	% Diff from Baseline	Satisfactory	Comments
TORMAM Visibility of details	No significant deterioration from baseline	-	No significant deterioration seen		✓	

Mean Glandular Dose (MGD)

AEC mode = Auto-Filter *Processing = LCC*

PMMA	< ±25% change from baseline	*kV/T/F*	*MGD (mGy)*	*kV/T/F*	*MGD (mGy)* *Calculated*	*MGD (mGy)* *Displayed*	*% diff between displayed & calculated MGD*			
2 cm	Displayed values of MGD not > 30% different from calculated values	26 WAl	0.98	26 WAl	1.00	0.97	-3.0%	2%	✓	
3 cm		28 WAl	1.07	28 WAl	1.13	1.16	2.7%	6%	✓	
4 cm		30 WAl	1.40	30 WAl	1.37	1.44	5.1%	-2%	✓	
4.5 cm		31 WAl	1.85	31 WAl	1.81	1.93	6.5%	-2%	✓	
5 cm		33 WAl	2.20	33 WAl	2.17	2.35	8.1%	-1%	✓	
6 cm		36 WAl	3.39	36 WAl	3.35	3.66	9.4%	-1%	✓	
7 cm		42 WAl	4.57	42 WAl	4.54	4.89	7.7%	-1%	✓	

Measurement	Criteria or specification	Baseline(s)		Results		% Diff from Baseline	Satisfactory	Comments
Automatic Exposure Control (AEC Performance)								
Contrast to Noise Ratios (CNRs)								
		Image Size = 24x30	*AEC mode = Auto-Filter*		*Processing = LCC*			
Variation with PMMA		kV/T/F	*CNR*	kV/T/F	*CNR*			
2 cm		26 WAl	7.0	26 WAl	7.5	7.0%	✓	
3 cm		28 WAl	5.2	28 WAl	5.8	11.5%	✓	
4 cm	< 20% change from baseline	30 WAl	4.5	30 WAl	4.6	3.3%	✓	
4.5 cm		31 WAl	4.6	31 WAl	4.6	0.6%	✓	
5 cm		33 WAl	4.3	33 WAl	4.3	0.0%	✓	
6 cm		36 WAl	3.9	36 WAl	3.8	-2.3%	✓	
7 cm		42 WAl	3.1	42 WAl	3.1	-1.6%	✓	
Image Quality								
CDMAM								
		Image Size = 18x24	*AEC mode = Auto-Filter*		*Processing = LCC*			
CDMAM Detail detection – threshold gold thickness, µm	Comparable with other units of same type. No significant change from baseline.	*Detail diameter, mm*	*Threshold gold thickness µm*	*Detail diameter, mm*	*Threshold gold thickness µm*		✓	
		0.08	1.910	0.08	1.725			
		0.10	1.152	0.10	1.000	-13%		
		0.13	0.678	0.13	0.676	0%		
		0.16	0.455	0.16	0.477	5%		
		0.20	0.357	0.20	0.364	2%		
		0.25	0.268	0.25	0.272	2%		
		0.31	0.190	0.31	0.200	5%		
		0.40	0.151	0.40	0.162	7%		
		0.50	0.125	0.50	0.128	2%		
		0.63	0.105	0.63	0.107	2%		
		0.80	0.087	0.80	0.089	2%		
		1.00	0.076	1.00	0.079	4%		
Best slice in focus (average):		21						

Comments

None, satisfactory.

Reported By:	*Mandeep Rai* *Trainee Healthcare Scientist*	*Mary Kelly* *Principal Physicist*	*16th August 2018*

Appendix 2: Dose surveys

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

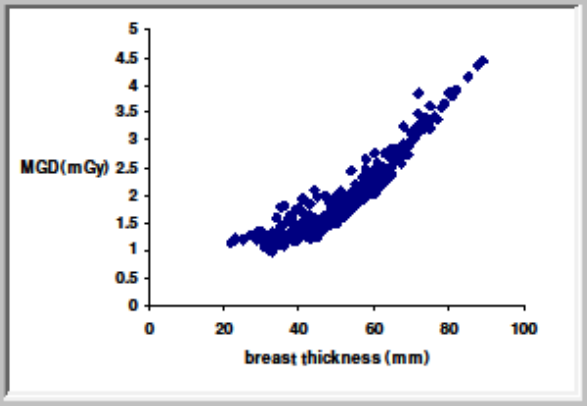
NHSBSP Breast Dose Survey

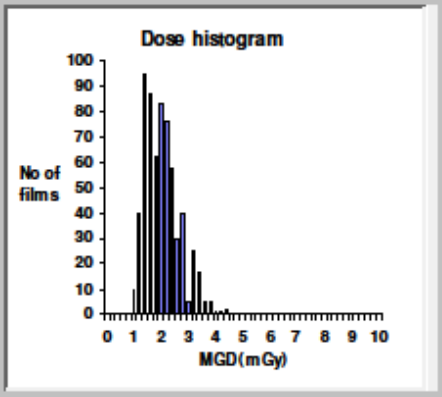
Survey No:	415
Centre:	Jarvis Breast Centre
Date of first exam:	21/02/2018
Date of last exam:	20/07/2018
X-ray make:	Hologic
Model:	3Dimensions
Local id:	Small Flat tomo
Installation:	fixed
kV mode:	auto
standard kV:	
Routine/age trial:	routine screening

Tomo mode: Tomo

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:	Al		





Count of Images

view	main films	Extra films
CC	293	
OB	336	

Average doses for main images

view	No of films	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	293	1.04	4.43	2.07	55
OB	336	0.99	4.15	2.02	54

Average doses per screening examination

	No of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
One view	51	0.49	2.51	1.05
Two view	283	1.02	4.29	2.12

Average dose for 50-60mm thick breasts

View	No of films	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
OB	114	1.96	0.04	55

Summary of X-ray factors selected

Anode	Filter	kV	films
W	Al	26	2
W	Al	27	6
W	Al	28	21
W	Al	29	95
W	Al	30	88
W	Al	31	99
W	Al	32	114
W	Al	33	91
W	Al	34	66
W	Al	35	41
W	Al	36	10
W	Al	38	5
W	Al	40	3

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

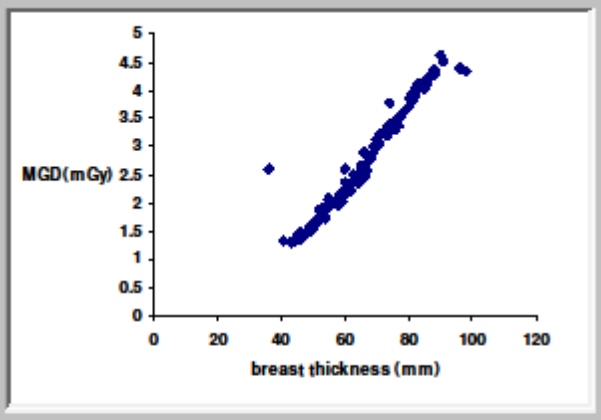
NHSBSP Breast Dose Survey

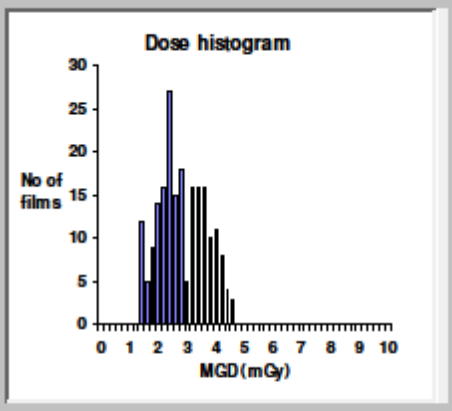
Survey No:	416
Centre:	Jarvis Breast Centre
Date of first exam:	21/02/2018
Date of last exam:	20/07/2018
X-ray make:	Hologic
Model:	3Dimensions
Local Id:	Large Flat tomo
Installation:	fixed
kV mode:	auto
standard kV:	
Routine/age trial:	routine screening

Tomo mode: Tomo

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:	Al		





Count of images

view	main films	Extra films
CC	98	
OB	105	

Average doses for main images

view	No of films	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	98	1.30	4.62	2.64	65
OB	105	1.37	4.53	3.02	70

Average doses per screening examination

	No of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
One view	11	1.00	3.81	1.60
Two view	92	1.34	7.31	2.98

Average dose for 50-60mm thick breasts

View	No of films	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
OB	18	2.02	0.11	56

Summary of X-ray factors selected

Anode	Filter	kV	films
W	Al	29	5
W	Al	30	10
W	Al	31	13
W	Al	32	21
W	Al	33	32
W	Al	34	36
W	Al	35	27
W	Al	36	26
W	Al	38	22
W	Al	40	7
W	Al	42	3
W	Al	43	3

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

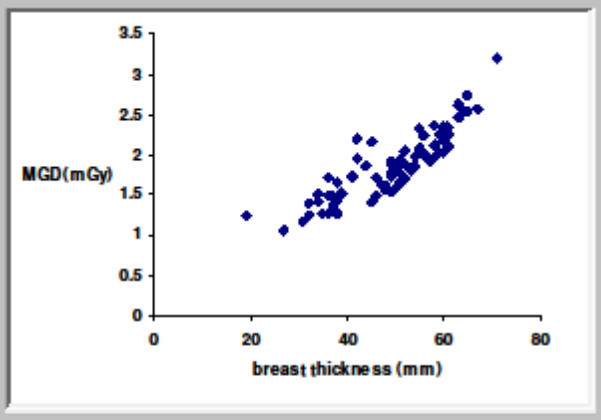
NHSBSP Breast Dose Survey

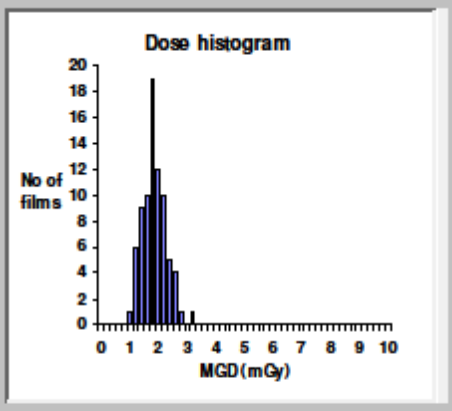
Survey No:	417
Centre:	Jarvis Breast Centre
Date of first exam:	21/02/2018
Date of last exam:	20/07/2018
X-ray make:	Hologic
Model:	3Dimensions
Local Id:	Small Curve tomo
Installation:	fixed
kV mode:	auto
standard kV:	
Routine/age trial:	routine screening

Tomo mode: Tomo

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:	Al		





Count of images

view	main films	Extra films
CC	37	
OB	40	

Summary of X-ray factors selected

Anode	Filter	kV	films
W	Al	26	1
W	Al	27	1
W	Al	28	5
W	Al	29	15
W	Al	30	12
W	Al	31	18
W	Al	32	13
W	Al	33	9
W	Al	34	3
W	Al	35	1

Average doses for main images

view	No of films	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	37	1.18	2.63	1.82	48
OB	40	1.07	3.20	1.89	50

Average doses per screening examination

	No of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
One view	3	0.86	0.88	0.87
Two view	37	1.16	3.52	1.89

Average dose for 50-60mm thick breasts

View	No of films	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
OB	16	1.95	0.10	55

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

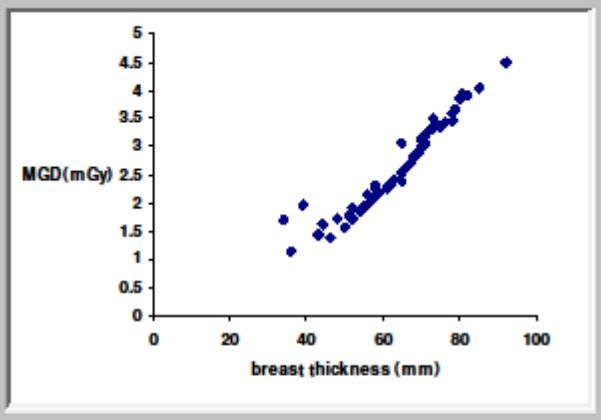
NHSBSP Breast Dose Survey

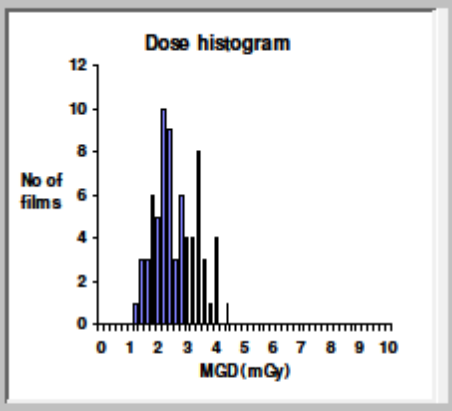
Survey No:	418
Centre:	Jarvis Breast Centre
Date of first exam:	21/02/2018
Date of last exam:	20/07/2018
X-ray make:	Hologic
Model:	3Dimensions
Local Id:	Large Curve tomo
Installation:	fixed
kV mode:	auto
standard kV:	
Routine/age trial:	routine screening

Tomo mode: Tomo

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:	Al		





Count of Images

view	main films	Extra films
CC	36	
OB	35	

Summary of X-ray factors selected

Anode	Filter	kV	films
W	Al	28	2
W	Al	29	5
W	Al	30	3
W	Al	31	6
W	Al	32	11
W	Al	33	7
W	Al	34	13
W	Al	35	12
W	Al	36	6
W	Al	38	4
W	Al	40	1
W	Al	42	1

Average doses for main images

view	No of films	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	36	1.15	4.05	2.29	59
OB	35	1.45	4.49	2.93	68

Average doses per screening examination

	No of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
One view	1	0.57	0.57	0.57
Two view	35	1.47	4.27	2.63

Average dose for 50-60mm thick breasts

View	No of films	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
OB	3	1.88	0.32	54

Appendix 3: Fault reports requiring engineer visits

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: Radiographer questionnaire

NHSBSP tomosynthesis equipment evaluation form 11: Radiographer's 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	Compared with 2D	Comments
1. How do you rate the supplier's operator manual (if used)?							Better/ Same/ Worse	
2. Would you prefer an in-house simplified version?		Yes / No						
3. How good was the clinical applications training for tomosynthesis provided by the supplier for: a. modality?							Better/ Same/ Worse	

	Same as Dimensions	Excellent	Good	Average	Satis - factory	Poor	Compared with 2D	Comments
b. acquisition workstation?							Better/ Same/ Worse	
4. How do you rate the system's ease of use for tomosynthesis?								
5. How easy was it to fit/remove the tomosynthesis faceplate?								
6. How convenient was it for making the exposures with? a. foot pedal								
b. single button								
7. How do you find carrying out the: a. special QA tests for tomosynthesis?		Difficult / Average / Easy						
b. calibration procedures for tomosynthesis?		Difficult / Average / Easy						

	Same as Dimensions	Excellent	Good	Average	Satis - factory	Poor	Compared with 2D	Comments
8. Were the compression times acceptable for each exposure? (If not explain in comments)		Yes / No					Better/ Same/ Worse	
9. Did the system performance limit patient throughput?		Yes / No					Better/ Same/ Worse	
10. How do you rate the comfort of women during tomosynthesis exposures, including acceptability of gantry motion?							Better/ Same/ Worse	Enter any informative comments made by women
11. Range of controls and indicators (on-screen icons) for tomosynthesis: a. Were all the expected controls present?		Yes / No					Better/ Same/ Worse	
b. Were they easy to find?		Yes / No					Better/ Same/ Worse	
c. Were the icons easy to use?		Yes / No					Better/ Same/ Worse	

	Same as Dimensions	Excellent	Good	Average	Satis - factory	Poor	Compared with 2D	Comments
12. How do you rate the time for an image to appear at the acquisition workstation?							Better/ Same/ Worse	
13. How do you rate image handling at the acquisition workstation: a. scrolling through the image levels?							Better/ Same/ Worse	
b. the processing facilities?							Better/ Same/ Worse	
c. use of query/retrieve?							Better/ Same/ Worse	
14. How easy was it to use, for tomosynthesis, the: a. keyboard?							Better/ Same/ Worse	
b. touchpad?							Better/ Same/ Worse	
c. mouse?								

	Same as Dimensions	Excellent	Good	Average	Satis - factory	Poor	Compared with 2D	Comments
d. scrolling through the tomosynthesis slices?								
15. How do you rate the following: a. image quality at the acquisition workstation for tomosynthesis images?								
b. visibility of fine calcs on this system in tomosynthesis mode?							Better/ Same/ Worse	
16. What was your level of confidence in the system?							Better/ Same/ Worse	
17. Were there any potential hazards with use in tomosynthesis mode to: a. you?		Yes / No					Better/ Same/ Worse	
b. the woman?		Yes / No					Better/ Same/ Worse	

18. Any additional comments on general or imaging performance in tomosynthesis mode

Additional questions for tomosynthesis biopsy

	Same as Dimensions	Excellent	Good	Average	Satis - factory	Poor	Compared with 2D	Comments
1. How easy was it to fit/remove the Affirm stereo attachment to the system?								

	Same as Dimensions	Excellent	Good	Average	Satis - factory	Poor	Compared with 2D	Comments
2. How do you rate the ease of use of the system for tomosynthesis biopsy with: a. needle?								
b. vacuum?								

3. Any additional comments on tomosynthesis biopsy

Appendix 5: Reader questionnaire

NHSBSP tomosynthesis equipment evaluation form 12a: Radiologists'/Readers' observations and findings

A copy of this form should be completed by each reader, once comfortable with use and operation of the equipment. For each question, please tick one of the "Excellent to Poor" columns and delete from the alternatives (Yes/No 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

	Same as Dimensions	Excellent	Good	Average	Satis-factory	Poor	Comments
1. How good were the operator manual instructions for tomosynthesis? (State N/A if not applicable/not used)							
2. How good was the application training for tomosynthesis provided by the supplier?							
3. Have you attended any external training course for tomosynthesis? If so, please enter Training Centre in the comments.		Yes / No					

	Same as Dimensions	Excellent	Good	Average	Satis-factory	Poor	Comments
4. How do you rate the use of the reporting workstation controls for tomosynthesis? a. mouse/trackerball							
b. keyboard							
c. keypad							
5. How do you rate the image handling tools (zoom, cine for example) for tomosynthesis?							
6. How do you rate the visibility and usability of on-screen icons for tomosynthesis?							
7. Did you sometimes change the slab thickness when reviewing the tomosynthesis images?		Yes / No / slabs not used					
8. How do you rate the reading/reporting flow pattern in tomosynthesis?							

	Same as Dimensions	Excellent	Good	Average	Satis-factory	Poor	Comments
9. How do you rate the time for an image to appear on the screen in tomosynthesis mode? a. new patient selection							
b. in-examination change							
c. during a biopsy procedure							
10. How easy is it to adjust the height and angle of the reporting monitors to suit the user?		Easy / Average / Difficult / NA					
11. How easy was it to navigate between the tomosynthesis slices?		Easy / Average / Difficult / NA					
12. How do you rate the following properties of the tomosynthesis images?							

	Same as Dimensions	Excellent	Good	Average	Satis-factory	Poor	Comments
a. contrast b. sharpness							
13. How do you rate the visibility of fine calcs (including shape)? a. in tomosynthesis images							
b. in Intelligent 2D (synthetic) images							
14. How do you rate the value/quality of Intelligent 2D (synthetic) images?							
15. How do Intelligent 2D images compare with a. 2D images?		Poorer / Same / Better					
b. C-view images as seen on Dimensions?		Poorer / Same / Better					

	Same as Dimensions	Excellent	Good	Average	Satis-factory	Poor	Comments
16. How do you rate the usefulness of the mapping tool on the SecurView to display the slice at which the selected feature appears?							
17. Are tomosynthesis images acquired with curved paddles acceptable?		Yes / No					
18. How easy was it to record findings for tomosynthesis on NBSS?		Easy / Average / Difficult / NA					
19. What is your overall impression of the quality of the tomosynthesis images?							
20. What is your overall level of satisfaction with using this tomosynthesis system for assessments?							

21. Any additional comments on general or imaging performance of the system for tomosynthesis

Appendix 6: Manufacturer's comments

7.17 General comments

In regards to comment: "it would be desirable to have a management system, so that images acquired on other systems would be visible on the 3Dimensions, which would be useful for biopsy, and sometimes essential".

The Hologic Mammography systems allow to retrieve images from PACS when the Query Retrieve function is activated. This is a setup which is to be activated at PACS level and it is supported by the system. It is possible to retrieve images from different vendors, as far as they are in MG or BTO format.

This is particularly of use in assessment clinics or during biopsy procedures, to revise prior acquisitions.

8.14 Comparison of Intelligent 2D images

As mentioned in the report conclusions, Hologic recommends that Synthesised 2D images are reviewed with the tomosynthesis dataset. Should you compare the 2D image with the Synthesised 2D image, the latter needs to be read in combination with its corresponding tomosynthesis dataset.

9.3 Image sizes

The table reported in chapter 9.3 refers to tomosynthesis images in non compressed format. Compression is available for the tomosynthesis datasetimages, both in Jepeg Lossless and Jpeg 2000 Lossless formats.