Public Health England

NHS

NHS Breast Screening Programme Equipment Report

Practical Evaluation of the Hologic® Affirm Prone Biopsy System

March 2019

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Contents

Executive summary

The Hologic Affirm Prone Biopsy System was evaluated to establish its practical suitability for use in the NHS Breast Screening Programme (NHSBSP).

Most operators rated the image quality as good or excellent and had a correspondingly high level of confidence in the system for both tomosynthesis and 2D stereo biopsy procedures.

Clinical radiation doses were reduced whilst using tomosynthesis biopsy, in comparison with 2D stereo biopsy procedures, by on average a factor of 2.9 for the minimal number of steps and by 2.6 including all steps. Routine (radiographer-led) quality control testing demonstrated a high level of system stability, with data consistently staying within threshold limits.

Downtime during the screening evaluation timeframe was very minimal (and not as a result of system failure). The system was highly reliable.

The system was successfully integrated with the department's IT and archiving infrastructure.

The overall conclusion of this evaluation is that the Hologic Affirm Prone Biopsy System is suitable for use in the NHSBSP.

1. Introduction

1.1 Evaluation centre and timeline

The practical evaluation centre was the West of Scotland Breast Screening Service, which is one of the screening centres in the Scottish Breast Screening Programme (SBSP). The service utilises 7 mobile units, including 1 double mobile, and covers the West of Scotland including Greater Glasgow and Clyde, Lanarkshire, Highland and West Forth Valley Health Boards.

The centre invites 280,000 women over the 3 year screening cycle. Approximately 65,000 women are screened per year with nearly 4,000 recalled for assessment. In 2016 1,338 biopsies were carried out and 500 of these were X-ray guided cases. A total of 72 biopsies were performed of which 53 were large volume and the remaining 19 were 14 gauge core needle biopsy.

The technical evaluation was carried out in August 2016 and was performed on an Affirm Prone Biopsy System in Belgium. The practical evaluation was carried out between November 2016 and March 2017.

The equipment was tested according to NHSBSP guidance[1-5] as far as possible, with modifications due to the unique nature of prone biopsy systems (for example, the small field size).

1.2 Equipment evaluated

1.2.1 X-ray set, table and workstation

Figure 1. Hologic Affirm Prone Biopsy System

The Affirm Prone Biopsy System has a broad focus tungsten target with a silver filter for conventional 2D imaging and an aluminium filter for tomosynthesis imaging. The system operates over a range of 20-39kVp for the silver filter and 20-49kVp for the aluminium filter, and over a range of 3-500mAs. Two exposure modes are available: Manual and automatic exposure control (AEC), where the mAs is controlled automatically.

The source to detector distance is 80cm, allowing more space for the biopsy system than the 70cm used for the upright biopsy system. The amorphous selenium detector is the same type as in the upright Dimensions system. The system has a single 14.3cm x 12.5cm field of view.

The system uses the same paddles for 2D and Tomosynthesis:

- 15cm (total width) lateral, with no window
- standard with 6cm x 7cm window
- standard with 5cm x 5cm window
- axillary with 5cm x 5cm window

Compression can be applied using the manual handwheel or with the foot pedal.

A 3MP acquisition display monitor was provided as part of the acquisition workstation (AWS), whilst a 2MP monitor is also available.

1.2.2 Prone Biopsy System

The Affirm Prone Biopsy System functions in a similar way to the Affirm Upright Biopsy System, especially in terms of graphics and work flow, although it does not have a touch screen console. Graphics are very similar to those on other Hologic equipment, and the screen is simple to navigate. The biopsy control module comprises a touch screen complete with a visual display, demonstrating a simulated needle approaching the target whilst positioning.

Figure 2. Smart window/biopsy control module

The Smart window on the biopsy control module (Figure 2) has several helpful features:

- the client name can be clearly identified
- the selected biopsy needle/biopsy marker device is clearly visible, ensuring a smooth seamless delivery of procedure in a safe, timely fashion
- the smart window displays a schematic diagram of the breast; the target appears, giving a visual, easily identifiable safety margin
- on advancing the needle, it is possible to visualise a representation of the needle approaching the lesion. This feature provides reassurance to the operator during the procedure, and was particularly good whilst training

Ergonomic working is encouraged with height adjustable monitors and a fully height-adjustable workstation, which can easily be altered according to individual preference. The table has adjustable foot-rests for client comfort, and was supplied with a comfort pack to assist with client cooperation. It is possible to position the client with their arm through the central aperture to assist with positioning of posterior lesions. The equipment has been used in this way throughout the evaluation period, yielding good results. The foot pedal controls are of the same design as other Hologic equipment, providing ease of use for staff.

An under-table and biopsy field work light is available.

1.3 Practical considerations

The unit was sited in a room which had another prone table system installed previously. The room was used solely for this equipment and was a good size. A specimen cabinet was installed in a neighbouring room. The centre chooses to use a movable lead glass screen as protection for staff during exposures.

There is a Hologic Affirm Upright Biopsy System within the screening unit that all biopsy staff have had experience using, over the past 2 years.

Prior to installing the Affirm Prone Biopsy System, the Eviva® Breast Biopsy System had been introduced with training for all appropriate staff. The Revolve Mammotome system was also currently in use along with 14 gauge core biopsy.

1.4 Objectives of the evaluation

The overall objective was to evaluate the clinical performance of the Hologic Affirm Prone Biopsy System, utilising both 2D and tomosynthesis imaging modalities.

Other objectives included:

- evaluating the usefulness of the table as part of the assessment process
- assessing the practical aspects of its use
- assessing performance and reliability of the equipment
- reporting radiation dose for all procedures

2. Acceptance testing, commissioning and performance testing

2.1 Acceptance testing and commissioning

The equipment was installed in November 2016 and commissioned according to NHSBSP guidelines[2,3] by SBSP physicists, in conjunction with the Radiation Protection Advisor (RPA). See Appendix 1 for the commissioning report.

Following the technical evaluation, the equipment was deemed acceptable. This followed extensive discussions with centre management and physicists from SBSP, NCCPM and the local medical physics service. These focussed on the lack of an automatic switch to disable movement of the table. However, the unit is fitted with a manual switch that should be enabled as soon as compression is applied. This switch then prohibits table movement and allows an exposure to be made. Without this switch activated, no exposure could be made and, therefore, the procedure could not continue. This manual switch was similar to, and improved, compared to the centre's previous prone biopsy system system, which had no exposure lock.

The prone table cannot be compared directly with a conventional mammography unit in terms of compression and automatic disabling of further movement. Typically compression is lighter in biopsy procedures in general, as the breast is in a more relaxed position in the prone position. Therefore setting a threshold level for automatic movement disabling is not feasible.

The RPA was content for the unit to be installed, providing local standard operating procedures (SOPs) were followed.

3. Quality control

Quality control (QC) tests were carried out, based on previous prone table tests and broadly on NHSBSP guidance. These are detailed below.

3.1 Daily QC tests

The following daily tests were carried out and the results recorded in a spreadsheet. It is intended to carry out the block test daily in future. (This was carried out weekly during the evaluation period in line with the QC of the previous prone table.)

3.1.1 Daily monitor check

No issues with the monitor were reported and the test results were acceptable throughout the evaluation period.

3.1.2 Needle tests (tomosynthesis and 2D)

This was acceptable throughout the evaluation period, except for 1 occasion when a engineer visit was required (see Section 5.). The results were subsequently within acceptable limits.

Figure 3. Needle position errors in daily QC tests (2D)

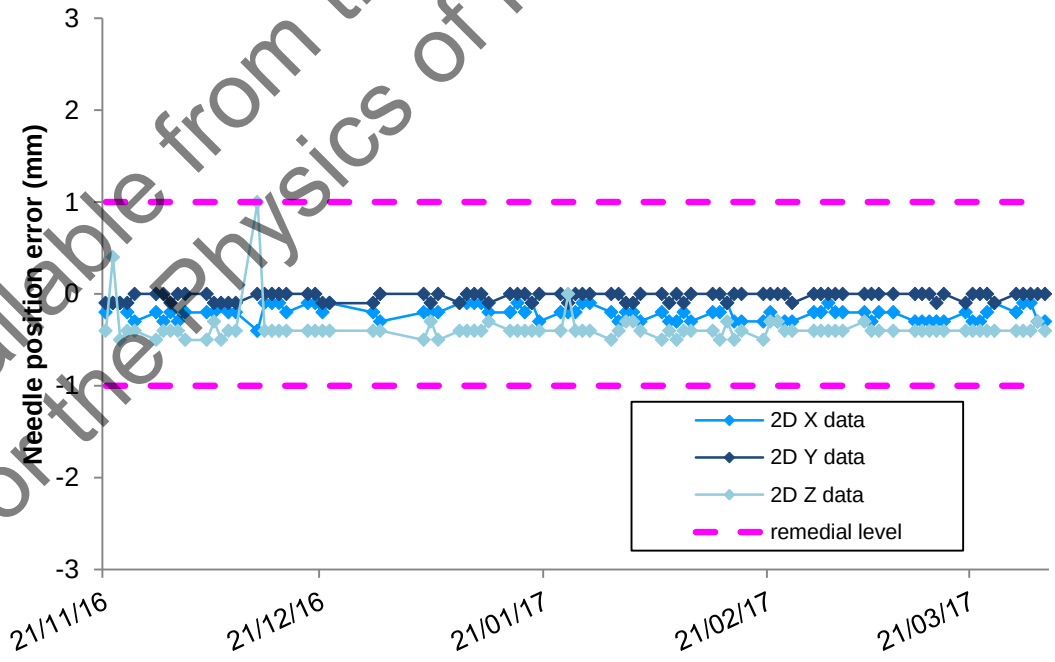
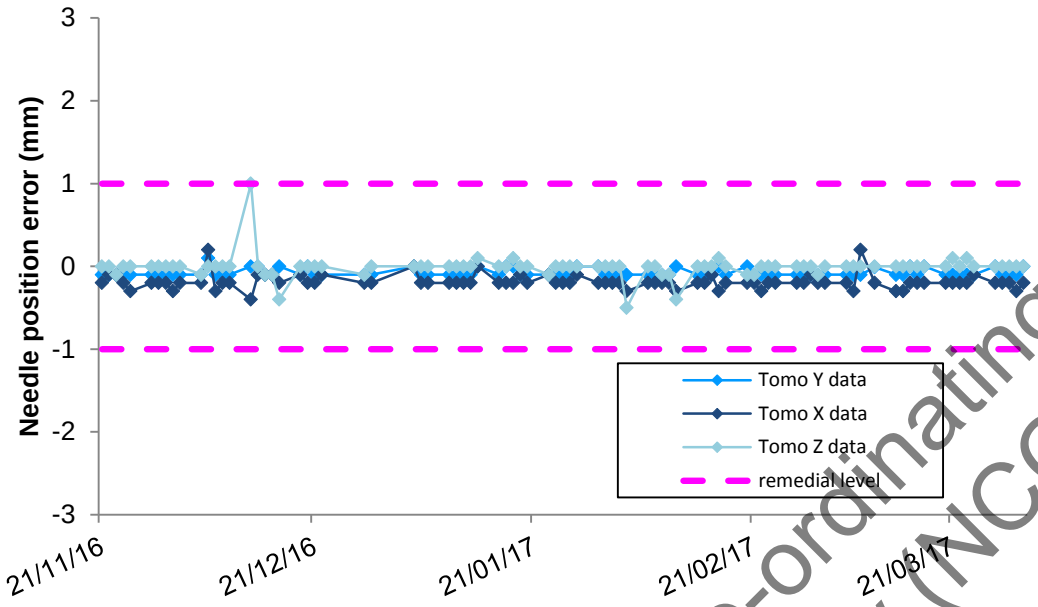


Figure 4. Needle position errors in daily QC tests (tomosynthesis)



3.2 Weekly QC tests

The following weekly tests were carried out and the results recorded in a spreadsheet:

3.2.1 Gain calibration and artefacts

No issues with the gain calibration were reported and the test results were acceptable throughout the evaluation period. No artefacts were reported.

3.2.2 Weekly needle tests

No issues with the weekly needle and tests were reported, and the test results were acceptable throughout the evaluation period. The following needles were tested:

- Eviva 9G 13cm, 20mm
- Bard 14G 16cm, 22mm
- Bard 14G 16cm, 15mm
- Mammotome Revolve
- Ultraclip
- Hydromark/Cormark
- Spinal Needle

3.2.3 Weekly block tests

The results of the 4.5cm perspex block test were consistently within limits, with the exception of mAs fluctuations on 3 occasions, due to the kV changing from the baseline value. Future tests will include a 4.5cm block contrast to noise ratio (CNR) measurement and 2cm and 7cm block measurements of signal to noise ratio (SNR) and CNR. These have been delayed due to the requirement to design new test objects.

Figure 5. mAs recorded weekly for 4.5cm of perspex (2D)

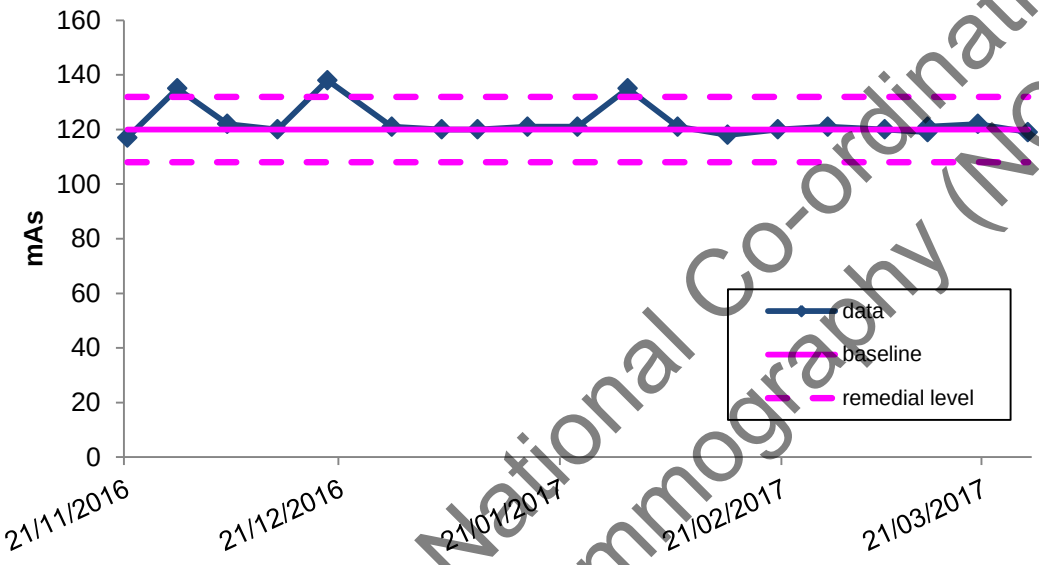


Figure 6. SNR recorded weekly for 4.5cm of perspex (2D)

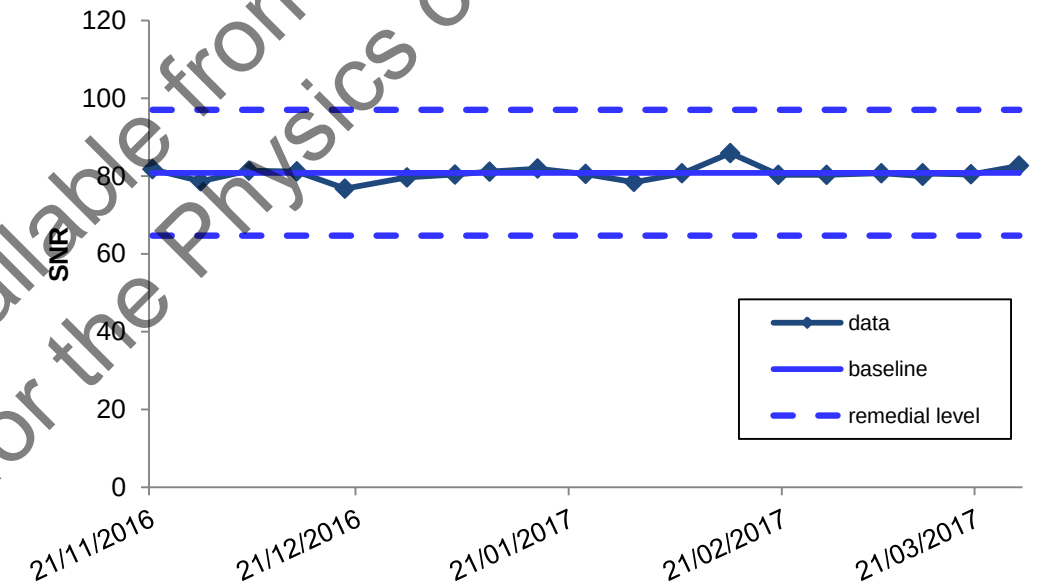
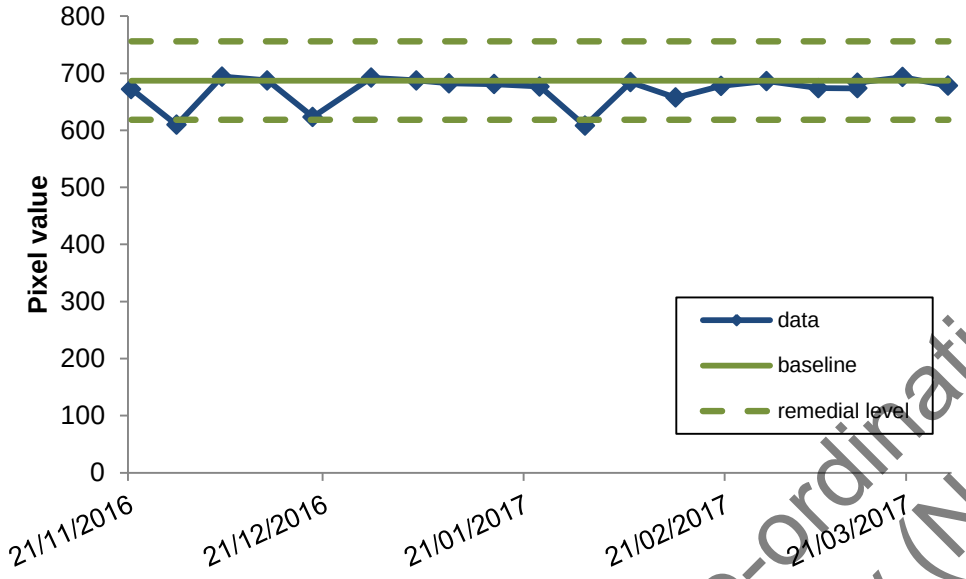


Figure 7. Pixel value recorded weekly for 4.5cm of perspex (2D)



4. Data on biopsies conducted

4.1 Clinical dose audit

Tables 1 and 2 show the average MGD values for the 2D stereotactic and tomosynthesis procedures, with the minimum steps shown in Table 1 and the full set of steps in Table 2. The data set includes a range of compressed breast thicknesses (CBT), with mean CBT 5.4cm for 2D and 5.7cm for tomosynthesis. The individual doses and different views for each client are shown in Appendix 2.

As only 1 breast is imaged during a biopsy procedure, the average MGD to the whole of the glandular tissue (both breasts) could be estimated as half of the MGDs quoted above.

Another factor to consider is the proportion of the breast under the window section of the paddle, which may be a smaller proportion of the breast area compared to upright systems (depending on the field size selected). No paddle has been included in the calculations for this report, leading to an over-estimate of dose for the 65-80% area of the breast under the paddle for 2D exposures. The paddle attenuates 20-30% of the X-ray exposure.

It should be noted that no area correction factor was applied as the full field size is greater than 100cm^2.

Table 1. Average values of MGD for essential/minimum components of biopsy

Step	Stereotactic procedure dose (mGy)	Tomosynthesis procedure dose (mGy)
Scout	Stereo scout (single 2D): 2.6	Tomo scout: 2.8
Targeting pair	Stereo pair: 5.4 (2.7mGy per exposure)	N/A
Total	8.0	2.8

Table 2. Average values of MGD for all components of biopsy, with optional steps

Step	Stereotactic procedure MGD (mGy)	Tomosynthesis procedure MGD (mGy)
Scout	Stereo scout (single 2D): 2.6	Tomo scout: 2.8
Targeting pair	Stereo pair: 5.4 (2.7mGy per exposure)	N/A
Pre-fire pair (check)	5.5	4.8
Post-fire pair (check)	5.0	Not routinely taken
Post biopsy pair*	5.5	N/A
Post biopsy (optional for marker insertion)	Single 2D: 2.6	Tomo: 2.7
Total	26.7	10.3

4.2 Comparison of displayed dose with calculated MGD

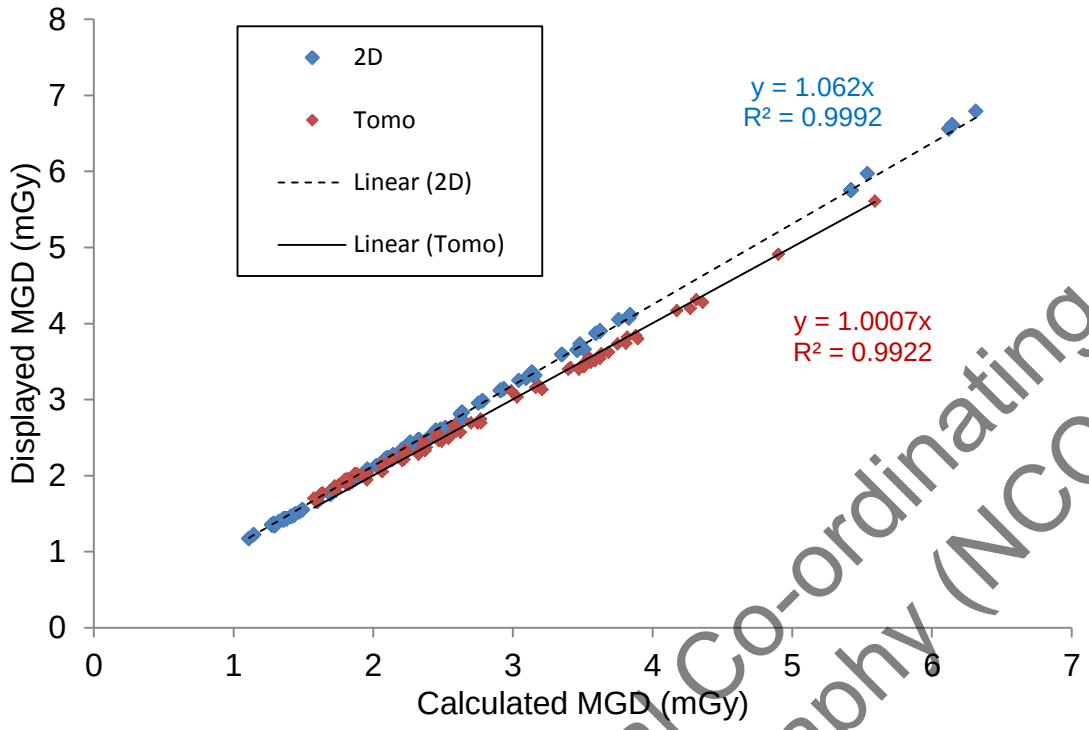
The calculated doses were compared with the displayed doses for the 2D and tomosynthesis images. The results are shown in Table 3 and Figure 8.

Table 3. Comparison of calculated and displayed MGD

Average value per exposure for mode:	**2D**	**tomosynthesis**
Calculated MGD (mGy)	2.48	2.75
Displayed MGD (mGy)	2.63	2.76
Displayed MGD / calculated MGD	1.06	1.01

The values show good agreement, particularly for the tomosynthesis doses.

Figure 8. Comparison of displayed and calculated MGDs

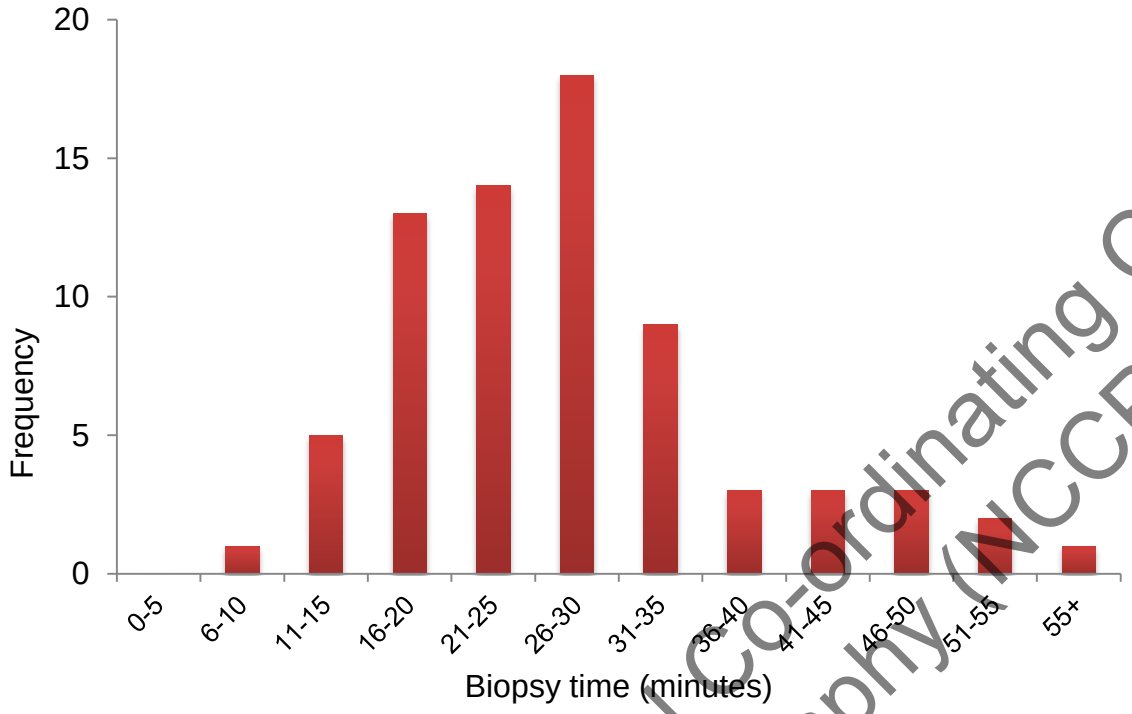


4.3 Biopsy times

The time taken was recorded for all biopsies carried out during the evaluation period. The time is from the commencement of positioning to the removal of the needle and release of compression. The distribution of biopsy times is shown in Figure 8. Some of the unusually long times are related to the level of difficulty for the biopsy, in particular, location of the lesion. Several cases also had sampling from 2 sites. The quickest biopsy was performed in 10 minutes.

Since the end of the evaluation, biopsy times have been decreasing as staff become more skilled in using the Hologic Affirm Prone biopsy system. Current times are approximately 10 minutes for a straightforward biopsy compared to 20 plus minutes previously.

Figure 9. Distribution of biopsy times



4.4 Clinical workflow

Adhering to NHSBSP protocol, women attended the department for assessment, following recall from participation in the SBSP.

Daily QC testing of the equipment is performed in the morning prior to commencement of the clinic. Clients attending for assessment at this centre are given appointments at morning clinics commencing at 08:50. At the start of the clinic 3 or 4 appointments are allocated to clients with calcification demonstrated in their screening mammograms. It is highly likely that these clients will present for stereotactic biopsy.

Women have additional imaging, clinical examination and an ultrasound scan of the relevant area identified on the screening mammograms, as requested by radiologists. Tomosynthesis has not yet been approved for use in Scotland in assessment clinics.

Stereotactic biopsies are performed on women with lesions not adequately demonstrated on ultrasound, or where the clinician believes it would be more accurate than performing biopsy under ultrasound guidance.

The majority of stereotactic biopsies in the unit are performed by advanced practitioners. One of the main advantages for the department was that staff were already efficient and skilled at using the Affirm Upright Biopsy System and could perform biopsies as soon as the case was confirmed by radiologists. There was a learning curve for staff to adapt to using tomosynthesis images for biopsy. Initially a

core group of radiographic staff used the Affirm Prone Biopsy System. As staff became more confident in using the equipment, the training was extended to other radiographic staff.

At the outset of the evaluation period, clients who required a stereotactic biopsy were categorised according to extent of calcification/lesion type to determine suitability for Affirm Prone Biopsy System and to allocate to 2D or tomosynthesis imaging.

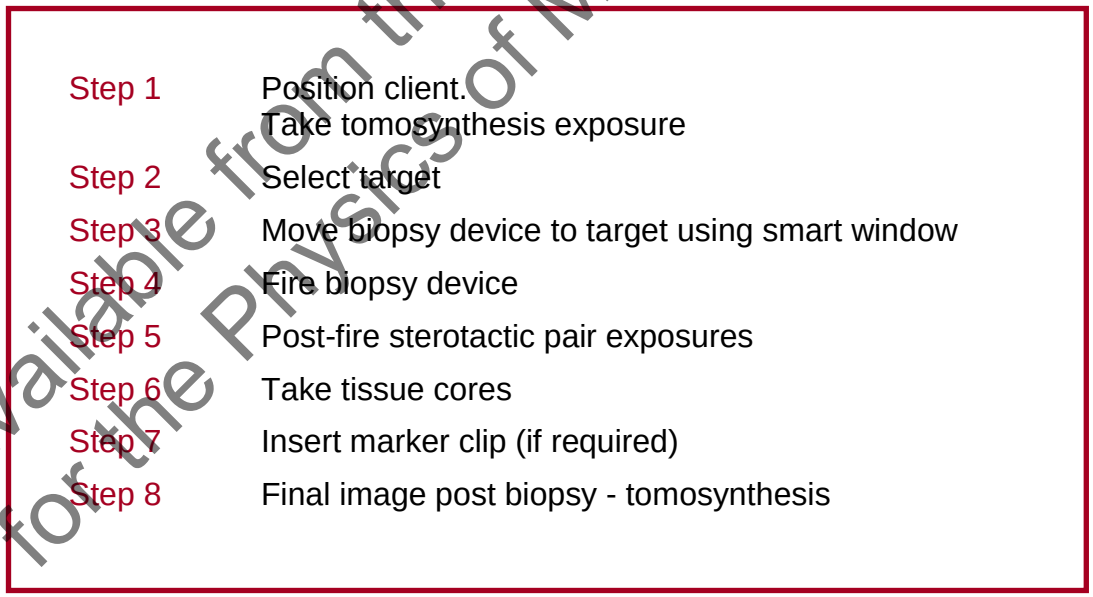
Following discussion with operators, advanced practitioners and radiologists it was agreed that tomosynthesis biopsy would be used in cases of distortions or regions of calcifications greater than $1cm^2$. Cases with calcification in a region less than $1cm^2$ were imaged using 2D, as they were judged less suitable for tomosynthesis biopsy.

Image manipulation post-acquisition was a straightforward procedure. Functions mirrored those found on the Affirm upright system. However, image manipulation functions were simple and logical to use if an operator should have no prior knowledge of the Affirm.

4.4.1 Tomosynthesis biopsy procedure

The complete procedure for tomosynthesis is outlined in Figure 10. The final step (8) is optional. All operators received training for all aspects of the procedure.

Figure 10. Tomosynthesis biopsy procedure



4.4.2 2D stereotactic biopsy procedure

The complete procedure for 2D stereotactic biopsy is outlined in Figure 11. The final step indicated 8 is optional, as for tomosynthesis.

Figure 11. 2D stereotactic biopsy procedure

Step 1	Position client Take 2D exposure followed by stereo pair exposures
Step 2	Select target
Step 3	Move biopsy device to target using smart window
Step 4	Fire biopsy device
Step 5	Post-fire sterotactic pair exposures
Step 6	Take tissue cores
Step 7	Insert marker clip (if required)
Step 8	Final image post biopsy - stereo pair exposures

4.5 Biopsy results

72 biopsies were carried out. These comprised 38 2D stereo biopsies and 34 tomosynthesis biopsies:

- 25 cases with <1cm calcification
- 26 cases with >1cm calcification
- 13 opacities
- 8 distortions

53 cases were large volume, using 9 gauge Eviva or 8 gauge Mammotome.

4.6 Lateral approach

Two procedures using the lateral approach were performed at the end of the evaluation. The switch to the lateral approach required neither change of position nor change of paddle and was easily implemented.

5 Equipment reliability

The equipment was very reliable throughout the evaluation period. There were only 2 faults:

- a switch issue when a woman dismounted the table towards one end, rather than in the centre. This was possibly a sensitive switch. An SOP was written, ensuring that the patient dismounted at the centre of the table
- the daily needle test was out of calibration and intervention was required. The local engineer attended promptly and performed a recalibration. The test results were then within acceptable limits

The downtime was only a few hours for each fault.

6 Electrical and mechanical robustness

The safety issue for disabling movement is discussed in Section 2.1. There were no further issues.

7 Radiographers' comments and observations

The views of 12 radiographers were collected, regarding the use of 2D and tomosynthesis biopsy with the prone table. They are presented in Appendix 3.

7.1 Operator manual vs in-house version

Questionnaire respondents agreed that the supplier's operator manual was excellent (2) or good (3), but some preferred to use an in-house version.This is possibly as a result of familiarity of format, as the in-house version is of similar style to other in-house SOPs.

7.2 Clinical applications training

The majority of respondents rated the application training as excellent (3) or good (6). Training was provided over several days and was delivered in an efficient timely fashion. The training was provided by applications specialists from Hologic.

Staff questions were well received and responded to by the Hologic applications team. A core team of staff were primarily trained in the use of the equipment. The core group used the equipment and then cascaded information to other members of staff. The majority of radiography staff were already skilled and efficient in using the Affirm upright biopsy system, which enabled them to easily transfer knowledge and skills, whilst receiving additional training on the Affirm Prone Biopsy System.

In addition, some staff had already used prone biopsy systems for several years, so were also familiar with the positioning of clients for biopsies. Familiarity with positioning for prone biopsy ensured a smooth transition to using the Affirm Prone Biopsy System.

7.3 Ease of use of equipment

All responses from staff rated the ease of use of the equipment as excellent (6) or good (6). Similarly, fitting and removal of the biopsy equipment and compression paddles also had a positive response from staff, rated as excellent (1) or good (11). In most cases, staff indicated that the equipment was excellent (7) or good (3) to clean. The local protocol is to use cling film over the compression paddle attachment area, to prevent bodily fluid contaminating the paddle.

The table system lock prevents inadvertent movement of the compression and detector during the procedure thus eliminating any potential imaging hazard. Release of the 'table lock button' enables imaging to take place.

The table has a fully automated height-adjustment function. This helps prevent repetitive strain and enables the table to be raised easily to full working height. This function only works in the upward direction and, due to safety requirements, is not possible in the downwards direction.

The table and detector movement footswitch is similar to other Hologic equipment, which streamlines working.

Users should be aware that the diagram on the console of the breast target area and detector displays rotation differently from the Affirm upright system, which could cause potential confusion to users who work on both upright and prone systems.

7.4 Image quality at the AWS

The image quality was rated as excellent (4) or good (6) for the 2D images and excellent (3) or good (7) for the tomosynthesis images. For the scout views, the majority of staff indicated that the image quality was excellent (6) or good (5) for tomosynthesis and excellent (5) or good (7) for the 2D stereotactic images. All exposure times were judged acceptable.

7.5 Time for the image to appear at the AWS

Staff found the time for an image to appear on workstation screen to be excellent (4), good (2) or average(6).

7.6 Quality assurance tests

SBSP physics worked in conjunction with the QA radiographer to agree tests and the frequency of testing for the Affirm Prone Biopsy System. Respondents stated that quality assurance tests were easy or average to complete. One radiographer commented 'tests took a little getting used to, after that testing was an easy to follow procedure'. Attachments for needle testing were robust and simple to attach. Consideration is being given to performing a daily perspex block test, in line with NHSBSP protocols.

8 Advanced practitioners' questionnaire

The views of the 3 advanced practitioners were collected, regarding the use of 2D and tomosynthesis biopsy on the prone table. Details are presented in Appendix 4.

8.1 Overall assessment

The department has several advanced practitioners who perform the majority of biopsies at assessment clinics. Theyperformed most of the biopsies with the Hologic Affirm Prone Biopsy System during the evaluation phase. Additional features, such as operator-dependent height adjustment, were found to be an advantage.

8.2 Operator manual from supplier

One of the operators found the manual excellent and one indicated a preference for an in-house simplified version. This may be because to staff are used to SOPs written in a particular style.

8.3 Applications training for tomosynthesis and sterteotactic iopsy

Operators found applications training good (2) or average (1). One commented that it took time to adapt skills and become confident at performing tomosynthesis biopsy. Inclusion of more training cases, including use of the lateral arm, was requested by 1 user. Training was delivered efficiently and in a manner to ensure understanding and confidence with the equipment.

8.4 Image quality for tomosynthesis biopsy

All staff (3) rated image quality as good or excellent, especially for parenchymal distortions. The time for images to appear on the screen was acceptable. Navigating through images was a simple and logical procedure. Staff became more confident in using tomosynthesis biopsy as they became more skilled and confident in using it.

Image quality was found to be excellent (2) or good (1) in 2D procedures and excellent (3) in tomosynthesis procedures.

8.5 Additional comments by advanced practitioners and radiologists

One operator commented on the usefulness of the multi-pass function which automatically generates up to 5 offset target points all equidistant (up to 5mm away) from the original target. Multi-Pass can work with either stereo or tomographic biopsy

images. This eliminates the need to use the Jog mode, which is a function that allows the user to manually overwrite the target coordinates of the Biopsy Control Module. The magnification tool was highlighted as very useful for better visual acuity, particularly as the monitor is not on a mobile arm.

9 Comfort of clients during the procedure

The comfort of clients was reported as ranging from satisfactory to excellent. Clients commented that the procedure was comfortable and well tolerated. A small number were positioned with an arm through the aperture and resting on the arm support, and this positioning was well tolerated. Some clients stated they were glad to be lying down for the procedure.

Most clients found the procedure length met their expectations. Four described the procedure as long, however all of these clients had either 2 biopsy sites or had to have a change in approach, which lengthened their time lying in the prone position.

The maximum client weight for use of the table is 400lbs (182kg) and it is not recommended for clients with recent hip replacements or neck problems. Clients should be encouraged to access and dismount from the centre of the table (see Section 5).

10 Information systems

The prone table was connected to the SBSS call/recall system and linked to a Carestream PACS and a SecurView workstation.This setup was necessary as SBSP's Carestream workstations do not have software for tomosynthesis.
Tomosynthesis images can therefore only be viewed on Hologic workstations (or other tomosynthesis-enabled workstations) at the present time.

11 Confidentiality

All confidentiality and data protection guidelines were followed. Access to all systems is restricted by password protection.

12 Conclusions and recommendations

The Hologic Affirm Prone Biopsy System was found to be easy to use, robust and reliable. Prior use of a prone table and familiarity with using the Affirm upright units enabled staff to become familiar and confident with this system quite rapidly.

Tomosynthesis biopsy was found to be excellent for both imaging and sampling of distortions, and for imaging of masses and calcifications which were not well demonstrated on ultrasound. 2D biopsy was found to be the procedure of choice when calcifications were faint or for small areas, less than 1 cm^2.

Switching from a frontal to a lateral approach was quick and easy to implement.

The equipment was reliable over the evaluation period and provided an effective method for carrying out X-ray guided biopsies. It provided a useful adjunct to the unit's equipment, enabling a more efficient service to be delivered for the women recalled for further assessment.

Training provided by the Hologic team was excellent, providing as much advice as was required by users.

Measurement of dose for 2D and tomosynthesis biopsy procedures has demonstrated reduced dose for tomosynthesis compared with 2D, confirming findings in a previous evaluation[6].

The Hologic Affirm Prone Biopsy System is found to be suitable for use in assessment in SBSP and NHSBSP.

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Appendix 1: Physics survey reports

A1.1 Summary report

Health Facilities Scotland
A Division of National Services Scotland

Gyle Square
1 South Gyle Crescent
EDINBURGH
EH12 9EB
Telephone 0131 275 6000
www.hfs.scot.nhs.uk

NHS National Services Scotland

Miss A Mumby
Superintendent Radiographer
Scottish Breast Screening Programme
Stock Exchange Court
77 Nelson Mandela Place
Glasgow G2 1QT

Scottish Breast Screening Programme
PHYSICS SURVEY REPORT FOR HOLOGIC PRONE BIOPSY SYSTEM

Equipment:	Hologic Dimensions Digital Unit	**Survey Date:**	7/8th November 2016
Location:	Room 7, Prone Room	**Survey By:**	A McCurrach, J Robertson
Base:	Breast Screening Centre Nelson Mandela Place Glasgow.		

Kilovoltage:	Within acceptable limits
Output:	Linearity and repeatability of output were acceptable.
HVT/Filtration:	Acceptable.
Digital:	Figures A1.1, A1.2 and A1.3 show the CNR, CDMAM and mean glandular dose results. These have been compared to the acceptable (remedial) and achievable levels for a 2D mammography system and no such levels are available for tomo and / or tomo biopsy systems. The system appears to be well set up.
Monitor	Acceptable
Image Transfer to PACS	Acceptable
Safety	As stated in the critical examination report there is a button that has to be selected to activate safety interlocks to prevent movement when compression is applied. Staff require training on the use of this button to ensure patient safety is maintained.

Anne McCurrach
Mammography Physicist

1st December 2016

A1.2 Additional physics data

Commissioning and acceptance testing of the Hologic Affirm Prone Biopsy System was carried using the same methodology as that used for the technical evaluation.

The output and HVL measurements in 2D and tomosynthesis modes are shown in Tables A1.1 and A1.2 respectively and were measured with a lateral paddle.

Table A1.1. Output and HVL (2D)

kV	Target/filter	Output (μGy/mAs at 1m)	HVL (mm Al)
25	W/Ag	10.3	0.545
28	W/Ag	14.7	0.612
31	W/Ag	19.0	0.661
34	W/Ag	23.3	0.697
37	W/Ag	27.6	0.729

Table A1.2. Output and HVL (tomosynthesis)

kV	Target/filter	Output (μGy/mAs at 1m)	HVL (mm Al)
25	W/Al	18.1	0.459
28	W/Al	26.3	0.533
31	W/Al	34.5	0.603
34	W/Al	42.6	0.667
37	W/Al	50.8	0.726

Mean Glandular Doses (MGDs) for AEC exposures in 2D and tomosynthesis modes are shown in Figure A1.1 and in Tables A1.3 and A1.4. The MGDs include the preliminary exposure, which is not included in the image.

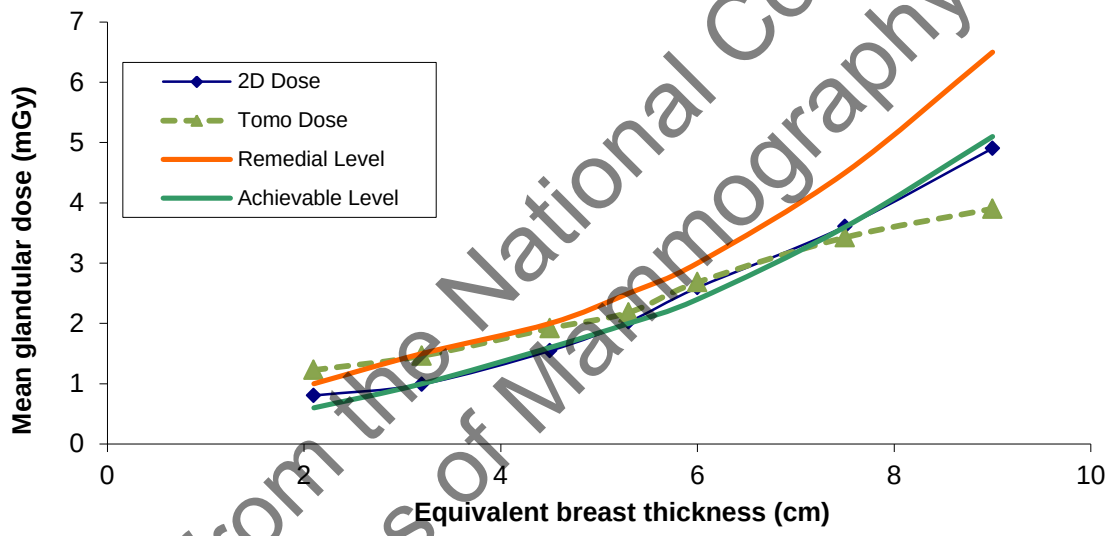
Table A1.3. MGD (Flat field 2D)

PMMA thickness (mm)	Equivalent breast thickness (mm)	kV	Target/ filter	mAs	MGD (mGy)	NHSBSP 2D dose limit (mGy)
20	21	25	W/Ag	69	0.81	1.0
30	32	26	W/Ag	91	0.99	1.5
40	45	28	W/Ag	126	1.55	2.0
45	53	28	W/Ag	178	2.03	2.5
50	60	30	W/Ag	195	2.59	3.0
60	75	33	W/Ag	234	3.61	4.5
70	90	36	W/Ag	287	4.90	6.5

Table A1.4. MGD (tomosynthesis)

PMMA thickness (mm)	Equivalent breast thickness (mm)	kV	Target/ filter	mAs	MGD (mGy)	NHSBSP 2D dose limit (mGy)
20	21	26	W/Al	56	1.23	1.0
30	32	26	W/Al	84	1.46	1.5
40	45	28	W/Al	96	1.92	2.0
45	53	29	W/Al	102	2.18	2.5
50	60	31	W/Al	102	2.68	3.0
60	75	34	W/Al	108	3.43	4.5
70	90	38	W/Al	100	3.90	6.5

Figure A1.1 Dose variation with equivalent breast thickness (flat field 2D)



CNRs for 2D images obtained under AEC are shown in Figure A1.2 and Table A1.5. Also shown are the target CNRs for the acceptable and achievable levels of image quality and the European limiting values, calculated according to the European protocol.

Figure A1.2 Flat field CNR variation with equivalent breast thickness

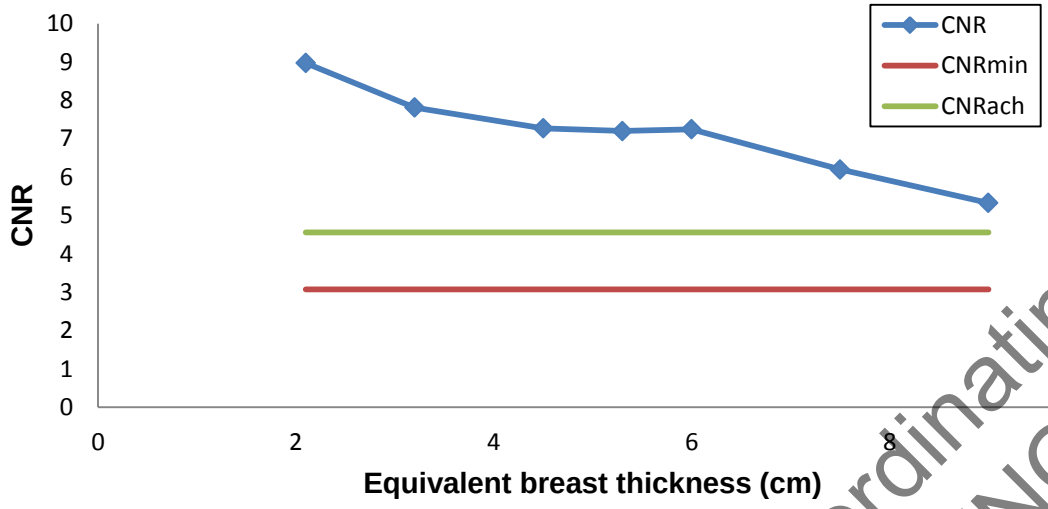


Table A1.5. CNR (2D)

PMMA thickness (mm)	Equivalent breast thickness (mm)	kV	Target/ filter	mAs	CNR	Target for minimum standard	Target for achievable standard	European limiting value
20	21	25	W/Ag	72	10.9	2.9	4.3	3.3
30	32	26	W/Ag	100	9.5	2.9	4.3	3.2
40	45	28	W/Ag	142	9.0	2.9	4.3	3.0
45	53	28	W/Ag	197	8.9	2.9	4.3	3.0
50	60	30	W/Ag	218	8.9	2.9	4.3	2.9
60	75	33	W/Ag	265	7.8	2.9	4.3	2.7
70	90	36	W/Ag	343	6.8	2.9	4.3	2.6

Focal plane CNRs for reconstructed tomosynthesis images obtained under AEC control are shown in Table A1.6.

Table A1.6. CNR (tomosynthesis)

PMMA thickness (mm)	Equivalent breast thickness (mm)	kV	Target/ filter	mAs	CNR (Flat Field)
20	21	26	W/Al	56	15.1
30	32	26	W/Al	84	12.5
40	45	28	W/Al	96	10.6
45	53	29	W/Al	102	9.8
50	60	31	W/Al	102	10.2
60	75	34	W/Al	108	7.9
70	90	38	W/Al	100	6.7

Table A1.7 and A1.8 show the threshold gold thicknesses from 8 partial CDMAM images and are results are shown in Figure 3. These images were scored by human readers, while the results for 2D Dimensions were from automatic readings. Computer scores are usually higher than those recorded by a human observer.Figure A1.3 also shows the NHSBSP limits for 2D mammography.

Table A1.7. 2D threshold gold thickness results

Detail diameter (mm)	Threshold gold thickness (µm)		
	Dimensions Auto reading	Acceptable limit	Achievable limit
0.1	0.67	1.68	1.10
0.13	0.43		
0.16	0.32		
0.20	0.23		
0.25	0.18	0.35	0.24

Table A1.8. Tomosynthesis threshold gold thickness results

Detail diameter (mm)	Threshold gold thickness (µm)		
	'Flatfield tomo'	'Tomo LCC scout'	Human readings from slice 23
0.1	0.80	0.87	
0.13	0.58	0.66	
0.16	0.36	0.46	
0.20	0.28	0.30	
0.25	0.35	0.23	

Figure A1.3 CDMAM results

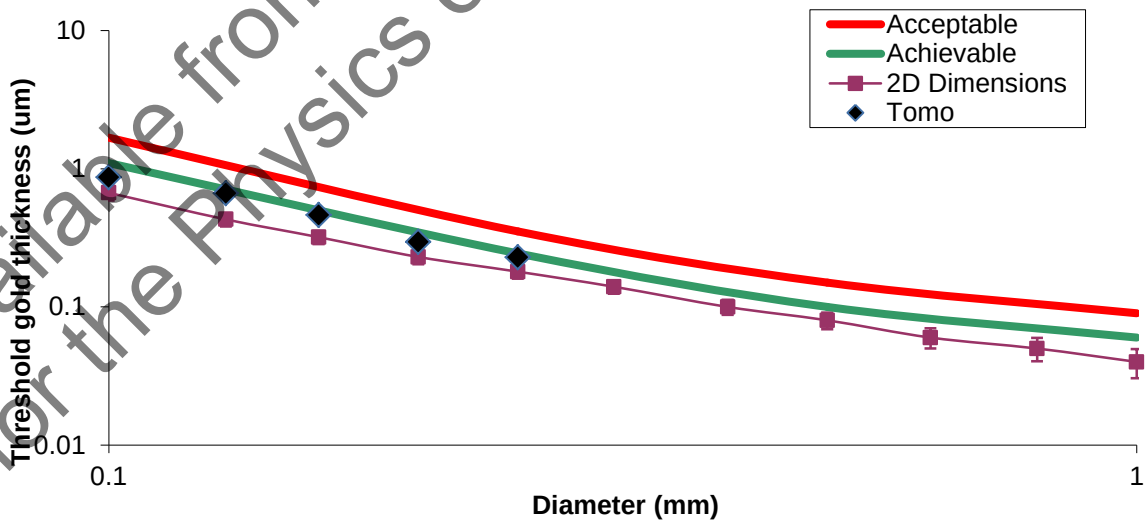


Table A1.9 and Figure A1.4 show the detector response in 2D and tomosynthesis modes, and SNR values.

Table A1.9. Detector response

	2D	Tomosynthesis
Air kerma (μGy) at PV = 400	99.8	675
SNR ref	58.0	12.2

Figure A1. 4 Detector response

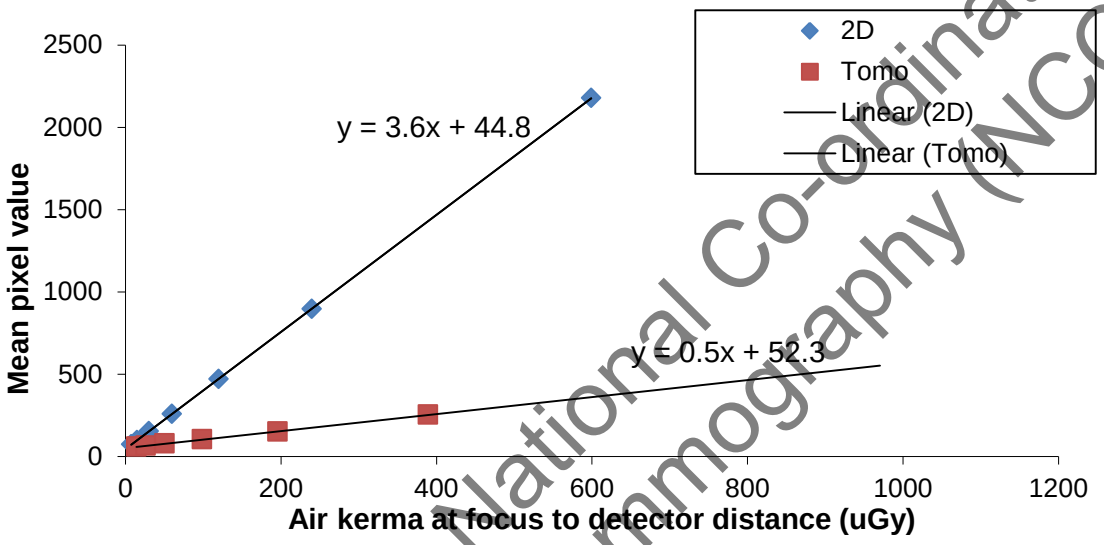


Table A1.10 shows the measured image size for 2D and tomosynthesis modes and the image retention factor.

Table A1.10 Image size and image retention

	2D	Tomosynthesis
Measured size (mm)	120 x 99	125 x 102
Image retention factor	0.03	

Measurements of full width at half maximum (FWHM), from the geometric distortion test object, are shown in Table A1.11.

Table A1.11. Flatfield tomosynthesis: Mean FWHM measurements of 1 mm diameter aluminium balls

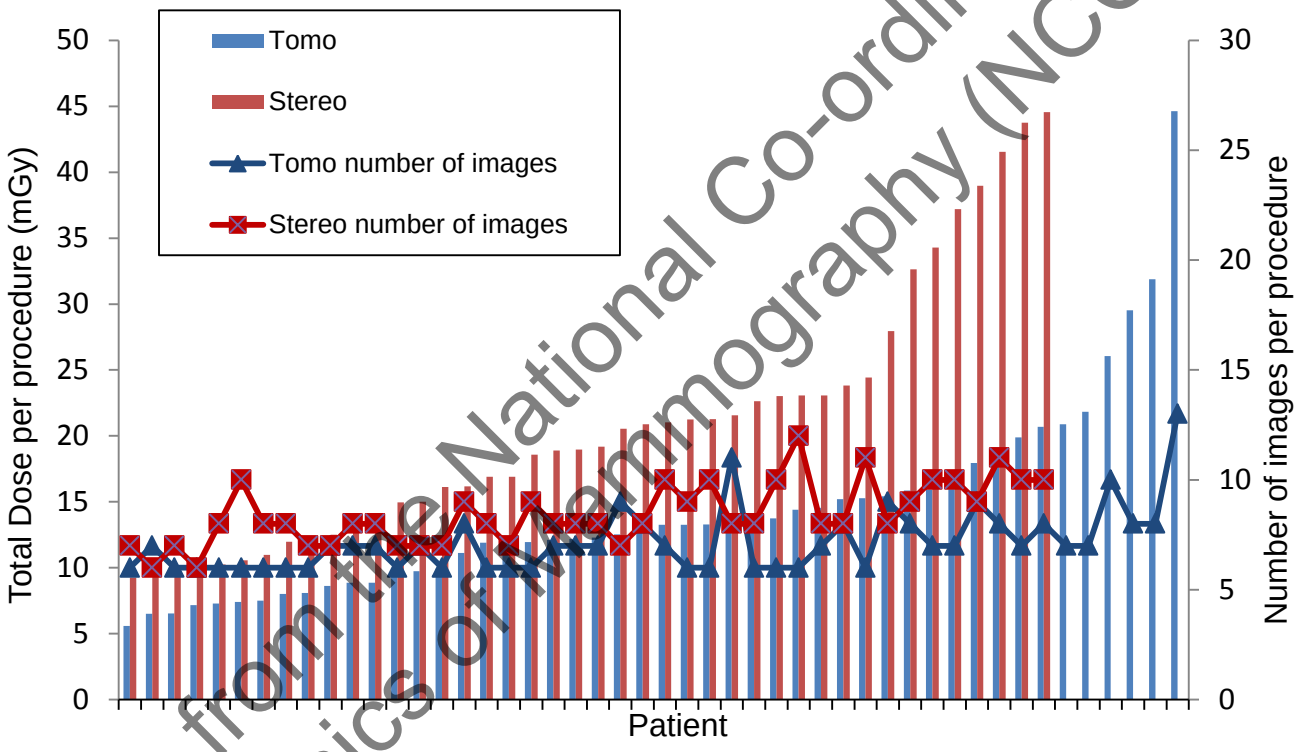
	FWHM within plane of best focus (range)	Composite FWHM using all planes (range)
x (perpendicular to chest wall edge)	0.86 mm (0.84 to 0.88)	0.87 mm (0.86 to 0.88)
y (parallel to chest wall edge)	0.87 mm (0.85 to 0.88)	0.90 mm (0.88 to 0.93)

Appendix 2: Dose surveys

A2.1 Comparing all 2D and tomosynthesis procedures

Data in the graph of total dose per procedure includes all views taken for each patient. In some cases more than 1 area of the breast is of interest and for a few cases both breasts are imaged.

Figure A2.1.Total dose and number of images for tomosynthesis and 2D stereo procedures



A2.2 Comparison of all contributing images

Figure A2.2. Tomosynthesis procedure - contribution of projections

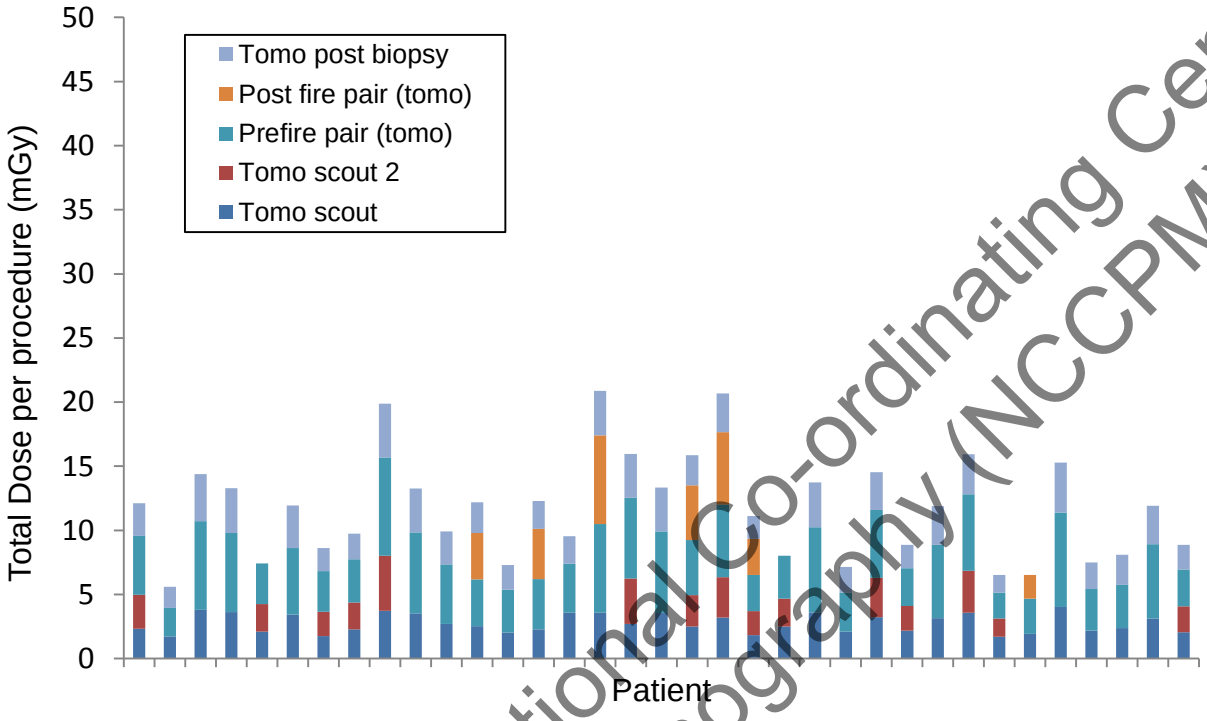
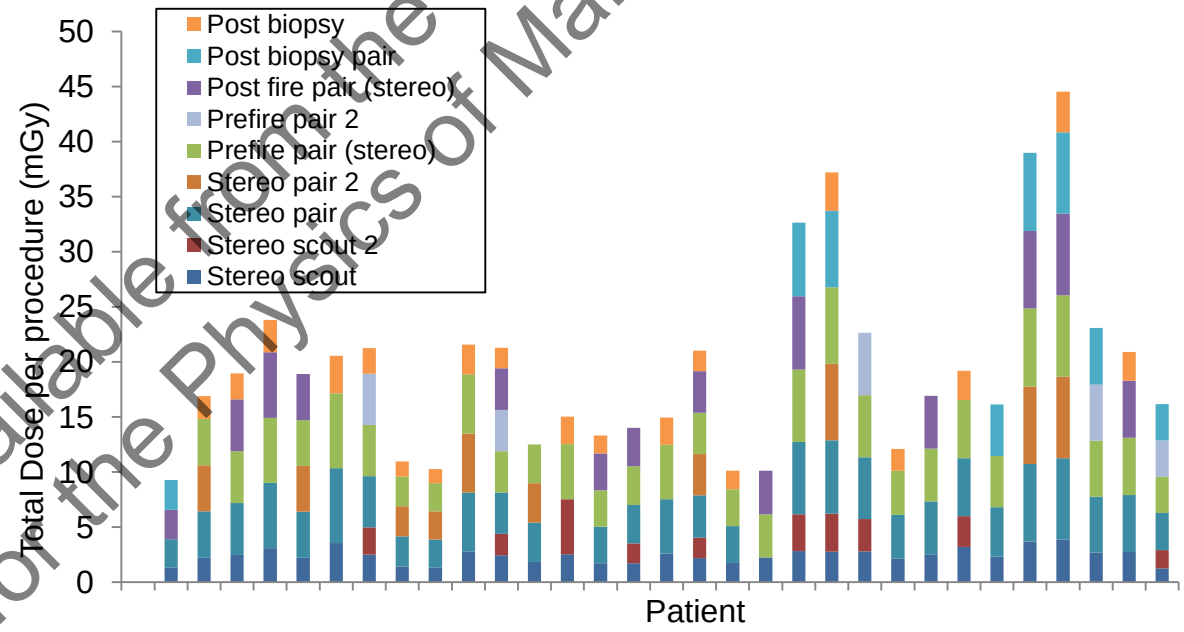


Figure A2.3. Stereo procedure - contribution of projections



Appendix 3: Radiographers' questionnaire

Radiographers' questionnaire	Excellent	Good	Average	Satisfactory	Poor	Not applicable	Yes	No	Easy	Average	Difficult	Additional comments
How do you rate the supplier's operator manual (if used)?	2	3		1		6						
Would you prefer an in-house simplified version?						1	5	6				
How good was the clinical applications training for tomosynthesis core needle biopsy provided by the supplier	3	6	2			1						
How do you rate the ease of use of the equipment for tomosynthesis core needle biopsy?	6	6										
How easy is it to fit/remove stereotactic attchments?	1	11										
How easy is it to clean stereotactic equipment?		7	3	1	1							Use swabs to avoid body fluid contaminating equipment. A protective layer of cling film was routinely placed over some parts to keep clean
How do you rate the ease of tube angulation with biopsy equipment fitted?	4	8										

How do you rate the image quality of the scout for tomosynthesis biopsy?	6	5				1						
Radiographers' questionnaire	**Excellent**	**Good**	**Average**	**Satisfactory**	**Poor**	**Not applicable**	**Yes**	**No**	**Easy**	**Average**	**Difficult**	**Additional comments**
How do you rate the image quality of the scout for stereo 2D biopsy?	5	7										
Were exposue times acceptable for tomosynthesis biopsy for scout image?						3	8					
Were exposure times acceptable for tomosynthesis biopsy for images used in directing stereotactic equipment?						2	11					
How do you rate the time for an image to appear at the acquisition work station for tomosythesis biopsy?	4	2	6									
Were compression times acceptable for tomosynthesis core biopsy?		6				6						Time reduced by a much more streamlined procedure
Were compression times acceptable for stereo 2D core biopsy?	2	4				6						
How do you find carrying out QA tests for Affirm Prone Biopsy System?									7	5		QAS easy, apply careful phantom compression for needle tests

How do you rate the comfort of the women during prone biopsy	1	8	3									Problems with some ladies lying prone; comfortable unless neck/shoulder problems
How do you rate the image quality of tomosynthesis images at the acquisition work station?	3	7				2						
Radiographers' questionnaire	**Excellent**	**Good**	**Average**	**Satisfactory**	**Poor**	**Not applicable**	**Yes**	**No**	**Easy**	**Average**	**Difficult**	**Additional comments**
How do you rate the image quality of stereo 2D images at the acquisition work station?	4	6				2						
What was your level of confidence in the system for tomosynthesis biopsy?	2	8				2						
What was your level of confidence in the system for stereo 2D biopsy?	4	6				2						
Were there any potential hazards during biopsy (either mode) to you?						1		11				Ergonomic table: easy to use
Were there any potential hazards during biopsy (either mode) to the woman?						1		11				Padlock had to be depressed to enable imaging
How do you rate tomosynthesis biopsy in comparison to conventional biopsy?	4	7										

Any additional comments on tomosynthesis core needle biopsy?											Tomo much quicker than 2D stereo; No tomo imaging, hence imaging small lesions sometimes difficult prior to biopsy. Procedure flows well, excellent image quality - would be even better if we used tomosynthesis at assessment clinic. Generally faster procedure	
Any additional comments on stereo biopsy?												Would be useful to split screen and view prior and current side by side

Appendix 4: Advanced practitioners'/radiologists' questionnaire

Advanced practitioners'/radiologists' questionnaire	Excellent	Good	Average	Satisfactory	Poor	Not applicable	Yes	No	Other comments
How well do you rate the suppliers operator manual (if used)?	1					2			
Would you prefer an in-house simplified version?						1	1	1	
How good was the clinical applications training for tomosynthesis/stereo core needle biopsy provided by the the supplier?		2	1						Would have liked to have seen more cases; would have liked more training with lateral arm (became available later in the evaluation)
How do you rate the image handling tools for biopsy?	2	1							
How do you rate the ease of using prone affirm equipment for biopsy targetting?	1	2							
How do you rate the use of the display screen of the biopsy control module (touchscreen) for targeting/reaching the target?	2	1							
How do you rate the controls for adjusting needle position for multiple sampling?		3							
Comment on the accuracy of directing the needle positioning with tomosynthesis biopsy?		3							
Comment on the accuracy of directing the needle positioning with stereo 2D biopsy?	1	2							

How do you rate the image quality for tomosynthesis biopsy?	3								Took time to adapt skills and become confident at viewing Tomosynthesis images
How do you rate the image quality for stereo 2D biopsy?	2	1							
Advanced practitioners'/radiologists' questionnaire	**Excellent**	**Good**	**Average**	**Satisfactory**	**Poor**	**Not Applicable**	**Yes**	**No**	**Other comments**
What is your opinion of the following aspects of image quality when using tomosynthesis biopsy?									
a) Contrast	1	2							Navigating through images was a simple and logical procedure
b) Sharpness	1	2							
How do you rate the time for images to appear on screen using tomosynthesis to direct the needle for biopsy?	1	1	1						
How do you rate the time for images to appear using stereo 2D to direct the needle for biopsy?	1	2							
What is your overall level of satisfaction with using tomosynthesis biopsy system?	2	1							Magnification tool very useful for better visual acuity particularly as the monitor is not on a mobile arm
What is your overall level of satisfaction with using stereo 2D biopsy system?	3								
How do you rate tomosynthesis compared with stereo biopsy?		3							Faster procedure, need to be very careful with positioning and depth