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Practical evaluation of Hologic Affirm digital breast tomosynthesis biopsy system

NHS Breast Screening Programme Equipment Report 1501

December 2015

NHS Cancer Screening Programmes

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Contents

Executive summary

The Hologic Affirm breast tomosynthesis biopsy system was found to be useful and practical in the assessment of suitable cases, particularly for distortions and for masses not seen on ultrasound.

Users who had the opportunity to become proficient at using the Affirm tomosynthesis biopsy equipment responded with a positive assessment.

Measurements indicated that there is potential for a significant dose saving with tomosynthesis biopsy as compared with stereotactic biopsy.

1. Introduction

1.1 Evaluation centre and timeline

The evaluation centre is the Jarvis Breast Centre, which is a unit of the NHS Breast Screening Programme (NHSBSP). The centre invited nearly 70,000 women during the year 2013-14 for screening. Of these, more than 52,000 were screened, resulting in more than 3,500 recalls for further assessment. Some 1,300 biopsies were performed during that period. The centre meets relevant national quality standards[1] for breast screening and meets the criteria for evaluation centres outlined in the Guidance Notes for Equipment Evaluation.[2]

The centre was involved with the practical evaluation of the Hologic Selenia Dimensions 3D mammography system for the NHSBSP. Following the publication of this report, the centre was asked to carry out the practical evaluation of the Hologic Affirm tomosynthesis biopsy guidance system.

This evaluation was carried out between May and December 2014. A total of 91 biopsy cases were carried out on this equipment during this period. The majority of these cases, 75, were core needle biopsies and the remaining 16 were vacuum biopsies.

1.2 Equipment evaluated

The Hologic Selenia Dimensions has previously been evaluated for use in the NHSBSP. Both technical and practical evaluations[3-7] have been published, describing its performance in 2D and tomosynthesis modes.

In this evaluation, the Hologic Selenia Dimensions was used with the Affirm breast biopsy guidance system to perform tomosynthesis biopsy. Most of the biopsies were carried out with the Achieve 14G core biopsy gun. A few vacuum biopsies were carried out using the Hologic ATEC system and Eviva handpiece, shown in Figure 1.

The Affirm system consists of two main components: a guidance module and a control module. The guidance module holds and guides the biopsy equipment during the operation. The control module, which includes a touchscreen display, is used to show the target, system status and safety margins during the operation. A touchscreen display which the radiologist or practitioner uses to target the lesion is shown in Figure 2. The x, y and z co-ordinates can be chosen from this target display.

The Affirm system was fully integrated with the Selenia Dimensions. It offered the capability of both stereotactic and tomosynthesis options. However, the stereotactic option was not used during this evaluation.

Version 1.7.2 of the acquisition workstation (AWS) software was in use for the first half of the evaluation. An upgrade to version 1.8.2 (limited market release) was installed in September 2014. It included a number of enhancements for the biopsy system. One of these was the Multi-Pass system for automatic targeting of additional sites close to the initially targeted one. An example of this multiple targeting with the Multi-Pass system is shown at Figure 3.

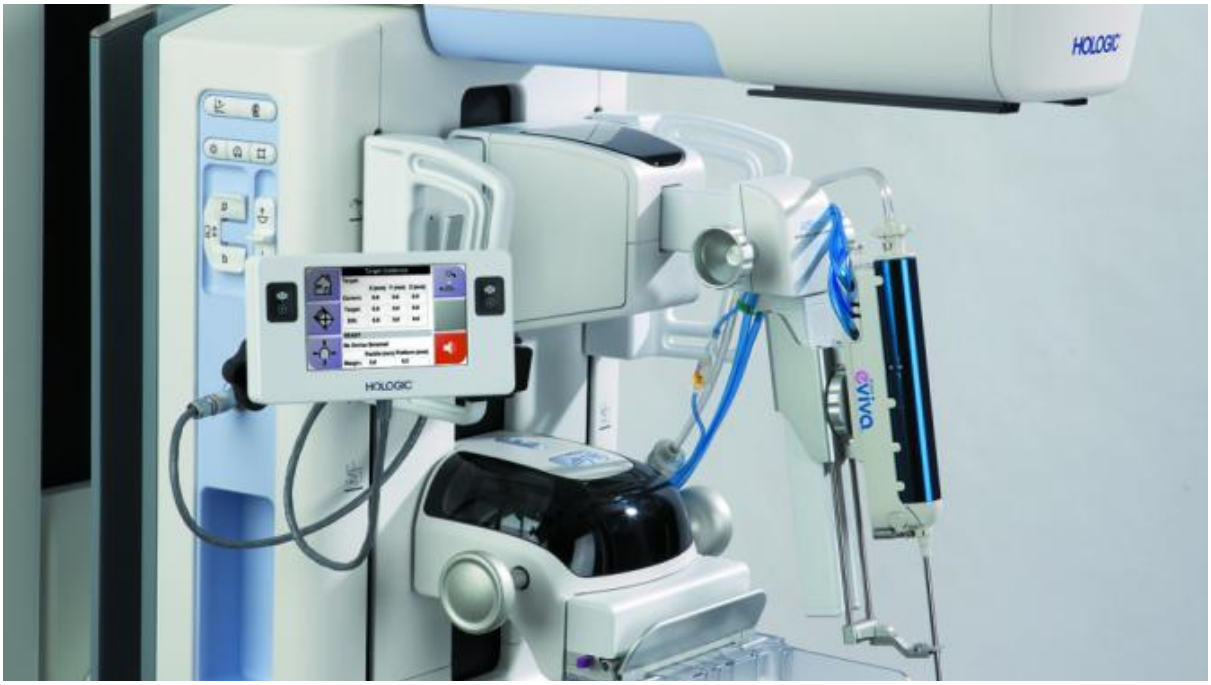

Figure 1. Selenia Dimensions with Affirm biopsy guidance unit and Eviva handpiece

Figure 2. Hologic Affirm control module touchscreen display

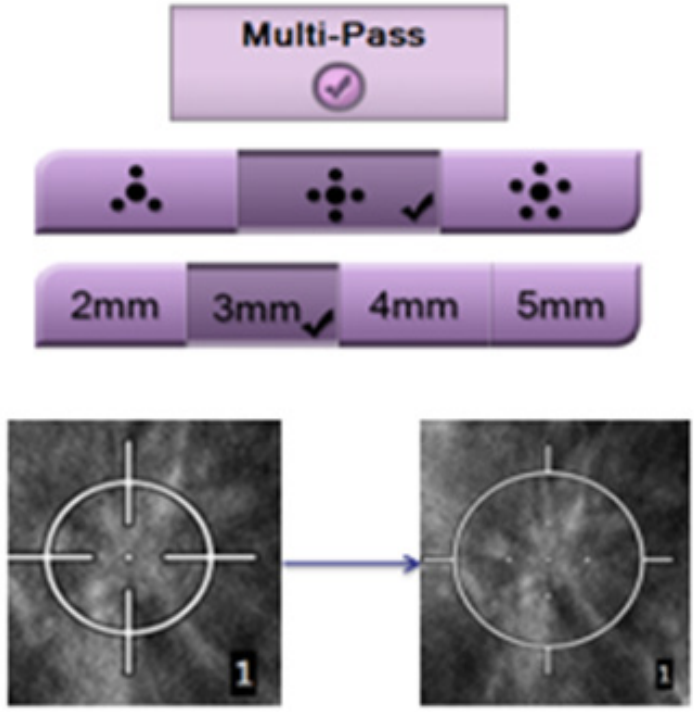

Figure 3. Multiple target sites selected with Multi-Pass system

1.3 Practical considerations

The Selenia Dimensions equipment used for this evaluation was located in a relatively small room set away from the main clinic area. Staff had no previous experience with the operation of the Affirm biopsy unit before it was installed for this evaluation.

A biopsy chair was provided, that could be converted from a sitting position into a flat couch. However, due to the size of the room, it could not always be used as a couch with the patient in the preferred decubitus position. This issue is discussed further in Section 13; although relevant to the evaluation, it is not related to the use of tomosynthesis biopsy. Figure 4 gives a general view of the room with equipment and couch.

Another practical difficulty was that the specimen cabinet was located in another room, at the far end of the department. This caused some delay, as specimens had to be carried there for imaging. Again, this issue is not related to the use of tomosynthesis biopsy.

Figure 4. General view of room with X-ray equipment and biopsy chair

1.4 Objectives

The overall objective was to evaluate the clinical performance of tomosynthesis biopsy using the Hologic Selenia Dimensions and the Hologic Affirm breast biopsy guidance system, and to evaluate the associated technical issues.

The detailed objectives were to:

- evaluate the usefulness of the Affirm tomosynthesis biopsy system as part of the assessment process
- assess the practical aspects of use and report on the operators' views and experience
- assess the performance and reliability of the equipment when in use for tomosynthesis biopsies
- report on radiation dose to the breast from imaging during tomosynthesis biopsy

2. Acceptance testing, commissioning and performance testing

The Selenia Dimensions unit was first commissioned in June 2011 when it was installed in the centre for the TOMMY clinical trial project. It was in continuous use over a period of twenty months. At the completion of the clinical aspects of the project, the unit was mothballed for about a year until the start of this evaluation. The system was then re-commissioned in April 2014 by Hologic for the purpose of this evaluation. The re-commissioning included an upgrade of the acquisition workstation (AWS) software to version 1.7.2, which enabled biopsies to be carried out in tomosynthesis mode. This was followed by the installation of the Hologic Affirm biopsy system, which included integration with the local PACS for image storage. A subsequent upgrade to AWS software version 1.8.2 is described in Section 1.2.

A routine radiation protection and performance survey of the system was carried out in May 2014 by the local physics service, the Regional Radiation Protection Service (RRPS), based at the Royal Surrey County Hospital, prior to the start of the evaluation. These tests included measurement of dose and image quality, in both conventional and tomosynthesis modes.

The physics report for these tests is included at Appendix 1. The check of the biopsy needle positioning indicated an error of 1mm during initial tests. Although this is just within the tolerance limit (1mm), the local physics service advised that it should be reduced before the evaluation started, and Hologic carried out this adjustment.

Further tests were carried out after faults, which are described in Section 5, were rectified.

3. Routine quality control

Routine quality control (QC) was undertaken in accordance with the relevant NHSBSP guidelines[8] relevant to 2D exposures, and in accordance with the latest guidelines for tomosynthesis exposures[9]. Different radiographers carried out these tests from day to day.

Daily, weekly and monthly tests were carried out as appropriate. The results remained within the appropriate remedial limits during the period of the evaluation. The results of the QC tests are included in Appendix 2.

In addition, a test firing of the biopsy gun was carried out on every day that the system was used for biopsies, to ensure that the targeting was accurate to within 1mm (x and y directions) or 3mm (z direction), as required by the national quality standards[1]. It was found to be within tolerance on all occasions.

4. Data on biopsies conducted

4.1 Clinical workflow

Women attending the centre for evaluation, following a recall from screening as part of the NHS breast screening program, undergo a full assessment as per the NHSBSP protocol.

The majority of women attending for assessment are given appointments in a morning clinic which starts from 08:30. Up to five appointments are allocated to those with calcification seen on their screening mammograms, who are more likely to require stereotactic biopsy than those with other types of mammographic features.

Daily QC testing of X-ray equipment in the centre is performed in the morning. The unit under evaluation was tested after the other X-ray equipment in the centre and was available for use from 09:30 every morning.

All women have a clinical examination and an ultrasound scan of the relevant area of the breast as identified on the screening mammogram. Stereotactic biopsies are performed on those women with indeterminate abnormalities not visible on ultrasound, or where the assessing clinician feels that it would be more accurate than performing a biopsy under ultrasound guidance. The majority of these abnormalities are calcifications.

In the centre, the majority of stereotactic biopsies are performed by one of three highly experienced advanced practitioners. For this evaluation, four of the clinicians also performed some of the initial tomosynthesis biopsies to become familiar and proficient with the equipment. The main training issues related to the use of the Affirm system, rather than the tomosynthesis function, as no one in the centre had used the Hologic stereotactic biopsy system before. Once the clinicians were confident about using the equipment, the training was extended to the advanced practitioners.

At the beginning of the evaluation period, any woman who required a stereotactic biopsy was considered suitable for the tomosynthesis biopsy system. It soon became apparent that not all women were suitable. Choices had to be made depending on which breast required biopsy and where in the breast the lesion was located, as some positions of the couch were precluded because of the room layout. Allocation to tomosynthesis biopsy was also based on staffing and other operational issues of the clinic. All cases of distortion were allocated to tomosynthesis biopsy, as all clinicians felt that this was the type of lesion where tomosynthesis excelled in visualisation. There was no specimen radiology required so the procedure was less complicated and took less time. Masses not seen on ultrasound were also allocated to the tomosynthesis biopsy system. Cases with faint calcifications were judged to be less suitable for tomosynthesis biopsy.

4.2 Tomosynthesis biopsy procedure

The complete procedure for a tomosynthesis biopsy is given in Figure 5. The last two steps, shown in green, are optional and only used in vacuum biopsies. Radiologists and advanced practitioners received training in the use of all the steps shown. With experience, however, they found that some of the images taken for checking purposes (the pre- and post-fire views, marked with * below) were not always required. As the evaluation progressed, staff became more confident in the procedure and rarely used these views.

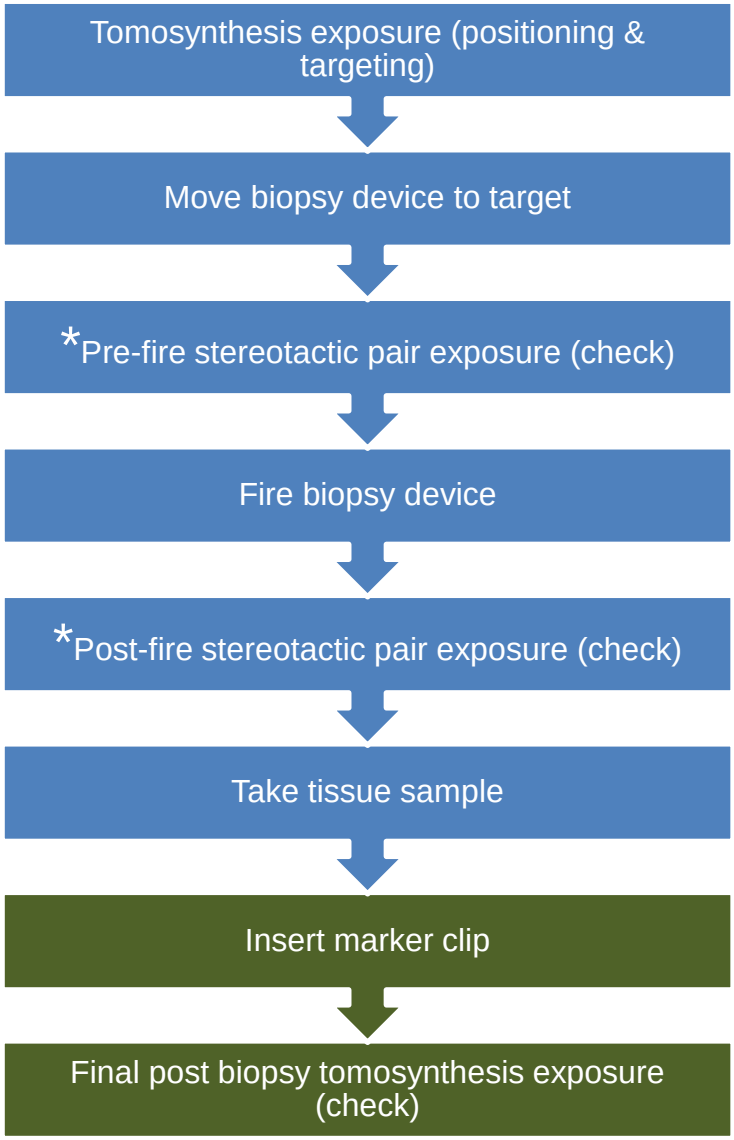

Figure 5. Steps in the tomosynthesis breast biopsy procedure.

4.3 Biopsy times with tomosynthesis images

Biopsy time was recorded for 65 of the 75 core needle biopsies carried out during the evaluation period. This is the time between needle to skin and release of compression. The distribution of biopsy times is shown in Figure 6. Two of the unusually long times (41–45 minutes) were due to problems with the specimen cabinet (failure to retrieve patient information from the worklist). The highest time recorded (55 minutes) was for a case with two targets.

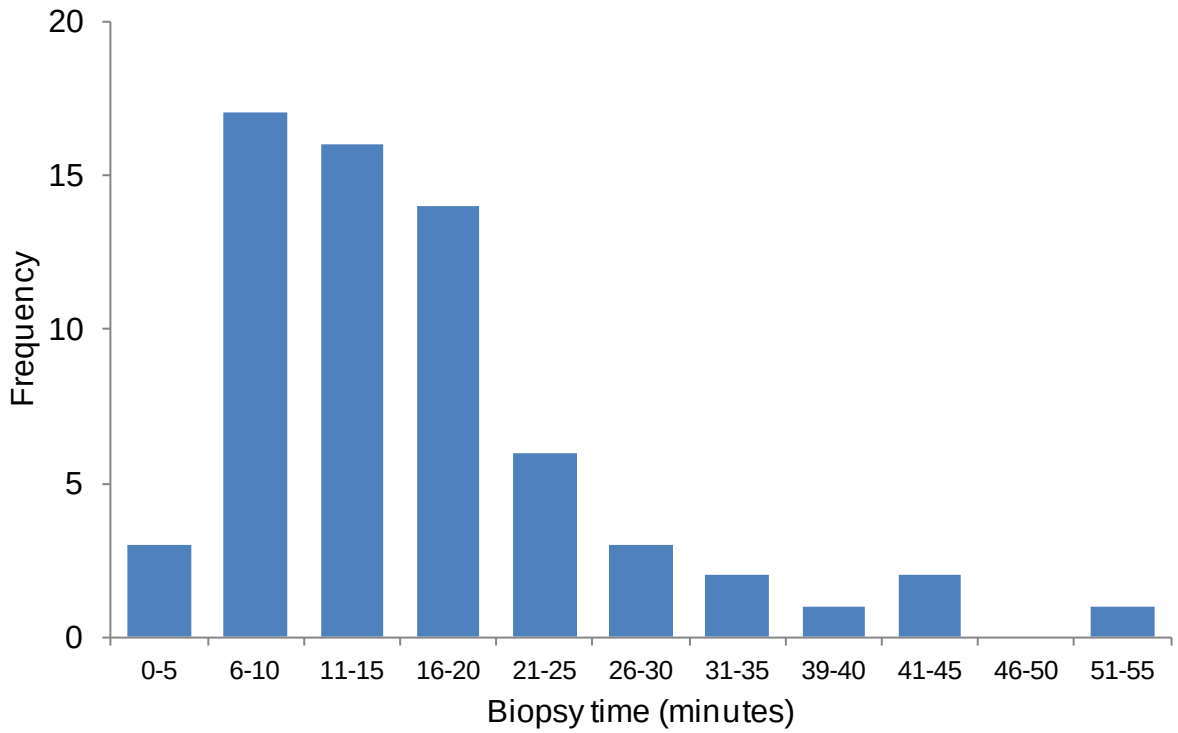

Figure 6. Distribution of biopsy times

4.4 Clinical dose – comparing stereotactic and tomosynthesis biopsies

An experienced radiographer simulated both stereotactic and tomosynthesis procedures, using a gel phantom compressed to 40mm thickness by a compression force of 52N. This method was used to compare doses in a standard way, because the evaluation centre does not use the Hologic Affirm for stereotactic biopsies. The mean glandular dose (MGD) for each step of both procedures is shown in Table 1.

If none of the optional steps are performed, as discussed in Section 4.2, the minimum total MGD is 1.33mGy for tomosynthesis biopsy and 3.12mGy for stereotactic biopsy, giving a dose saving of 1.79mGy. If all the steps shown are carried out, the total MGD to the model breast is 6.86mGy for the tomosynthesis biopsy, and either 10.32mGy or 9.24mGy for the stereotactic biopsy, depending on the marker insertion step chosen. The resulting dose saving is either 3.46mGy or 2.38mGy for tomosynthesis biopsy. This indicates a substantial saving either way when using tomosynthesis biopsy.

Table 1. Dose comparison – stereotactic and tomosynthesis biopsies

	Steps in procedure	Stereotactic procedure dose (mGy)	Tomosynthesis procedure dose (mGy)
Essential	Scout exposure	1.08	1.33
Essential for stereotactic only	Targeting pair	1.02 + 1.02	
	Total for minimum steps	3.12	1.33
Optional	Pre-fire pair (check)	1.02 + 1.02	1.05 + 1.05
Optional	Post-fire pair (check)	1.02 + 1.02	1.05 + 1.05
Optional alternative for marker insertion	Final post biopsy exposure pair or scout	1.02 + 1.02 1.08	1.33
	Total for all steps	10.32 or 9.24	6.86

5. Equipment reliability

The equipment was generally reliable during the evaluation period. Only three faults were recorded on the NHSBSP Equipment Fault Report Forms during the period. These faults occurred in the four-year old Selenia Dimensions X-ray equipment and are not related to the tomosynthesis biopsy.

The first was a detector failure, which was resolved by the replacement of the detector. In the second fault, the display monitor of the AWS had to be replaced. The third fault was incorrect display of the compression thickness, and this was corrected by an engineer.

The total downtime resulting from these faults was ten days. Details are given at Appendix 3.

6. Electrical and mechanical robustness

There were no safety issues, and no electrical or mechanical problems were encountered during the evaluation period, other than the faults reported in Section 5.

7. Radiographers' comments and observations

7.1 Overall assessment

A new standard evaluation form (evaluation form 11 in the evaluation guidelines modified for use with tomosynthesis biopsy systems) was used to collect the views of radiographers regarding the use of tomosynthesis biopsy.

A total of 15 out of 22 questionnaires were returned. At the time when the questionnaire was filled out, half of the respondents had assisted with between 1 and 3 biopsies, while the other half had assisted with more cases (4–12). The responses are amalgamated in the tables at Appendix 4 with the main points explained below.

7.2 Core biopsy and general questions

The following comments and observations relate to tomosynthesis core biopsies and include responses to questions which were common to both core and vacuum biopsies.

7.2.1 Operator manual provided by supplier

About half the respondents answered this question. They rated the manual good (4), average (2), satisfactory (1) and poor (1).

7.2.2 In-house version of operator manual

A large proportion of the respondents (10 out of 11) said they would prefer an in-house version of the operator manual.

7.2.3 Clinical applications training for tomosynthesis core biopsies

Four respondents said that the applications training was excellent, while another six said that it was good. Of the rest, three rated it as average and one satisfactory. One commented that she could not be in the centre at the time of the training. Another commented that the trainer was fantastic and very patient, while someone else rated the trainer as excellent. There was one comment that not enough time was given to training. Someone said that there were too many staff to go through training.

7.2.4 Ease of use of equipment for tomosynthesis core biopsies

On the ease of use, one said it was excellent with another nine good. Four said it was average. One commented that she thought it would be excellent once her proficiency had increased.

7.2.5 Fitting and removal of equipment

7.2.5.1. Stereotactic equipment

Two respondents thought that the fitting and removal of stereotactic equipment was excellent while another eight said it was good. Three respondents said it was average, with the remaining two saying it was poor. Of those who commented on the operation, one thought it slotted in very easily whereas four found it awkward, possibly due to limited experience.

7.2.5.2. The needle guide

When fitting or removing the needle guide, seven respondents found the operation to be either excellent (1) or good (6) whereas four thought it was average with one satisfactory and two poor. One commented that it was difficult to line up first time and several attempts were necessary. Another found it clumsy and hard to locate when changing holders. A third one said that care had to be taken not to over-tighten.

7.2.6 Cleaning the stereotactic equipment

On the ease of cleaning the stereotactic equipment the responses were good (7), average (4), satisfactory (1) and poor (3). The three who commented all pointed out that they could not immerse it in cleaner, but could only use Clinell wipes to clean. They had to use cling film to protect the touchscreen display from becoming contaminated.

7.2.7 Ease of rotation of support arm and ease of angulation of X-ray tube

On the ease of rotation of the support arm and the ease of angulation of the X-ray tube assembly, one respondent found it excellent with six good. Of the others, there were three average, one satisfactory and one poor.

7.2.8 Image quality of scout

The responses about the image quality of the scout were all positive with two excellent, twelve good and one average.

7.2.9 Exposure times for tomosynthesis biopsies

All those who responded found the exposure times acceptable (14).

7.2.10 Time for image to appear at AWS

Two responses were excellent for the time taken for the image to appear on the screen. There were ten good responses and one average.

7.2.11 Compression time for tomosynthesis core biopsy

Nine respondents found the compression time acceptable with one not acceptable. One comment was that the client was compressed for much longer than for conventional 2D stereos and felt that the going to and from the jogger to the AWS took too much time. A comment made about compression time being longer due to the specimen cabinet being located in another room was not relevant to tomosynthesis biopsy.

7.2.12 Calibration tests for tomosynthesis biopsy equipment

Some respondents had not performed these tests. One found the tests easy. Three others found the calibration tests for the tomosynthesis biopsy equipment acceptable while another three found it difficult. One commented that she had no experience and another said she needed more training and/or advice on the tests.

7.2.13 Comfort of women during exposures

The comfort of women during exposures was rated as excellent (1), good (7), average (6). One respondent thought it was poor. Two comments related to the size of the room, rather than the biopsy procedure. One said that the women had not commented on the moving gantry, and the compression was tolerated just as with conventional biopsies.

7.2.14 Image quality at AWS

For the image quality at the AWS, one responded that it was excellent, ten said good and the remaining four average.

7.2.15 Specimen cabinet location

There were no positive comments about having the specimen cabinet in another room. Only one said it was average with four satisfactory and seven poor. One comment was that it took too long to get the specimen information because of the location of the cabinet. Another commented that “walking through the department with biopsy samples is never great”.

The responses were more positive about potentially having the specimen cabinet in the same room where the biopsy is taking place: excellent (1), good (9), average (1). One comment was that this was only for a trial. The preference, for an operational system, would be to have the cabinet close by in the same room.

7.2.16 Level of confidence in system for core biopsy

Responses to this question reflected the experiences of different individuals as more experienced respondents were more positive. Six responses rated confidence as good, five average, one satisfactory with three poor. One comment was that while they were confident, they did not feel it was best for the clients. Another commented that it was average for calcium from what they had seen. There were a number of comments about the limited amount of experience which meant that confidence in using the system was not very high.

7.2.17 Hazards during tomosynthesis core needle biopsy

While eleven of the radiographers said there was no hazard to them, three thought there was a potential hazard. However, these comments related to the environment and the room rather than the equipment itself. One comment was that the small cramped space made moving around very difficult/bad especially if the client was recumbent. Another comment was that the lack of space in the room led to potentially poor posture for the radiographer.

Eleven respondents also said there was no hazard to the woman. One comment was that as long as a clear explanation was given to the woman, there was no hazard. Three thought there was a hazard but these comments again were related to the size of the room. Another comment was that there was no space to move around and it was a difficult position for the woman. There was another comment about the difficulty of releasing compression manually when use of the foot pedal is difficult.

7.2.18 Comparing tomosynthesis biopsy to conventional 2D biopsy

Two responses given said excellent and six good for this comparison. There were also six satisfactory to average responses and a number of comments as follows:

- better for distortion, but does not seem as good for calcium
- coarse calcium as good, but not for fine calcium
- not very accurate for calcium
- less familiar, therefore more difficult
- good and quick, but need more training
- will be fine with more practice

7.2.19 Additional comments on core needle biopsy

A number of additional comments on various aspects of the system are listed below.

- software upgrade to 1.8.2 made it much better in terms of image quality and ease of use
- ladies tolerate the procedure well
- releasing compression by foot means it is a little sudden for client
- more experience needed

7.3 Vacuum biopsy questions

Responses to the vacuum biopsy questions were very limited as most radiographers had little or no experience of working with vacuum biopsy. Comments tended to relate to the environment or were because the vacuum procedure was new to the centre. These are detailed further in Table A4.2 at Appendix 4.

7.3.1 Operator manual from supplier

Two said that the manual was good while two said it was poor.

7.3.2 In-house version of manual

On the question whether they would prefer an in-house version, three said yes and one no.

7.3.3 Clinical applications training for vacuum biopsy

Two respondents said the clinical applications training was excellent, three good, one average. Another two said it was satisfactory.

7.3.4 Ease of use of equipment for vacuum biopsy

Two respondents said it was easy to use, one said average with one satisfactory. There were also two who said poor. One radiographer commented on lack of training, while another commented on it being “rather complicated and temperamental”.

7.3.5 Fitting and removing vacuum biopsy equipment

There was one response of excellent, two average, one satisfactory and one poor. One comment was that it was the responsibility of the nurses to do this, while the radiographers only fitted the needle guide and the biopsy module.

7.3.6 Cleaning vacuum biopsy equipment

On cleaning the equipment, there was one good response with one average and two poor. One comment was that it was the nurses’ responsibility.

7.3.7 Accuracy of positioning

For the accuracy of positioning, there were three good responses, two average, two satisfactory.

7.3.8 Compression times for vacuum biopsy

Six respondents said that the compression times were acceptable.

7.3.9 Confidence in system for vacuum biopsy

One respondent thought confidence in the system was excellent, two said good, one average, one satisfactory and two poor.

7.3.10 Hazards with vacuum biopsy

Two respondents said that there were potential hazards to the radiographer with vacuum biopsy while four found no hazard. The comments mainly related to the room size.

There were four responses of yes and one no for hazards to the woman with vacuum biopsy. The comments related more to the room and the vacuum biopsy procedure itself rather than to the tomosynthesis biopsy.

7.3.11 Additional comments on vacuum biopsies

There were no additional comments relating to the tomosynthesis procedure with vacuum biopsy.

8. Radiologists' and advanced practitioners' comments and observations

8.1 Overall assessment

Another new evaluation form (based on evaluation form 12 of the evaluation guidelines) was used to collect the views of radiologists and advanced practitioners regarding the use of tomosynthesis biopsy. A total of seven out of eight questionnaires sent out were returned. The responses are amalgamated in the tables at Appendix 5.

Four of the respondents were radiologists who used both the core and vacuum biopsies with tomosynthesis during the evaluation. The other three, who were advanced practitioners, carried out core biopsies.

8.2 Core biopsy and general questions

The following comments and observations relate to tomosynthesis core biopsies and include responses to questions which were common to both core and vacuum biopsies.

8.2.1 Operator manual from supplier

Only two of the respondents had looked at the operator manual. One rated it as good and the other as average.

8.2.2 Applications training for tomosynthesis core biopsies

Four said that the applications training was excellent with the other three qualifying it as good.

8.2.3 Image handling tools

The four radiologists all thought that the image handling tools were either excellent (2) or good (2). Two of the advanced practitioners rated them as good.

8.2.4 Ease of use in targeting for core biopsy

Three of the respondents qualified this as excellent with another three saying that it was good. One said that it was better since the software upgrade. Another commented that the angle of approach allowed “good visualisation of pre-fire position” and the greater space between the tube head and the biopsy device meant that the gun could be rotated through 90° when taking samples. Another comment was that it was good with the new software and further training.

8.2.5 Use of touchscreen in targeting and needle selection

There were three excellent responses and four good for this question. One comment was that the touchscreen had nice graphics showing the needle and lesion position.

8.2.6 Controls for multisampling for core needle biopsies

8.2.6.1 Before software upgrade

One said that the controls were good with three average, one satisfactory and one poor. The one positive respondent thought that the jog mode was good. There was one comment about multi-sampling needing “several separate manipulations of the controls”.

8.2.6.2 After software upgrade

The respondents were more positive about the controls for multi-sampling after the software upgrade, with two excellent and four good. One comment was that the software was easier to use with the automatic repositioning facility. There were two more positive comments about the Multi-Pass facility.

8.2.7 Accuracy in directing needle positioning

Two thought accuracy in directing the needle was excellent and three said good, with one average and one satisfactory.

8.2.8 Image quality for scout

Image quality was thought to be excellent (1), good (5) and average (1). One commented that it was good for masses and distortions, but very poor and not reliable for calcium. The other comment was that it was good to have a facility to view the whole breast as well as the initial targeted area.

8.2.9 Contrast and sharpness

8.2.9.1 Contrast in biopsy images

The responses were generally positive. One rated it as excellent, four good and one average. One comment was that it was very difficult to see faint calcifications.

8.2.9.2 Sharpness in biopsy images

One rated it as excellent, three good with one average and one satisfactory. One commented that it was excellent for distortions.

8.2.10 Time for image to appear on screen

There were six excellent responses and one good.

8.2.11 Quality of tomosynthesis images for core biopsy

Three of the respondents thought the quality of the tomosynthesis images were excellent, three good and one average. There was one comment about how excellent the images were for distortion.

8.2.12 Overall level of satisfaction with using tomosynthesis for core needle biopsies

One of the respondents rated her overall level of satisfaction as excellent, five thought it was good and one average. The respondent who said average liked the Multi-Pass facility included in the upgrade.

8.2.13 Comparing tomosynthesis biopsy with conventional 2D biopsy

When comparing tomosynthesis biopsy with conventional 2D biopsy, three of the respondents found it excellent, with two saying it was good. One commented that it was better for distortion or ISQ, but worse for calcification. Of those who found it excellent, one radiologist said that tomosynthesis biopsy was quicker and easier, especially with distortion which may only be seen in one of the pair of images in conventional 2D imaging. She also

said that it was easier to target with tomosynthesis. One advanced practitioner who had responded excellent also said that tomosynthesis was excellent for distortion and good for calcium, but poor for fine calcium. Another commented that it was as good as 2D biopsy, but not necessarily better.

8.2.14 Additional comments by radiologists and advanced practitioners

There was one comment saying that the updated software helped very much in targeting lesions and was much more user friendly.

8.3 Vacuum biopsy questions

Vacuum biopsies were carried out by the four doctors amongst the respondents. Only one of the advanced practitioners responded to the questions as she had had more opportunities of following the relevant training. Out of the seven respondents, there were a total of five who responded to the questions on vacuum biopsy. These are detailed further in Table A5.2 at Appendix 5.

8.3.1 Applications training for tomosynthesis vacuum biopsies

All four radiologists said that the applications training provided by the supplier was excellent, with the advanced practitioner saying that it was good.

8.3.2 Ease of use in directing tomosynthesis vacuum biopsies

Three of the respondents thought that using tomosynthesis to direct vacuum biopsies was excellent with the other two regarding it as good. One of them commented that she would like a quick reference guide.

8.3.3 Time for images to appear on screen

This was very similar to the response for the core biopsy in Section 8.2.10.

8.3.4 Accuracy with tomosynthesis directing vacuum biopsies

The accuracy of directing vacuum biopsies was deemed excellent by four respondents. The last one gave no rating, but commented that it was difficult with diffuse calcium, but very good with distortions.

8.3.5 Additional comments on vacuum biopsies

The main comment coming from one of the radiologists said it was very easy to use and preferable to conventional biopsies. There was good patient feedback with two ladies who had had initial 2D conventional core biopsies finding the vacuum biopsies less painful or uncomfortable, although both had more bruises. This comment, though, related more to the general use of vacuum biopsy.

9. Information systems and PACS

The Selenia Dimensions unit and a SecurView DX reporting workstation were originally installed by Hologic for the TOMMY project. It was integrated with the local Sectra PACS for storage of the images on the imaging VLAN (local area network). The Dimensions was also connected to NBSS to display the worklist at the workstation. Images were stored in SC format on a SecurXchange mini-PACS at this time.

When the Dimensions was re-commissioned for this evaluation, the upgrade of the AWS software enabled the use of the BTO format, which is fully compliant with the DICOM 3 standard. This allowed storage of both 2D and tomosynthesis images on the local Sectra PACS. All images were available for clinical review on the reporting workstations connected to the PACS as well as on the SecurView DX.

10. Confidentiality

The evaluation complied fully with NHS Cancer Screening Programmes' Confidentiality and Disclosure Policy.[10]

11. Security

All electronic patient data was stored on NBSS and the images were stored on the local Sectra PACS. Access to these systems is restricted to authorised users only, by password protection.

Access to the Selenia Dimensions AWS is controlled by typing username and password or by fingerprint recognition. Access to the SecurView DX and the PACS reporting workstations is also password protected, as is access to the specimen cabinet.

12. Training

All the radiologists and advanced practitioners were trained and experienced in the use of tomosynthesis for assessments as described in an earlier practical evaluation. In addition, they each received individual training at the centre in the use of the Affirm system and vacuum biopsy, and in tomosynthesis biopsy, from the Hologic applications specialists.

The majority of radiographers were already trained and experienced in operating the Selenia Dimensions in tomosynthesis mode. All those involved in this practical evaluation received further training from the Hologic applications specialist before operating the Affirm tomosynthesis biopsy equipment at the centre.

QC training was also provided.

The Hologic applications staff provided the training on site both at the beginning of the evaluation, and also after the software upgrade which took place about half way through the evaluation.

13. Discussion

13.1 Practical issues

Although users were generally positive about tomosynthesis biopsy, some of the radiographers' opinions were influenced by the practical difficulties described in Section 1.3 – the relatively small size of the room and the location of the specimen cabinet at the far end of the department.

The decubitus position is the position of choice by the unit's practitioners for the majority of biopsies, as it minimises vasovagal episodes, and also limits visualisation of the technique by the patient. The position of the couch in the room was arranged according to the position of the lesion in the breast and whether the right or left breast required a biopsy. The couch could not always be placed in the room with sufficient space around it for the practitioners to work in a safe and uncluttered environment.

The specimen cabinet was installed in a larger room used for conventional stereotactic biopsies. This meant that the core specimens had to be carried through the centre to be X-rayed in the specimen cabinet before the procedure could be completed. Very often, the biopsy practitioner left the X-ray room in order to view the specimen radiograph, which added to delay in the procedure when it occurred.

13.2 Types of lesion

Different mammographic abnormalities were biopsied with this equipment, including calcifications, round masses, irregular masses and distortion. The majority of abnormalities biopsied were calcifications. Coarse calcification, masses and distortions were well visualised, with distortions being particularly well seen. It was easy to identify spiculations and the centre of the lesion could be targeted with ease.

For faint calcifications which are difficult to see on standard 2D images, the tomosynthesis images did not improve the visualisation of the area. This was in keeping with the results found during the evaluation of the Hologic Selenia Dimensions tomosynthesis system where calcifications were seen equally well with tomosynthesis and in 2D images. As a result, practitioners tended to avoid biopsying faint calcifications with the Affirm system. They preferred to use the standard 2D equipment which was already in use in the centre. Alternatively, the Affirm could have been used in 2D mode for these cases, but this was not part of the current evaluation.

Longer biopsy times may be due to lack of experience. On occasions radiologists asked for additional views during the procedure, and the less experienced radiographers then had to seek advice from more experienced colleagues on how to take these views.

13.3 Training and experience

Almost all radiographers in the centre received training in the tomosynthesis biopsy procedure. Because of rotation between the centre and the vans, many had few occasions to carry out the procedure and long intervals between such occasions. In retrospect, it was too ambitious to try to give all radiographers an opportunity to experience the system. It would have been better to have trained four or five “super-users”, who would then have cascaded information to the others. An instruction sheet developed in-house might have helped to prompt those who used the system infrequently. None was developed for this evaluation, but several staff expressed a wish for such a document.

Some of the radiographers’ comments, for example, a perceived difficulty in attaching the Affirm to the Selenia Dimensions, are attributable to those individuals who had had limited experience with the equipment.

13.4 Radiographers’ comments

Generally, those radiographers who had occasion to use the equipment more gave more positive assessments of the system than those who had less experience. A number of factors caused some inconvenience to the radiographers during the evaluation. The location and size of the X-ray room (small and out of the main clinical area) and the specimen cabinet (in another room where the majority of 2D stereotactic biopsies are taken), in particular, seemed to colour the overall perceptions of some respondents. This gave rise to the negativity, which was apparent in their answers. These limitations of the evaluation setup were not at all related to the Affirm or the tomosynthesis biopsy procedure.

Some radiographers made a number of comments on the fitting and removing of the stereotactic equipment and the needle guide which were not related to the equipment itself, but rather to the experience which come through usage of the equipment. Similarly, the comments radiographers made about cleaning the stereotactic equipment with wipes instead of by immersion in cleaning solution were mainly a reflection of this procedure being different from what they are used to in the centre.

Issues with possible contamination of the touchscreen were also the result of the way practitioners operate in the centre. They usually change the needle position themselves rather than having a nurse or radiographer do it. The screen is therefore covered with cling film during use, to prevent contamination.

Negative comments on vacuum biopsy are again related principally to the effects of the environment, such as the size of the room, and not to the Affirm or the tomosynthesis biopsy procedure.

13.5 Radiologists' and advanced practitioners' comments

Comments from radiologists and advanced practitioners were generally more positive and they found the tomosynthesis biopsy procedure very useful for appropriate cases. In particular, the upgrade with the Multi-Pass system was seen as an important improvement on the previous software version.

Other features that were found to be useful included the following:

- the 10° angle of approach of the needle gives better visualisation of the needle tip and lesion
- facility to view the whole breast as well as the initial targeted area during positioning
- it is easier to target lesions with tomosynthesis biopsy

14. Conclusions and recommendations

The Hologic Affirm tomosynthesis biopsy system was found to be useful and effective, particularly for distortions and for masses not seen on ultrasound. It was thought to be less useful for cases of faint calcifications.

Positive feedback was given by the clinicians and the advanced practitioners who carried out biopsy procedures. The opinions of radiographers were more mixed, with generally more positive comments made by those who had assisted with more than two or three biopsies.

The equipment performed well over the evaluation period, with only a few technical faults which were resolved. Measurements indicated a significant dose saving for tomosynthesis biopsy compared with stereotactic biopsy.

The Hologic Affirm tomosynthesis biopsy system is recommended for use in assessment in the NHSBSP.

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Appendix 1: Physics routine survey report

Regional Radiation Protection Service NHS

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Mammography Physics Routine Survey Report

Hologic Selenia Dimensions with Tomosynthesis

Jarvis Breast Screening Centre

1 Introduction

A routine radiation protection and performance survey of the digital mammography equipment was undertaken on the 30th April 2014. 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 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 draft NHSBSP Physics QC Protocol for Breast Tomosynthesis (Sept 2013). The unit has not been used clinically for some time and has undergone a number of software upgrades since it was last tested in March 2013. A tomosynthesis biopsy trial is to be carried out using this system and the localisation accuracy was tested on 19th May with the applications specialist from Hologic.

2 Equipment

Mammography Unit: Hologic Selenia Dimensions

3 Equipment Performance

Tomosynthesis performance testing results have been compared with baseline values and remedial limits specified in the draft NHSBSP Physics protocol where given as well as with results from another system of the same type installed elsewhere. Detailed summaries of the results for both the 2D conventional imaging and tomosynthesis imaging performance are appended to this report. Any comments are reflected in Section 4 below.

4 Conclusions and Recommendations

Results of the routine performance testing of the conventional 2D imaging were generally satisfactory. The tomosynthesis imaging functions of this system have been tested and in most cases meet the requirements of the draft NHSBSP Protocol, although some issues have been raised in the recommendations section below.

Recommendations

Tomosynthesis Mode

Flag	*Conclusions*	*Recommendations*	*Local Action Taken (where required)*	*Sign & Date*
R/A	The tomosynthesis biopsy localisation error was 1mm in the X direction, which is at the remedial limit.	4.1 The engineer should be asked to adjust this as soon as possible.		
A/G	An artefact was noted on the tomosynthesis reconstructed slices and some of the projections for the 7cm PMMA image when acquired using a clinical view (see attached image). The artefact was not seen when the same exposure was taken using a flat field tomo view, although this may be an intermittent artefact.	4.2 The artefact was not seen on any other images and could not be repeated. Details have been sent to Hologic for comments and no action is required.		
A/G	In tomosynthesis mode Contrast to Noise Ratios (CNRs) have increased from baseline values and image quality as measured using the CDMAM has also improved. This appears to be due to an increase in Mean Glandular Dose (MGD) from baseline. Doses are within ±25% from baseline values however the MGD for 2cm PMMA is at the remedial limit for 2D mammography, which has been suggested as a reference dose for tomosynthesis.	4.3 The increase in dose/image quality from baseline has been raised with Hologic. No action is required.		
A	The difference between the displayed MGD and the calculated value is greater than 30% for 2cm PMMA in tomosynthesis mode.	4.4 The engineer should be asked to check this at the next visit. It is recommended that Physics should also attend at this visit.		
R/A	Local QC testing had not been implemented at the time of the survey. The users have discussed the requirements with the Lead Physicist and undergone QC training with Hologic since the survey.	4.5 Local QC testing should be implemented as soon as possible. Testing should be in line with the draft NHSBSP Report 1313 Routine Quality Control Tests For Breast Tomosynthesis (copy enclosed with this report) and local protocols should be updated. Baselines and remedial levels should be set. If the artefact noted in 4.2 is seen then Physics should be informed.		
A	IRMER Procedures will require updating to include tomosynthesis examinations.	4.6 Referral criteria for breast tomosynthesis should be added to the IRMER procedures. As there is no national criteria at present these will need to be completed locally.		

Conventional 2D Imaging

Flag	*Conclusions*	*Recommendations*	*Local Action Taken (where required)*	*Sign & Date*
A	The X-Ray beam overlaps the detector by more than 5mm on the back, left and right edges for the paddle left and right shifts.	4.7 This is unlikely to be a clinical issue however the service engineer should be asked if the alignment can be improved at the next visit.		
A	A small artefact was noted on the 24x30 images located towards the chest wall edge on the right hand side of the image (see attached images).	4.8 This is unlikely to be an issue for clinical images however they should be checked to confirm this. The service engineer should be asked to comment at the next visit.		
A/G	The Signal to Noise Ratio has increased by slightly more than 10% from baseline.	4.9 This will be reviewed at the next survey and no action is required.		
A	Contrast to Noise Ratios (CNRs) in magnification mode have increased by between 25-35% from baseline values.	4.10 This is due to an increase in dose in magnification mode which was implemented as part of a Hologic software upgrade (1.7.x) in order to improve image quality. No action is required and baselines will be reset. All clinical users should be made aware of the increase in dose.		

Key:

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

Mary Kelly
Principal Physicist

21st May 2014

Regional Radiation Protection Service

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Mammography Routine Performance Report
Results Summary

Location *Jarvis BSC* ***Survey Date*** 30/04/2014
X-ray Room Tommy Trial

Equipment

X-ray Set	Hologic	Selenia Dimensions
Detector	DR Hologic	 Selenia Dimensions
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		0.7	✔	
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		74	69	✔	
28kV WAg BF		75	70	✔	
28kV MoMo FF					N/A
28kV WRh FF		61	52	✔	
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		18.0	✔	
Maximum error (kg)	2 kg		0.4	✔	
Change over 30s	Should be no change			✔	
CBT indicator max error (mm)	±5 mm at 100 N		3.0	✔	
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			0	-4	-0.5	1		
18x24(L) BF W			0	-4	1.5	-1		
24x30 BF W			0	-0.5	1	0.5		
18x24 BF W			0	-5	0	-0.5		
Mag FF W			2	-4	1	-0.5		
X-ray to Detector Alignment	0-5mm overlap all sides		F	B	L	R	✔	1
18x24(R) BF W			2	8	5.5	9		
18x24(L) BF W			2	8	6.5	8.5		
24x30 BF W			2	4.5	2	2		
18x24 BF W			2	5	2	3.5		
Mag FF W			2	2	0.5	1.5		

5 Detector Performance

Measurement	Criteria	Baseline			Result			OK	Comments
Detector Response									
Air Kerma (µGy) at PV= 400	20% change frm baseline	113.7			116			✔	
Noise	10% change frm baseline	6			5.40			✔	
SNR	10% change frm baseline	57.7			64.6				2
Limiting Resolution (lp/mm)	<75% of baseline	7.1			6.3			✔	
SWCTF(perp) at 1lp/mm, 4lp/mm, 80% Nyquist	10% change frm baseline	0.36	0.23	0.18	0.36	0.23	0.19	✔	
SWCTF(para) at 1lp/mm, 4lp/mm, 80% Nyquist	10% change frm baseline	0.36	0.23	0.18	0.37	0.24	0.19		
Spatial Discontinuity	None							✔	
Image Retention	Retention factor <0.3				0.02			✔	
Uniformity	<10% variation				DR		0.5	✔	3
					CR Centre-side				
					Left-right				

6 Image Quality

Measurement	Criteria	Baseline	Result	OK	Comments
TORMAX					
Perpendicular lp/mm	Significant difference			✔	
Parallel lp/mm	from baseline				
Contrast (%) 6mm		0.58	0.58		
Contrast (%) 0.5mm		2	2.7		
Contrast (%) 0.25mm		2.7	5.4		
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		0.6	✔	
Back up Timer	Functioning		mAs BF: FF:	✔	

18x24									
CNR - variation with PMMA	10% change frm baseline	Settings			CNR	Settings			CNR	✔	
2 cm		25	W	Rh	10.11	25	W	Rh	10.35		
3 cm		26	W	Rh	9.38	26	W	Rh	9.43		
4 cm		28	W	Rh	8.52	28	W	Rh	8.31		
4.5 cm		29	W	Rh	7.89	29	W	Rh	8.30		
5 cm		31	W	Rh	7.97	31	W	Rh	8.06		
6 cm		31	W	Ag	7.60	31	W	Ag	7.76		
7 cm		34	W	Ag	6.45	34	W	Ag	6.25		

Mag											
CNR - variation with PMMA	10% change frm baseline	Settings			CNR	Settings			CNR	✔	4
2 cm		25	W	Rh	8.24	25	W	Rh	10.61		
3 cm											
4 cm		30	W	Rh	5.82	30	W	Rh	7.25		
4.5 cm		31	W	Rh	5.29						
5 cm											
6 cm		34	W	Ag	3.70	33	W	Ag	4.99		

8 Mean Glandular Dose

Measurement	Criteria	Baseline				Result				OK	Comments
18x24											
MGD (mGy) at thickness	25% change frm baseline	Settings			MGD	Settings			MGD		
2cm	<1mGy	25	W	Rh	0.58	25	W	Rh	0.62	✔	
3cm	<1.5mGy	26	W	Rh	0.81	26	W	Rh	0.85	✔	
4cm	<2mGy	28	W	Rh	1.14	28	W	Rh	1.11	✔	
"Standard breast" 4.5cm	<2.5mGy	29	W	Rh	1.38	29	W	Rh	1.42	✔	
5cm	<3mGy	31	W	Rh	1.95	31	W	Rh	1.92	✔	
6cm	<4.5mGy	31	W	Ag	2.64	31	W	Ag	2.51	✔	
7cm	<6.5mGy	34	W	Ag	3.00	34	W	Ag	2.82	✔	

Comments

1 The X-Ray beam overlaps the detector by more than 5mm on the back, left and right edges for the paddle left and right shifts.

2 The Signal to Noise Ratio has increased by slightly more than 10% from baseline.

3 A small artefact was noted on the 24x30 images located towards the chest wall edge on the right hand side of the image.

4 Contrast to Noise Ratios (CNRs) in magnification mode have increased by between 25-35% from baseline values.

Reported By: ***Emma Whitehead***
Medical Physicist

MAMMOGRAPHY PHYSICS REPORT

Hologic Selenia Dimensions, Tomosynthesis Performance

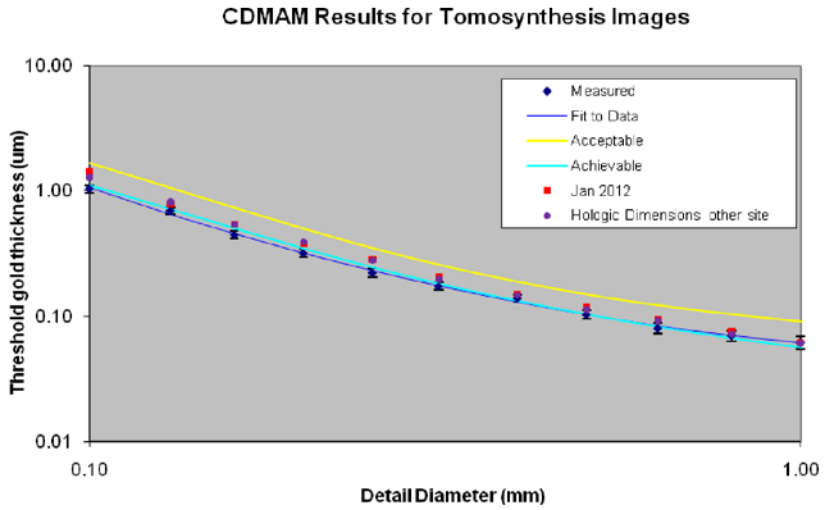
Jarvis Breast Screening Centre

Date of Survey: 30th April 2014

Survey Results						
Measurement	**Remedial level**	**Baseline(s)**	**Results**	**Change from baseline**	**Satisfactory**	**Comments**
Alignment						
X-ray field to reconstructed image alignment at chest wall	< 0mm or > 5mm overlap	-	+2.5mm	-	✓	
Primary beam attenuation	Primary beam must be blocked by detector & surrounding structure	-	Confirmed satisfactory.	-	✓	
Missed tissue at chest wall	> 5mm	-	4.5mm	-	✓	
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)	Significant change from baseline	26 WAl 19.8	26 WAl 19.5	-1.5%	✓	
		31 WAl 35.9	31 WAl 34.2	-4.6%		
		42 WAl 75.5	42 WAl 72.5	-4.0%		
Uniformity and artefacts	No clinically significant artefacts should be seen		Artefact noted on one image		×	1

Survey Results										
Measurement		**Remedial level**	**Baseline(s)**			**Results**			**Change from baseline**	**Satisfactory**	**Comments**
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**	7.5	32.7	57.9*	7.0	32.2	52.1	0.5mm	✓	
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	None	✓	
Scaling accuracy		>5% change from baseline**	3.5%	3.8%	4.2%	0.14%	0.04%	0.39%	-3.8%	✓	
FWHM perpendicular to detector (vertical or Z plane resolution), mm		>20% change from baseline**	11.4	11.1	10.6	11.5	11.1	10.8	1.9%	✓	
Spread parallel to detector, mm	X plane - parallel to tube axis	> 2 pixels or 50% change from baseline**	0.019 mm 0.17 pixels	0.021 mm 0.19 pixels	0.03 mm 0.27 pixels	0.037 mm 0.33 pixels	0.03 mm 0.27 pixels	0.01 mm 0.09 pixels	0.2 pixels	✓	
	Y plane - perpendicular to tube axis		0.102 mm 0.92 pixels	0.21 mm 1.89 pixels	0.089 mm 0.80 pixels	0.09 mm 0.81 pixels	0.145 mm 1.31 pixels	0.059 mm 0.53 pixels	0.6 pixels	✓	
** test object at 57.5mm at this survey **these are proposed as investigation levels NOT remedial limits*											
Automatic Exposure Control											
AEC Performance – Contrast to Noise Ratios (CNRs)		>20% change from baseline	***PMMA (cm)***	***kV/target/filter/CNR***	***kV/T/F***	***CNR***				✓	1, 2
						Flat field	Clinical				
			2	26 WAl 30.1	26 WAl	37.1	8.8	23%			
			3	28 WAl 23.0	28 WAl	28.3	6.8	23%			
			4	30 WAl 19.6	30 WAl	23.0	5.7	17%			
			4.5	31 WAl 19.4	31 WAl	22.7	5.5	17%			
			5	33 WAl 17.7	33 WAl	21.1	5.2	19%			
			6	36 WAl 16.0	36 WAl	18.3	4.5	15%			
			7	42 WAl 12.0	42 WAl	13.8	-	15%			

Survey Results							
Measurement	**Remedial level**	**Baseline(s)**		**Results**		**Change from baseline**	**Satisfactory**	**Comments**
Image Quality								
Detail detection – threshold gold thickness, µm	Comparable with other units of same type. No significant change from baseline***.	*Detail diameter, mm*	*Result, µm*	*Detail diameter, mm*	*Result, µm*		✓	2
		0.10	1.423	0.10	1.040	-27%		
		0.13	0.783	0.13	0.695	-11%		
		0.16	0.536	0.16	0.447	-17%		
		0.20	0.377	0.20	0.318	-16%		
		0.25	0.282	0.25	0.222	-21%		
		0.31	0.204	0.31	0.173	-15%		
		0.40	0.150	0.40	0.139	-7%		
		0.50	0.118	0.50	0.103	-12%		
		0.63	0.094	0.63	0.080	-14%		
		0.80	0.075	0.80	0.070	-7%		
		1.00	0.061	1.00	0.062	1%		

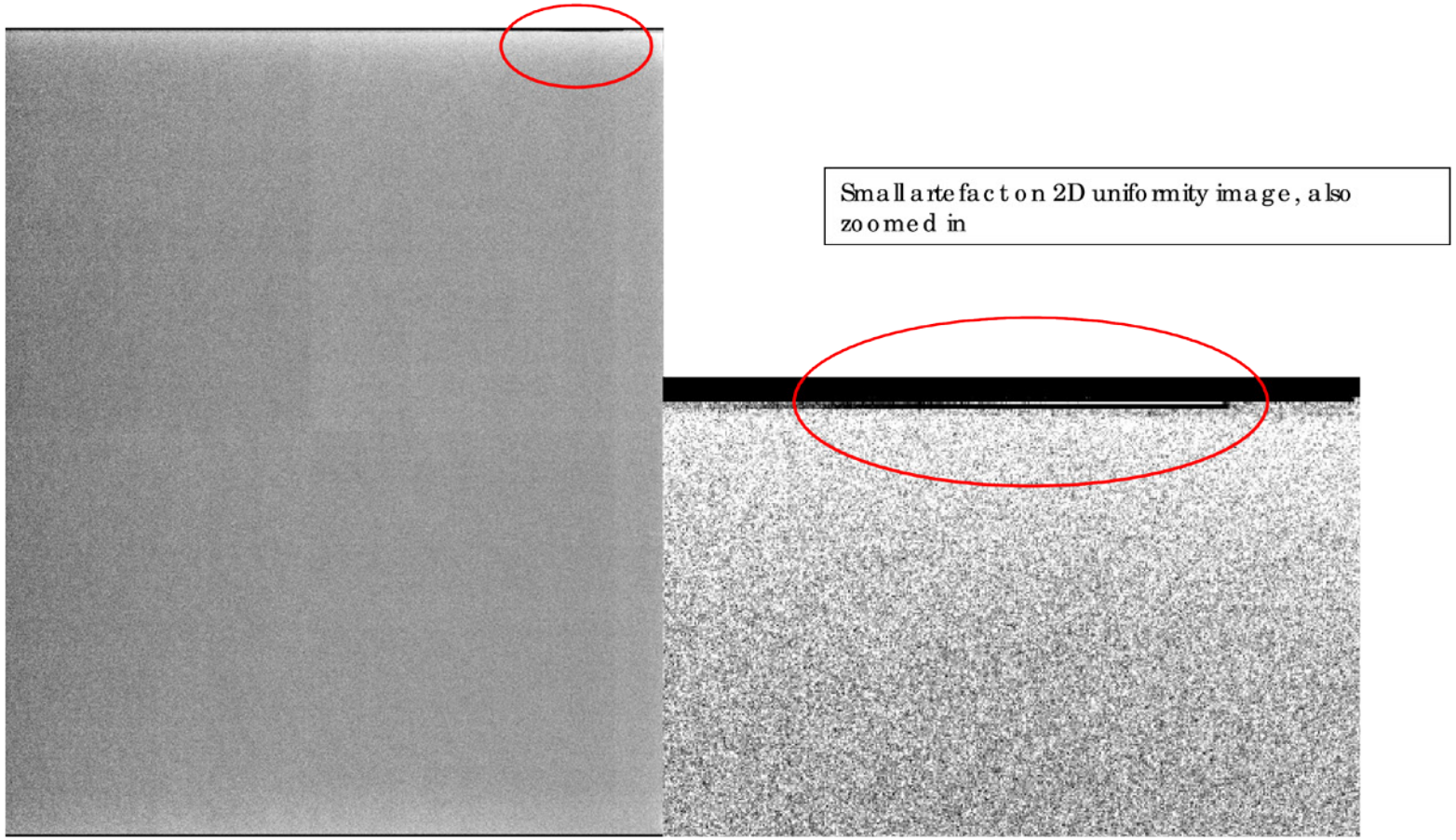


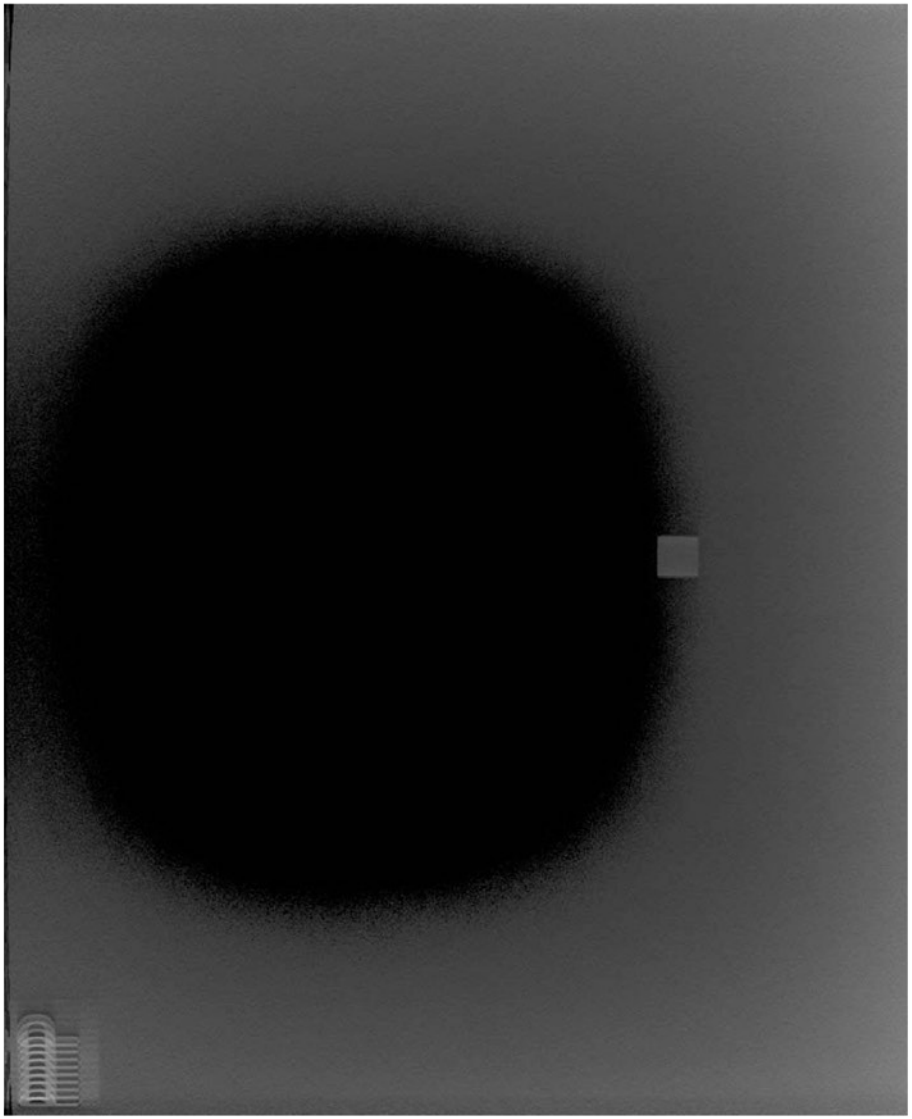
*** *Baseline values from Jan 2012 – the first survey after commissioning where the local Physics phantom was used*

Survey Results									
Measurement	**Remedial level**	**Baseline(s)**		**Results**			**Change from baseline**	**Satisfactory**	**Comments**
Mean Glandular Dose (MGD)									
Doses to typical breasts	> ±25% change from baseline Displayed values of MGD not > 30% different from calculated values	***PMMA (cm)***	***kV/target/filter/MGD***	***kV/T/F***	***MGD calculated***	***% difference displayed from calculated***		✓	2, 3
		2	26 WA1 0.88	26 WA1	1.04	-46.1	18%		
		3	28 WA1 1.08	28 WA1	1.23	-25.4	14%		
		4	30 WA1 1.52	30 WA1	1.60	-15.0	6%		
		4.5	31 WA1 2.00	31 WA1	2.09	-8.6	4%		
		5	33 WA1 2.42	33 WA1	2.56	-2.4	6%		
		6	36 WA1 3.63	36 WA1	3.97	2.7	10%		
		7	42 WA1 4.48	42 WA1	5.14	8.4	15%		

Comments

1. An artefact was noted on the tomosynthesis reconstructed slices and some of the projections for the 7cm PMMA image when acquired using a clinical view (see attached image). The artefact was not seen when the same exposure was taken using a flat field tomo view, although this may be an intermittent artefact.
2. In tomosynthesis mode Contrast to Noise Ratios (CNRs) have increased from baseline values and image quality as measured using the CDMAM has also improved. This appears to be due to an increase in Mean Glandular Dose (MGD) from baseline. Doses are within ±25% from baseline values however the MGD for 2cm PMMA is at the remedial limit for 2D mammography, which has been suggested as a reference dose for tomosynthesis.
3. The difference between the displayed MGD and the calculated value is greater than 30% for 2cm PMMA.


Small artefact on 2D uniformity image, also zoomed in



Slice from 7cm PMMA image showing artefact

Appendix 2: QC results

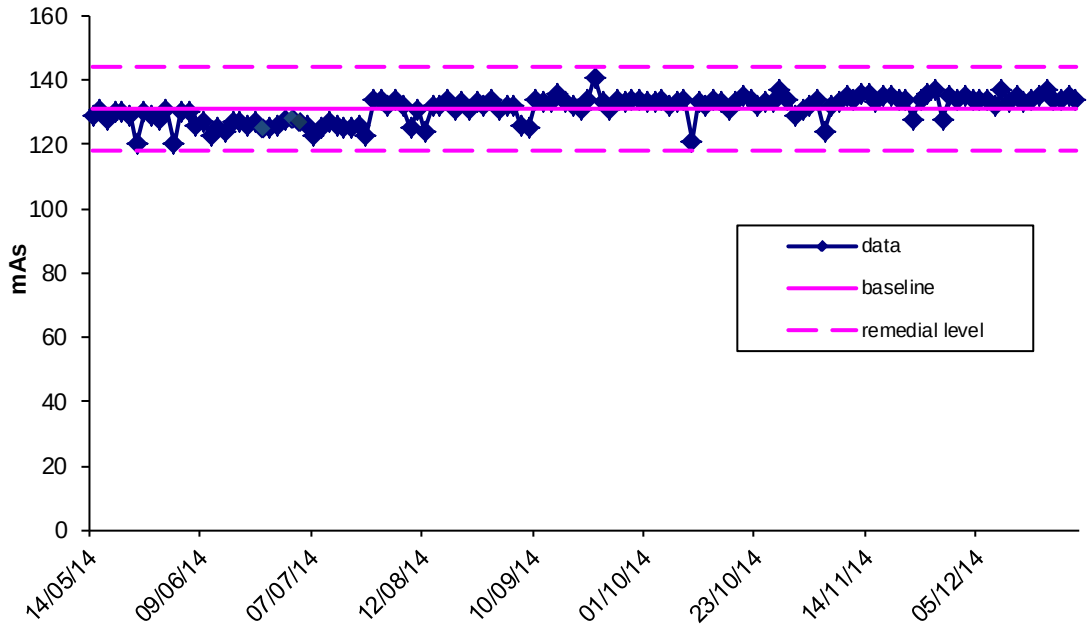


Figure A2.1 mAs recorded daily for 4.5cm of Perspex for 2D imaging

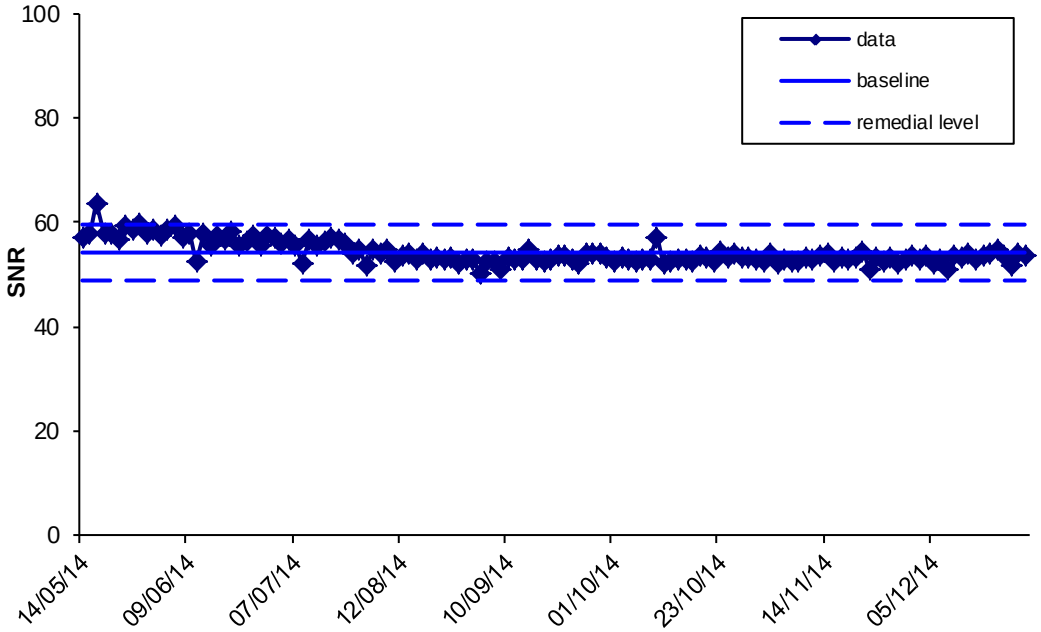


Figure A2.2 Daily SNR measurements for 4.5cm of Perspex for 2D imaging

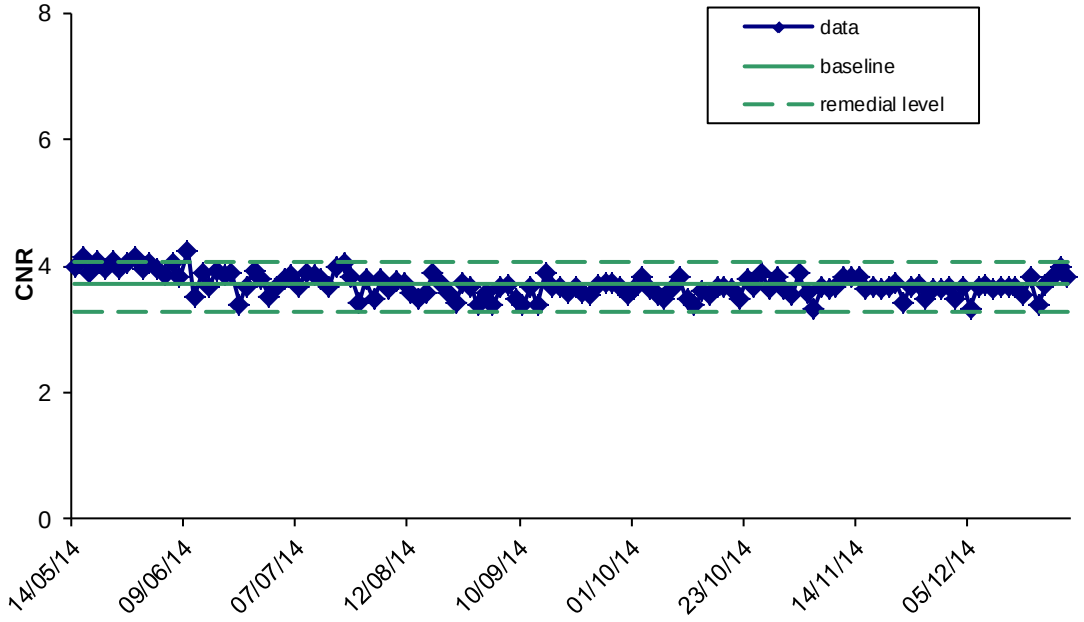


Figure A2.3 Daily CNR measurements for 4.5cm of Perspex for 2D imaging

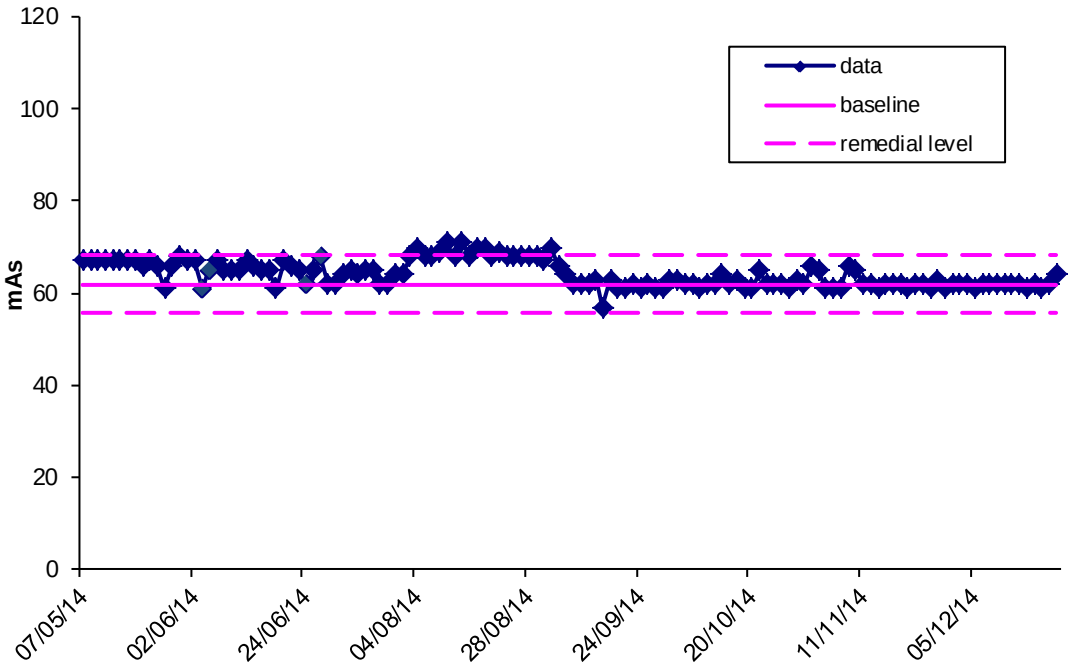


Figure A2.4 mAs recorded daily for 4.5cm of Perspex for tomosynthesis

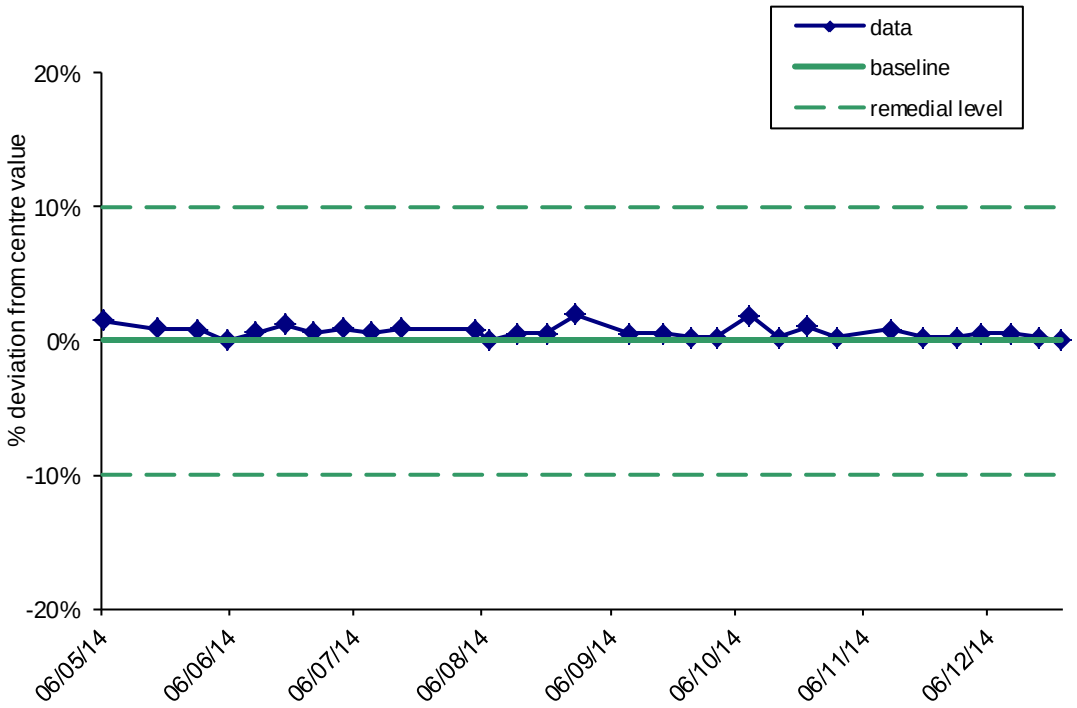


Figure A2.5 Weekly test of uniformity

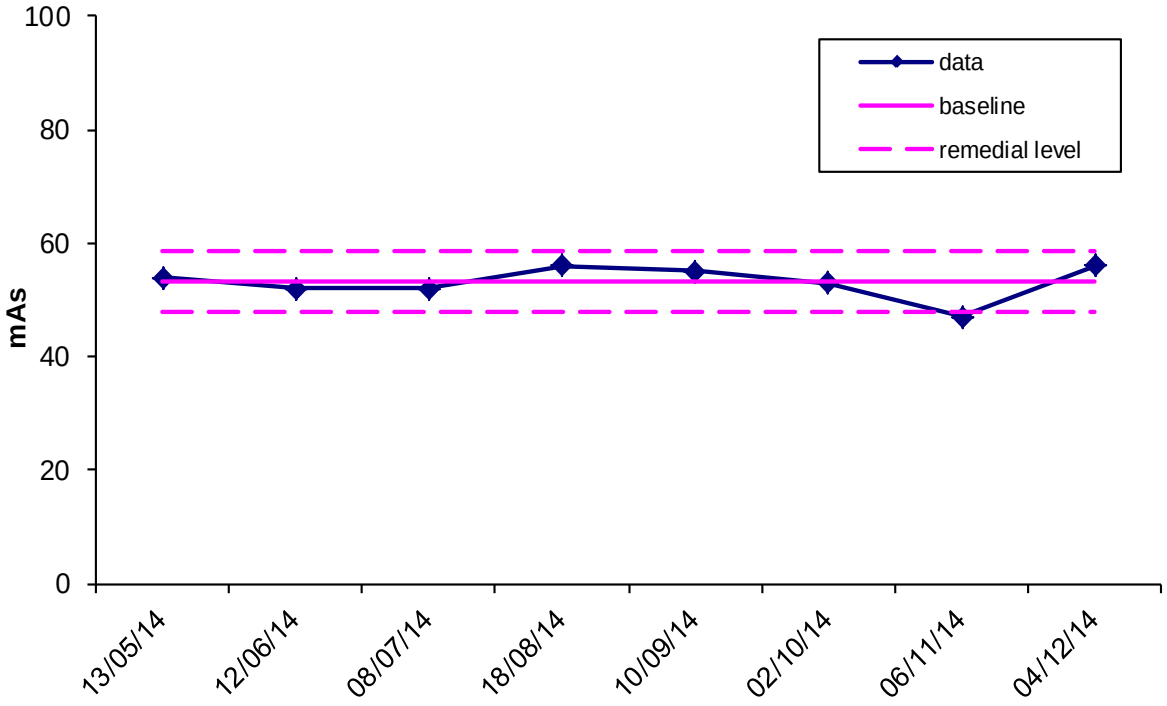


Figure A2.6 mAs recorded monthly for 2cm Perspex for 2D imaging

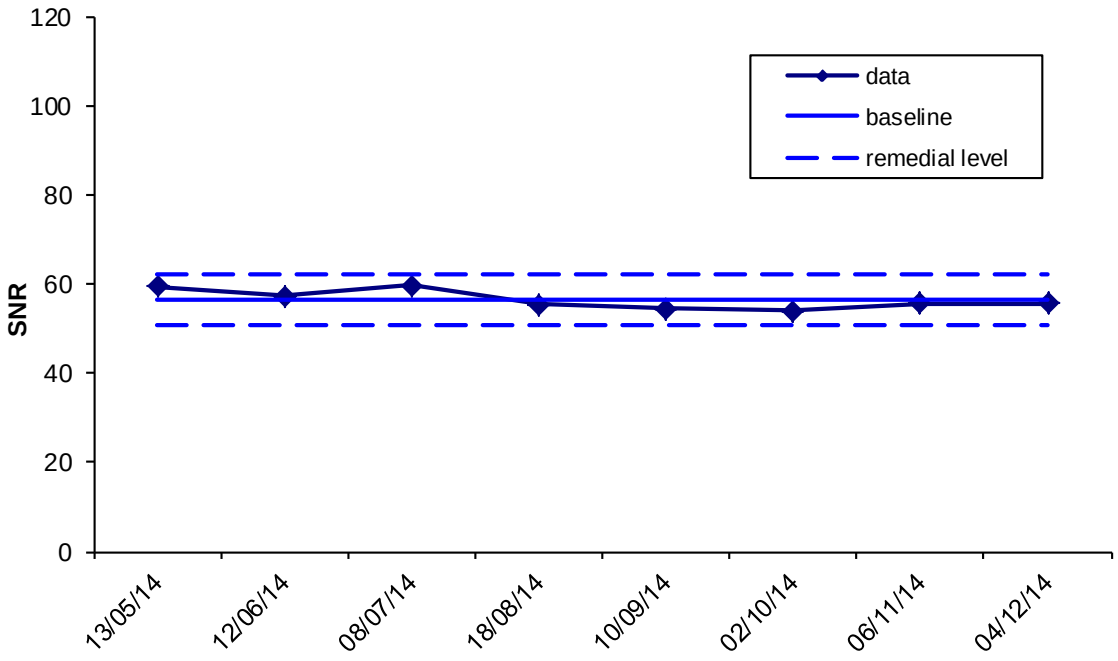


Figure A2.7 Monthly SNR measurements for 2cm of Perspex for 2D imaging

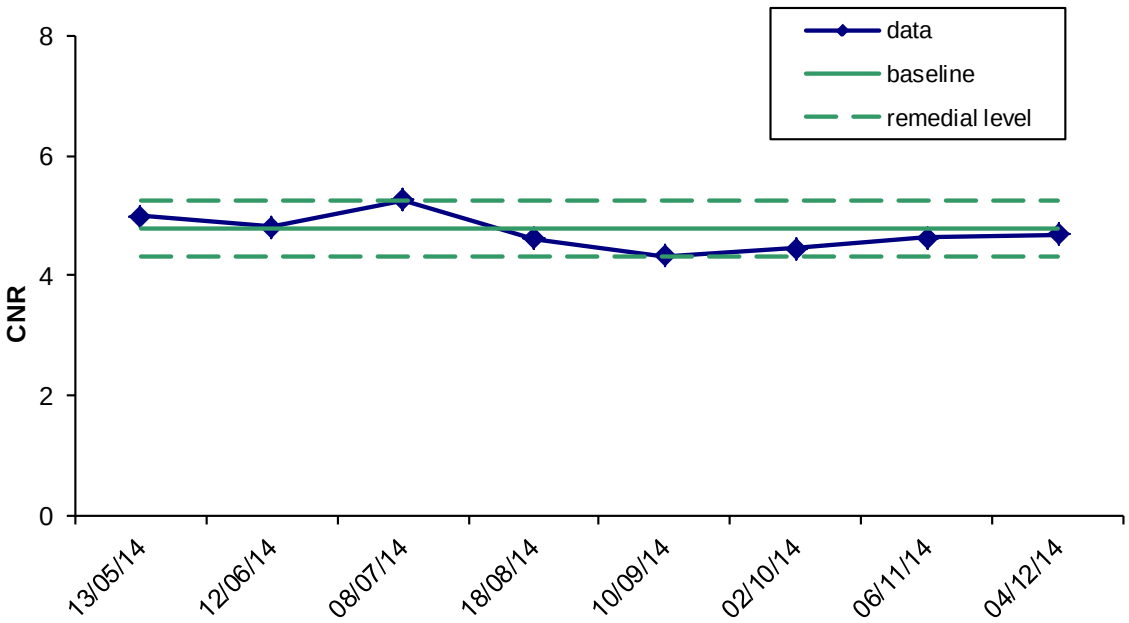


Figure A2.8 Monthly CNR measurements for 2cm of Perspex for 2D imaging

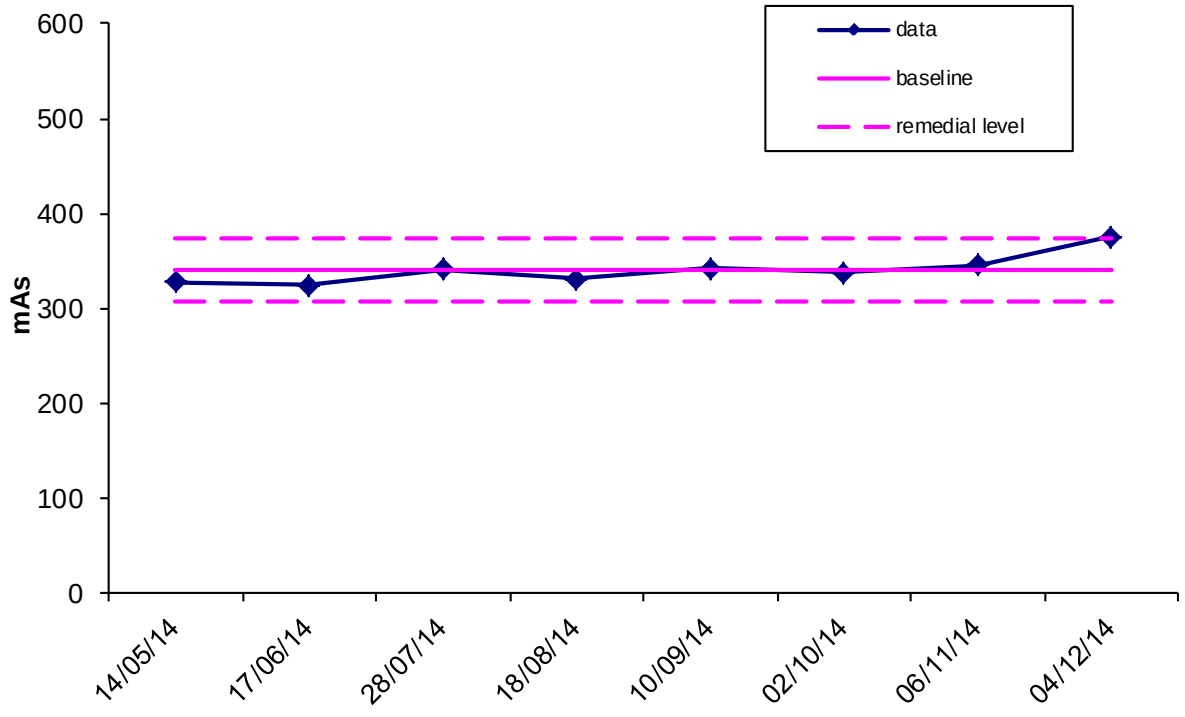


Figure A2.9 mAs recorded monthly for 7cm Perspex for 2D imaging

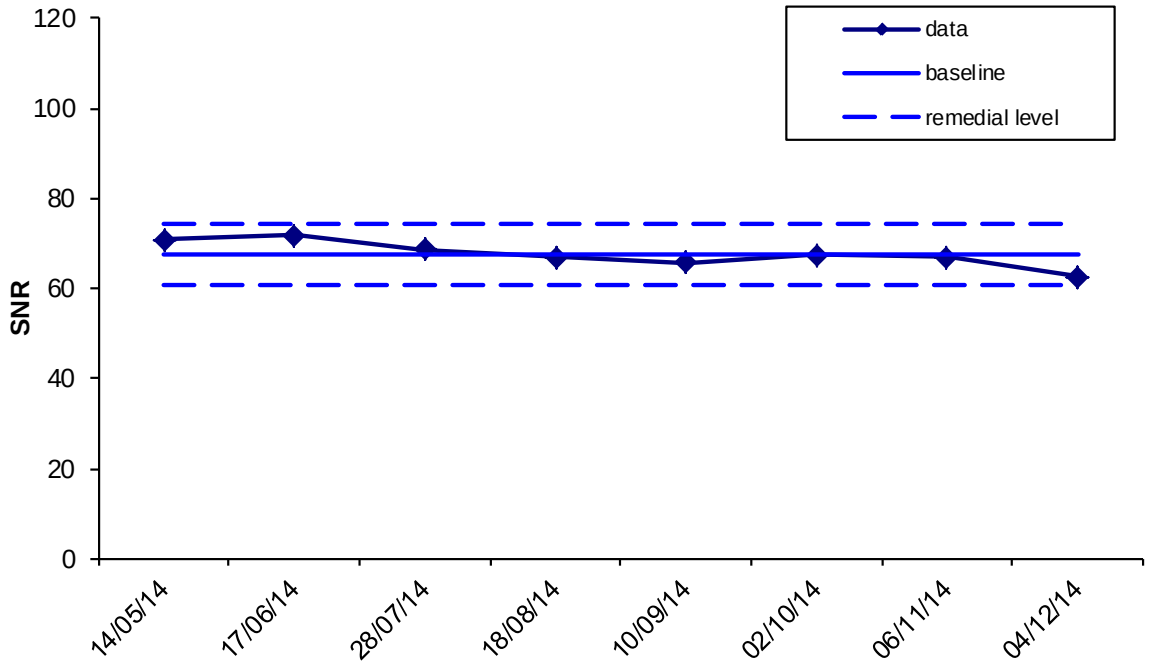


Figure A2.10 Monthly SNR measurements for 7cm of Perspex for 2D imaging

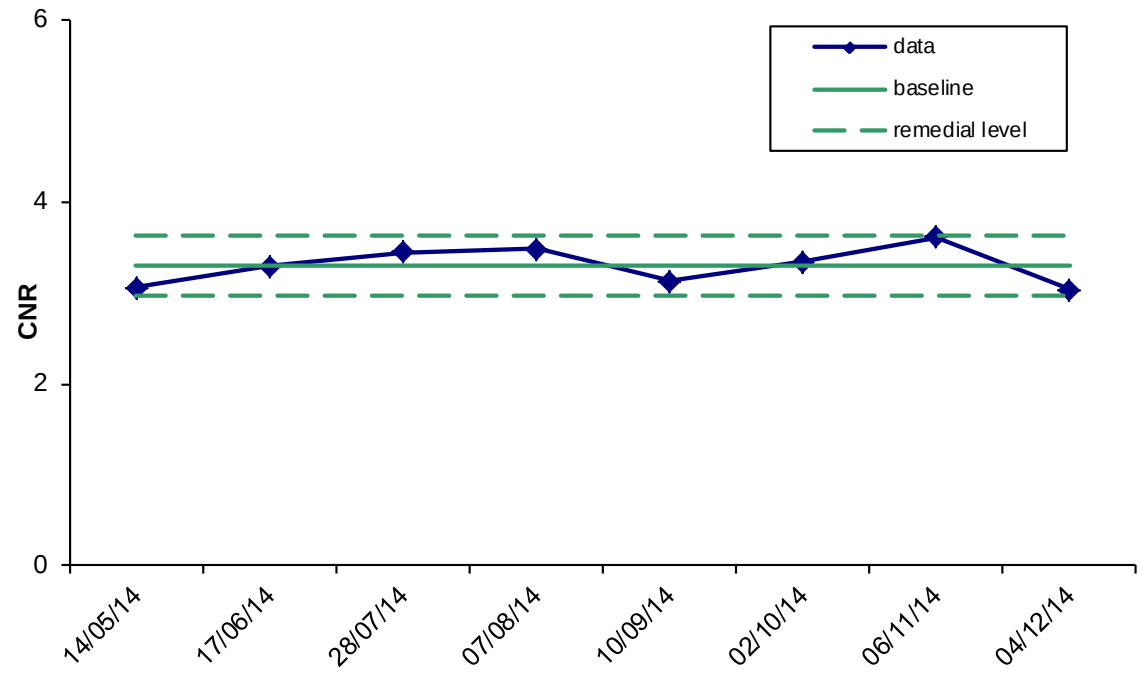


Figure A2.11 Monthly CNR measurements for 7cm of Perspex for 2D imaging

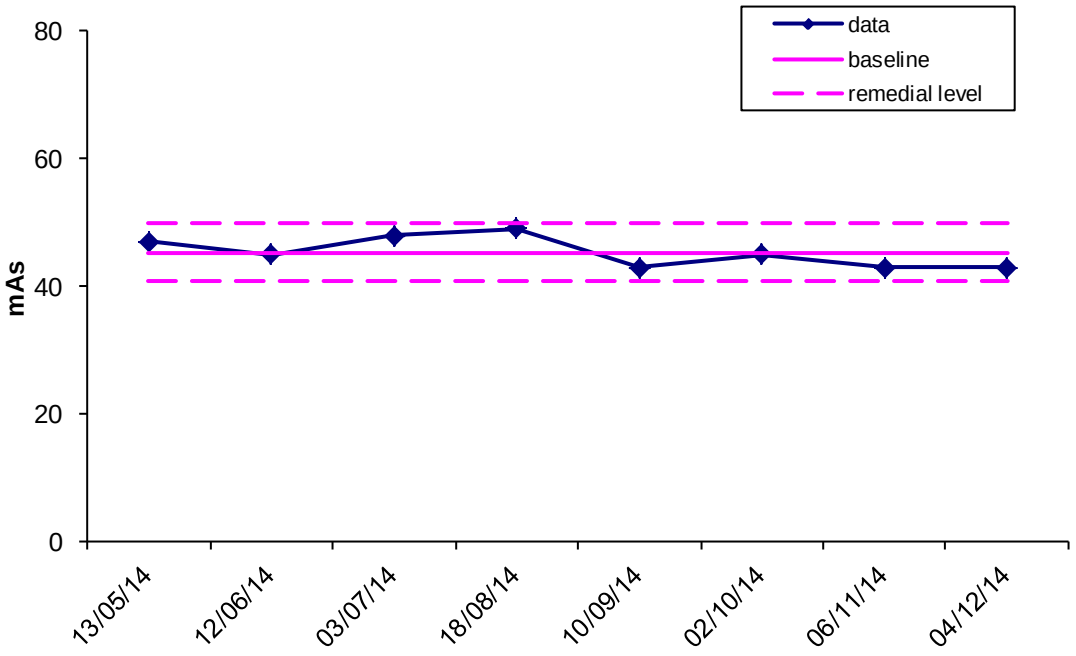


Figure A2.12 mAs recorded monthly for 2cm of Perspex for tomosynthesis

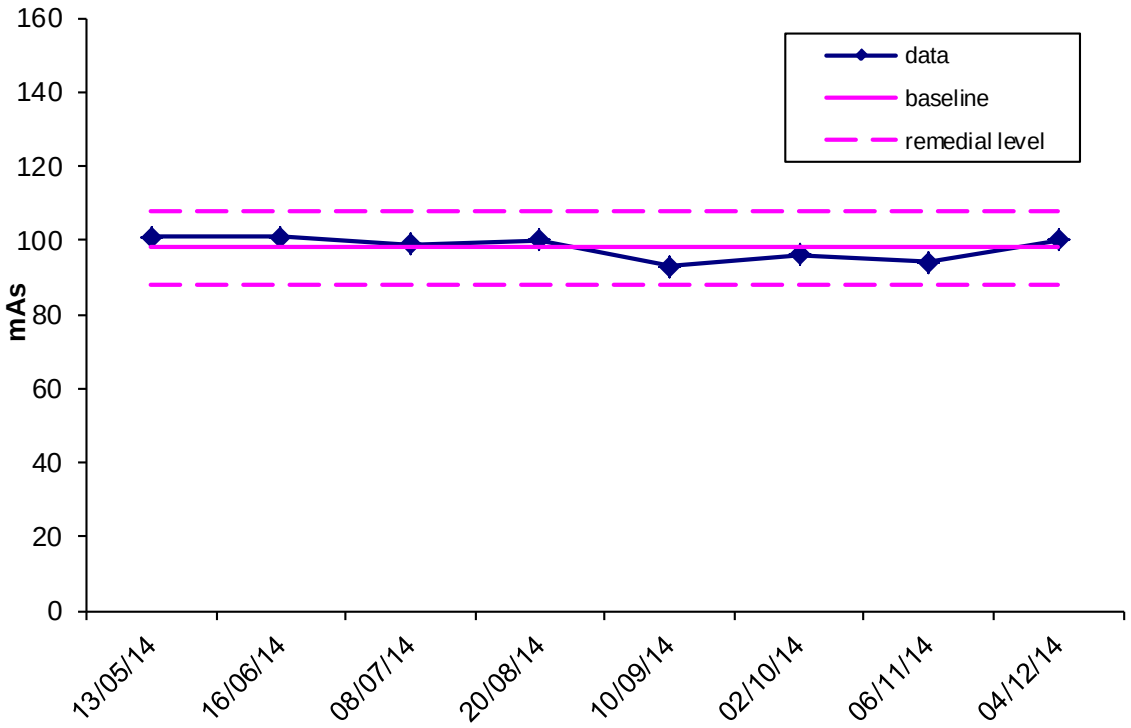


Figure A2.13 mAs recorded monthly for 7cm of Perspex for tomosynthesis

Appendix 3: Fault reports requiring engineer visits

Date	Fault	Action	Downtime (days)
22/07/14	Error codes DET 8.73, 8.69. Exposure not possible	Engineer replaced detector.	5
22/08/14	Half of AWS monitor screen obscured by white lines.	New Barco monitor fitted.	3
10/11/14	Compression thickness incorrectly displayed.	Repaired by engineer.	2

Appendix 4: Radiographers' answers to questionnaire

Table A4.1. Core needle biopsy and general questions

	Comments and observations
How do you rate the supplier's operator manual (if used)?	7 N/A, 4 good, 2 average, 1 satisfactory, 1 poor
Would you prefer an in-house simplified version?	4 N/A, 10 yes, 1 no
How good was the clinical applications training for tomosynthesis core needle biopsy provided by the supplier?	1 N/A, 4 excellent, 6 good, 3 average, 1 satisfactory
	Not enough time given to this - very rushed over lunch period The rota was favourable to me attending the training The trainer was fantastic and very patient The trainer was excellent Unfortunately I was not in the Jarvis for any of the sessions. I was taught by my colleagues Too many staff to get through the training
How do you rate the ease of use of the equipment for tomosynthesis core needle biopsy?	1 N/A, 1 excellent, 9 good, 4 average
	I cannot comment as I only used it once Good but may become excellent once my proficiency increases
How easy is it to fit/remove the a. stereotactic equipment?	2 excellent, 8 good, 3 average, 2 poor
	Slots in very easily A bit fiddly – there are several functions to perform when fitting/removing It is a bit awkward to fit the screen onto the handle It is really difficult to get off
b. needle guide?	

	1 N/A, 1 excellent, 6 good, 4 average, 1 satisfactory, 2 poor
	It can be difficult to line up first time – may need several attempts Care has to be taken not to over-tighten It is very clumsy – it is hard to locate when changing holders The needle guide winds in the opposite direction
How easy is it to clean the stereotactic equipment?	7 good, 4 average, 1 satisfactory, 3 poor
	The needle guide cannot be immersed in cleaner – therefore, how do you clean it? The display for moving the needle becomes contaminated. We used cling film to keep it clean I don't feel we are cleaning it as well as for normal stereo equipment. We cannot soak in a chemical cleaner to kill off any blood – can only use Clinell wipes Cleaning with Clinell wipes only. The hubs are disposable
How do you rate the ease of rotation of the support arm with the stereotactic equipment fitted and the ease of angulation of X-ray tube assembly?	3 N/A, 1 excellent, 6 good, 3 average, 1 satisfactory, 1 poor
	Not used Not sure I have not used it – so far I only used it at 0º
How do you rate the image quality of the scout for tomosynthesis biopsy?	2 excellent, 12 good, 1 average
	Good for distortions
Were the exposure times acceptable for tomosynthesis biopsy for a. the scout image?	1 N/A, 14 yes
	Really cannot comment – not enough experience
b. images used in directing stereotactic equipment ?	1 N/A, 14 yes
How do you rate the time for an image to appear at the acquisition workstation for tomosynthesis biopsy	

	2 N/A, 2 excellent, 10 good, 1 average
	Very quick Same as conventional biopsy
Were the compression times acceptable for tomosynthesis core biopsy? (If not, explain in comments)	5 N/A, 9 yes, 1 no
	Client is compressed for much longer than usual stereos. Jogging and going to and fro to AWS screen means that it takes much longer This seemed to vary from client to client – so it is very difficult to measure Lengthy due to specimen cabinet being at the other end of the department
How do you find carrying out the calibration tests* for tomosynthesis biopsy equipment? *(Not the QA tests for tomosynthesis)	8 N/A, 1 easy, 3 average, 3 difficult
	Done by QA superintendent Takes a long time Only done once, not familiar enough to say More training/advice required
How do you rate the comfort of women during tomosynthesis biopsy exposures, including acceptability of gantry motion?	1 excellent, 7 good, 6 average, 1 poor
	Should be better if lying down – so needs installation in a larger room Find this very distressing as the room is not suitable No comments made about the moving gantry. Compression is tolerated Seems very acceptable to all the women I have been involved with Seems comparable to standard stereo
How do you rate the image quality of tomosynthesis images for biopsy at the acquisition workstation?	1 excellent, 10 good, 4 average
How do you rate the use of the tomosynthesis biopsy system with the specimen	

cabinet : a. in another room (as now)?	3 N/A, 1 average, 4 satisfactory, 7 poor Takes far too long Insufficient space Needs must! Walking through the department with biopsy samples is never great
b. if it were sited in the same room as X-ray equipment?	4 N/A, 1 excellent, 9 good, 1 average This is the preference – but this is only a trial unit. Should have the cabinet close by in the same room Better in same room
What was your level of confidence in the system for tomosynthesis core needle biopsy?	6 good, 5 average, 1 satisfactory, 3 poor I feel confident, but don't feel it is best for clients Not very as did not use the equipment enough. Long gaps between use meant I lost confidence Lack of training and not enough practice and never observed a biopsy taking place, so confidence low when actually had to assist in performing one. Lucky that the doctor was an advanced practitioner and had experience of radiography side Very little exposure to equipment, so very good considering limited experience Not experienced enough yet Like the new software Average for calcium with what I have seen
Were there any potential hazards during tomosynthesis core needle biopsy to: a. you?	1 N/A, 3 yes, 11 no Not used enough to comment Small cramped space means moving around very difficult/bad especially if client is recumbent Lack of space in room - potential poor posture of radiographer
b. the woman?	1 N/A, 3 yes, 11 no No - provided clear explanation including gantry movement

	given prior Limited space to move around especially if lady is supine Difficult position for woman Difficult if you want to release compression because you want to do it manually not by using the foot pedal
How do you rate tomosynthesis biopsy compared to conventional biopsy?	1 N/A, 2 excellent, 6 good, 4 average, 2 satisfactory Conventional stereos for me go much quicker, slicker and more efficient Better for distortion. Does not seem as good as conventional for calcium Sure it will be fine, just need more practice For distortion excellent. Coarse calcium as good as conventional. Fine calcium not as good. Good and quick for radiographers, but more training needed Does not seem very accurate for calcs Less familiar, therefore appears more difficult - room too small Poor for calcs
Any additional comments on tomosynthesis core needle biopsies	Software upgrade to 1.8.2 is much better in terms of image quality and ease of use Ladies tolerate the procedure well Having to release compression by foot means it is a little sudden for client More use needed for me

Table A4.2. Vacuum biopsies

	Comments and Observations
How do you rate the supplier's operator manual (if used)?	11 N/A, 2 good, 2 poor
Would you prefer an in-house simplified version?	11 N/A, 3 yes, 1 no
	Can't comment Should be able to use the operator manual I think I would yes I did not see one, but would like one
How good was the clinical applications training for tomosynthesis vacuum biopsy provided by the supplier?	7 N/A, 2 excellent, 3 good, 1 average, 2 satisfactory
	Very little training given
How do you rate the ease of use of the equipment for tomosynthesis vacuum biopsy?	9 N/A, 2 good, 1 average, 1 satisfactory, 2 poor
	Limited training given Seem rather complicated and temperamental
How easy is it to fit/remove the vacuum biopsy equipment?	10 N/A, 1 excellent, 2 average, 1 satisfactory, 1 poor
	Nurses responsible for this Radiographers only fit needle guide and biopsy module
How easy is it to clean the vacuum biopsy equipment?	11 N/A, 1 good, 1 average, 2 poor
	Nurses responsible for this. Mainly single use.
Comment on the accuracy of positioning the vacuum equipment with tomosynthesis	8 N/A, 3 good, 2 average, 2 satisfactory
	Same as 3D without vacuum

Were the compression times acceptable for tomosynthesis vacuum biopsy? (If not, explain in comments)	9 N/A, 6 yes
What was your level of confidence in the system for vacuum biopsy with tomosynthesis?	8 N/A, 1 excellent, 2 good, 1 average, 1 satisfactory, 2 poor Not used enough – watched. Dare I?
Were there any potential hazards during tomosynthesis vacuum biopsy to: a. you?	9 N/A, 2 yes, 4 no Small space – even tighter with all vacuum equipment
b. the woman?	10 N/A, 4 yes, 1 no Bleeding – compression takes longer As for core biopsy Difficult to do lying down because of space – risk of fainting as equipment in front Additional trauma with potential tissue deficit over biopsy area and increased bleeds Limited training given Potential bleeding
Any additional comments on tomosynthesis vacuum biopsies	Vacuum is tolerable but again better lying down. Therefore bigger room needed. Interested to see results of histology compared with 3 D Never seen or done one Not enough knowledge to answer. Have only observed one case. I am uninformed Have not done any so can't comment Never used Not seen yet

Appendix 5: Radiologists' and advanced practitioners' answers to questionnaire

Table A5.1. Core needle biopsy and general questions

	Comments and Observations
How good were the operator manual instructions for tomosynthesis biopsy? (State N/A if not applicable/not used)	3 N/A, 1 good, 1 average Not used, but would be useful to have a quick reference guide Not used – would have been helpful Not aware that anything was available, did not ask and was not offered Found QA instructions on calibration of needles very difficult
How good was the applications training provided by the supplier for tomosynthesis core needle biopsy?	4 excellent, 3 good Fortunate to be in centre during training – not so for all staff due to rota Much improved with the new software
How do you rate the image handling tools for tomosynthesis biopsy?	1 N/A, 2 excellent, 4 good
How do you rate the ease of using the stereotactic equipment for targeting tomosynthesis core needle biopsy?	1 N/A, 3 excellent, 3 good Better since upgrade 10º angle of approach of needle gives good visualisation of pre-fire position of needle tip and lesion. Space between tube head and biopsy core device and needle holder means that core gun can be rotated through 90º to take samples

How do you rate the use of the display screen of the biopsy control module (touchscreen) for targeting and selecting needle sizes in tomosynthesis core needle biopsy?	3 excellent, 4 good Good facility with nice graphics which show needle and lesion position
How do you rate the controls for adjusting the needle position for multiple sampling (repositioning) in tomosynthesis core needle biopsy with:	
a. original software	1 N/A, 1 good, 3 average,1 satisfactory, 1 poor Clunky to jog needle to reposition multiple passes with separate manipulation of controls Jog mode good
b. updated software	1 N/A, 2 excellent, 4 good Much easier to use this software with automatic repositioning when selecting retarget facility Multi-Pass excellent New Multi-Pass upgrade very helpful
Comment on the accuracy of directing the needle positioning with tomosynthesis	2 excellent, 3 good, 1 average, 1 satisfactory As to be expected from any biopsy system
How do you rate the image quality for the scout for tomosynthesis biopsies?	1 excellent, 5 good, 1 average Good to have a facility to view whole breast as well as the initial targeted area although not used personally For mass/distortion good. For calcium very poor and not reliable

What is your opinion of the following aspects of image quality when using tomosynthesis images for performing core needle biopsies:	
a. contrast	1 N/A, 1 excellent, 4 good, 1 average Faint calcification can be very difficult to see. Personal experience when two images were pixellated and almost undiagnostic. No cause identified from further investigations.
b. sharpness	2 N/A, 1 excellent, 3 good, 1 average Excellent for distortions
How do you rate the time for images to appear on the screen in using tomosynthesis to direct the needle for core biopsies?	6 excellent, 1 good Very fast
What is your impression of the quality of images provided by the tomosynthesis core needle biopsy system?	3 excellent, 3 good, 1 average Excellent for distortions
What is your overall level of satisfaction with using this tomosynthesis core needle biopsy system?	1 excellent, 5 good, 1 average Liked Multi-Pass upgrade.
How do you rate tomosynthesis biopsy compared with conventional biopsy?	2 N/A, 3 excellent, 2 good Quicker and easier particularly for lesions previously had been better seen as one pair – with tomo easier to target Better for distortion, ISQ and worse for calcification Excellent for distortion. Good for calcium. Not so good for fine calcium (poor) As good as – but not necessarily better
Any additional comments on	

tomosynthesis core needle biopsies	The new software helps very much in targeting lesions – much more user friendly

Table A5.2. Vacuum biopsy

	Comments and Observations
How good was the applications training provided by the supplier for tomosynthesis vacuum biopsy	2 N/A, 4 excellent, 1 good
How easy was it to use the equipment for directing the tomosynthesis vacuum biopsy?	2 N/A, 3 excellent, 2 good A quick reference guide would be good
How do you rate the time for images to appear on the screen in using tomosynthesis to direct vacuum biopsies?	2 N/A, 4 excellent, 1 good As for core
Comment on the accuracy of directing vacuum biopsies with tomosynthesis	3 N/A, 4 excellent Difficult with diffuse calcium but very good with distortions
Any additional comments on tomosynthesis vacuum biopsies	Very easy to use, preferable to conventional stereo. Good patient feedback, two patients who had initial conventional stereo biopsies found vacuum less painful/uncomfortable although they had more bruises May be helpful for nursing staff to comment on their increased role to support