Public Health England

NHS

NHS Breast Screening Programme Equipment Report 1602

Practical evaluation of Fujifilm AMULET Innovality digital mammography system

February 2017

Public Health England leads the NHS Screening Programmes

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About this document

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Contents

Executive summary

The purpose of this evaluation was to assess the practical performance of the Fujifilm AMULET Innovality digital mammography system, in 2D mode. It was found to be suitable for use in the screening and assessment of women within the NHS Breast Screening Programme (NHSBSP).

The evaluation was carried out between March and July 2014. The system was reliable throughout this period; Quality control (QC) results were stable and within limits. The system was fully integrated with the breast unit's PACS and with the National Breast Screening System (NBSS).

The Innovality performed well and the radiographers found it easy to use after their initial applications training. They particularly liked the special Fit Sweet paddle, which was comfortable for women, and the iAEC which made it very easy to image breasts with implants. Some difficulties were reported with changing the paddles and with increasing compression slowly enough. Screening times averaged 6 minutes per woman, and could have been shorter if changing facilities were available.

Image quality was assessed as good or excellent for the majority of screening and assessment images, with none poor or inadequate.

A dose survey was carried out as part of this evaluation. The average mean glandular dose for 50-60mm breasts was 1.18mGy, which is well within the national diagnostic reference level.

1. Introduction

1.1 Evaluation centre and timeline

The Breast Unit at Barnsley Hospital serves a population of approximately 38,000 women, of screening age between 47 and 70, every year. The unit is a dedicated static site which provides services for breast screening and assessment as well as for symptomatic imaging. Assessment of recalled screening women is carried out on site every week.

The evaluation of the Fujifilm AMULET Innovality digital mammography system took place over the period of April to July 2014. It was carried out following the guidelines published by the NHS Breast Screening Programme[1]. The Innovality has tomosynthesis capability, but only the 2D mode was evaluated at Barnsley.

1.2 Equipment evaluated

1.2.1 X-ray set and workstation

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

The mammography gantry comprises of an automatically controlled C-arm with push button controls on either side. It also has foot pedals to adjust the gantry height and compression plate height. Integrated ambient lighting at the rear of the gantry is intended to help provide a relaxed environment during operation.

Additional operator controls are located on the C-arm, together with a display showing the compression force, compressed thickness and selected angulation. An additional display at the foot of the gantry shows the patient demographics. It changes automatically to show the compression force, compressed breast thickness and selected angulation when the foot controls are operated.

The Innovality is powered by a single phase voltage of 220/240V with a separate generator to the gantry. It has an amorphous selenium detector housed within a moulded carbon fibre casing, utilising optical switching technology. It uses a tungsten target with rhodium and aluminium filters but only rhodium is used for 2D operation.

The acquisition workstation (AWS) consists of two 3MP monitors mounted on swing arms, with a keyboard and a separate control pad. It has an integrated radiation shield within the console. A footswitch for exposure at workstation was provided. This operated satisfactorily, but was rarely used in the evaluation.

A “sleep” mode, operated by a sliding on/off button, was enabled for day-to-day operation. There was also a facility for shutdown which could be used if necessary.

Figure 1. Fujifilm AMULET Innovality X-ray set

1.2.2. Paddles

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

The 24cm x 30cm Fit Sweet paddle, shown in Figure 2, was in routine use. This paddle is somewhat flexible and compresses the breast in 2 planes – posterior to anterior

(chest wall to nipple) and lateral to medial aspect. It is designed to maintain good compression while minimising pain.

The 18cm x 24cm shifting paddle was generally used for the smaller breasts. When used in the oblique position, the paddle shifted to the appropriate side.

A 24cm x 30cm fixed paddle with a high edge was also available.

Specialist paddles, such as a 9cm x 10cm magnification paddle and a spot compression paddle, were also provided for the evaluation.

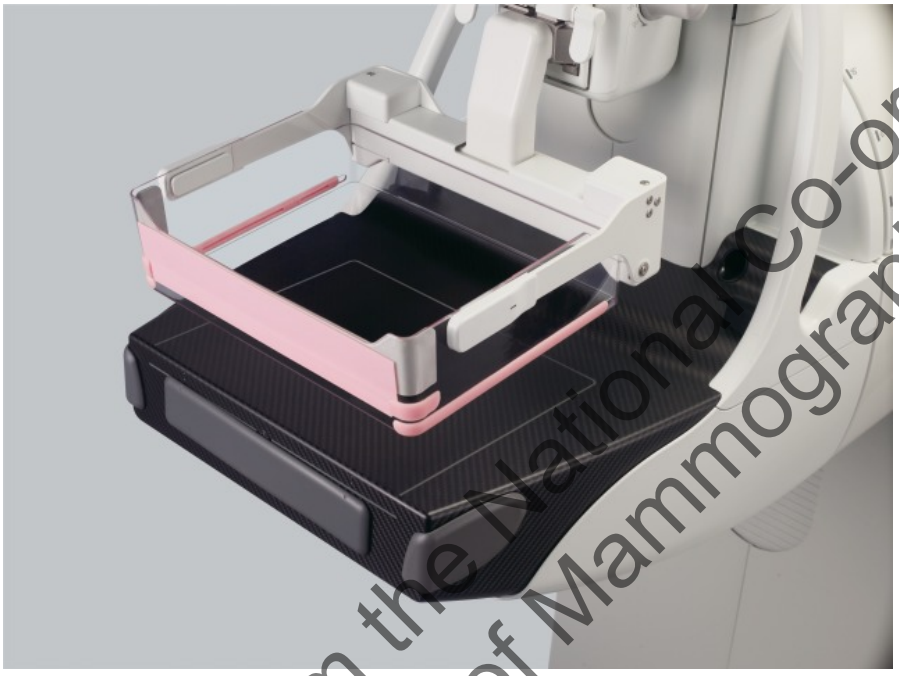

Figure 2. Fit Sweet paddle

1.2.3 Accessories

Different accessories were available for the evaluation. These included wall mounting for the paddles and a magnification table which provided 1.8x magnification.

1.2.4 Automatic exposure control

The automatic exposure control (AEC) for the Innovality operates in two different modes: AEC and iAEC. Three different dose settings can be used with either mode: N (Normal), L (Low) and H (High). Exposures under both AEC modes are determined by a pre-exposure which does not contribute to the image and is excluded from the post-exposure mAs.

In iAEC mode the pixel values from the whole pre-exposure image are used to determine the breast area, composition (dense, fatty or implant), and the position of the dense area. These values are used to determine the target/filter combination, tube voltage and mAs. Figure 3 shows the dense tissue identified in unaugmented and augmented breasts. Women with breast augmentation can therefore be imaged in the same manner as for normal breast tissue, without having to select specific parameters.

The AEC mode uses pixel values from a fixed region to determine the correct exposure parameters. It is a possible option for quality control tests, and was not used clinically. The operator has the option of selecting manual or semi-automatic exposures.

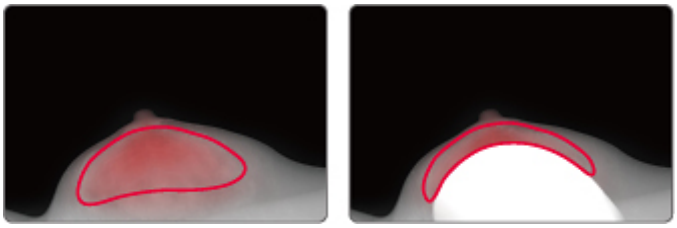

Figure 3. Dense areas selected by iAEC

1.2.5 Integration with NBSS and PACS

The Innovality was fully integrated into the existing Visbion PACS system used by the breast unit. This allowed the images to be reported alongside images from existing systems within the breast unit.

Integration of the National Breast Screening System (NBSS) with the Visbion PACS was already well established within the unit. There were some setup issues at the beginning which were resolved quickly and the Innovality integrated well with both NBSS and PACS.

The daily screening work list was sent directly to the AWS. The operators were able to select the client details and any prior images for the women who attended the clinic. When the examination was completed, the images were forwarded automatically to the PACS.

1.3 Objectives

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

The detailed objectives were as follows:

- to assess the reliability of the equipment in a busy screening environment

- to assess the user-friendliness of the equipment
- to assess image quality and dose against national standards
- to assess the efficiency of the interfaces between the equipment and the PACS and NBSS

2. Acceptance testing, commissioning and performance testing

The Innovality was installed in February 2014 alongside the existing Fujifilm imaging systems in one of the imaging rooms in the breast unit.

The commissioning of the system took place in March 2014 for the evaluation. This included integration with both the local screening Visbion PACS and with the main Agfa PACS of the imaging department. The system was also integrated with NBSS. Although the Innovality was an additional system for the breast unit, it was used as the primary system by the evaluation staff.

The acceptance and commissioning tests[2] were carried out by the local medical physics service and the physics reports are included at Appendix 1. This followed a thorough technical evaluation[3] from the National Coordinating Centre for the Physics of Mammography (NCCPM). The practical evaluation only proceeded when the technical evaluation was completed and a formal recommendation from NCCPM to progress was received. NCCPM also advised that the dose setting should be set on H to achieve optimal image quality.

3. Routine quality control

The daily calibration of the Innovality took place automatically once the “sleep” mode on/off button was operated to start the system. The system was ready for quality assurance testing within two and a half minutes.

Routine quality control (QC) was carried out as detailed in the NHSBSP guidelines[4]. Tests were carried out daily, weekly and monthly. All test results were recorded on the North East Yorkshire and Humberside regional QA spreadsheet. Testing was carried out when the unit's other existing Fujifilm systems (AMULETs) were tested, and all took the same time to complete.

3.1 Daily QC tests

A 45mm thick block of Perspex was imaged under AEC at the H dose setting. The values for mAs and signal-to-noise ratio (SNR) are shown in Figures 4 and 5. All the values recorded lie within the recommended remedial limits.

Mean pixel values were also recorded on a daily basis. These are shown in Figure 6. The values lie on almost a straight line, indicating that detector response was nearly constant throughout the evaluation period.

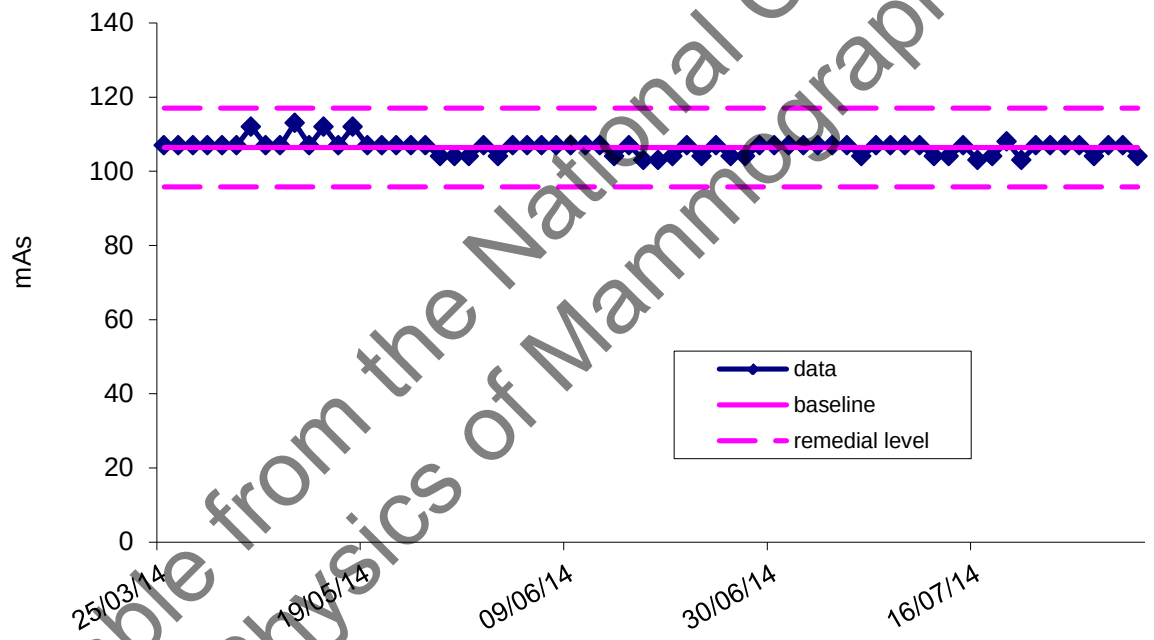

Figure 4. mAs recorded daily for 45mm of Perspex

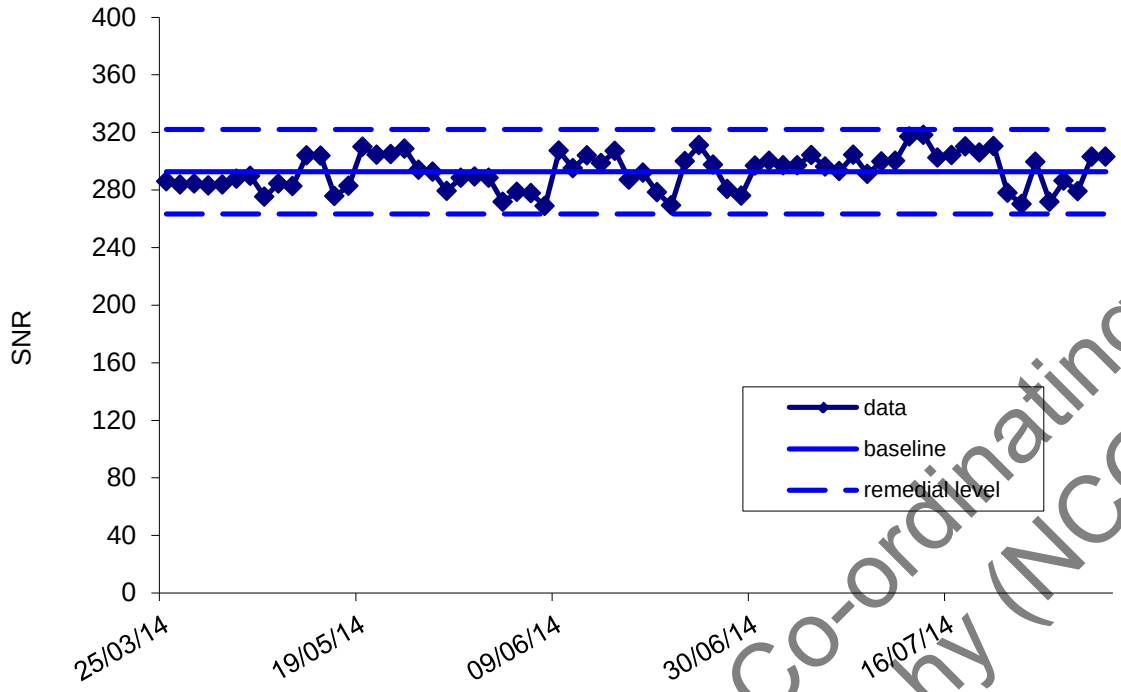

Figure 5. SNR recorded daily for 45mm of Perspex

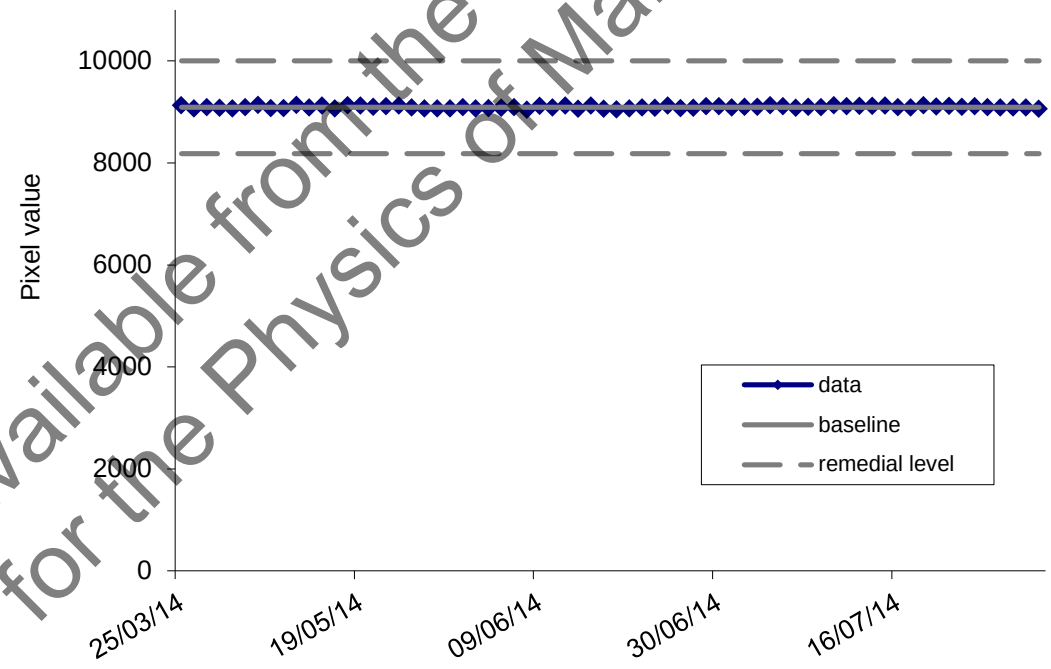

Figure 6. Mean pixel value recorded daily for 45mm of Perspex

3.2 Weekly QC tests

In addition to the daily tests, contrast-to-noise ratios (CNR) were recorded weekly. The results are shown in Figure 7. They were within the remedial levels showing that CNR was stable throughout the evaluation. CNR is one indication of image quality.

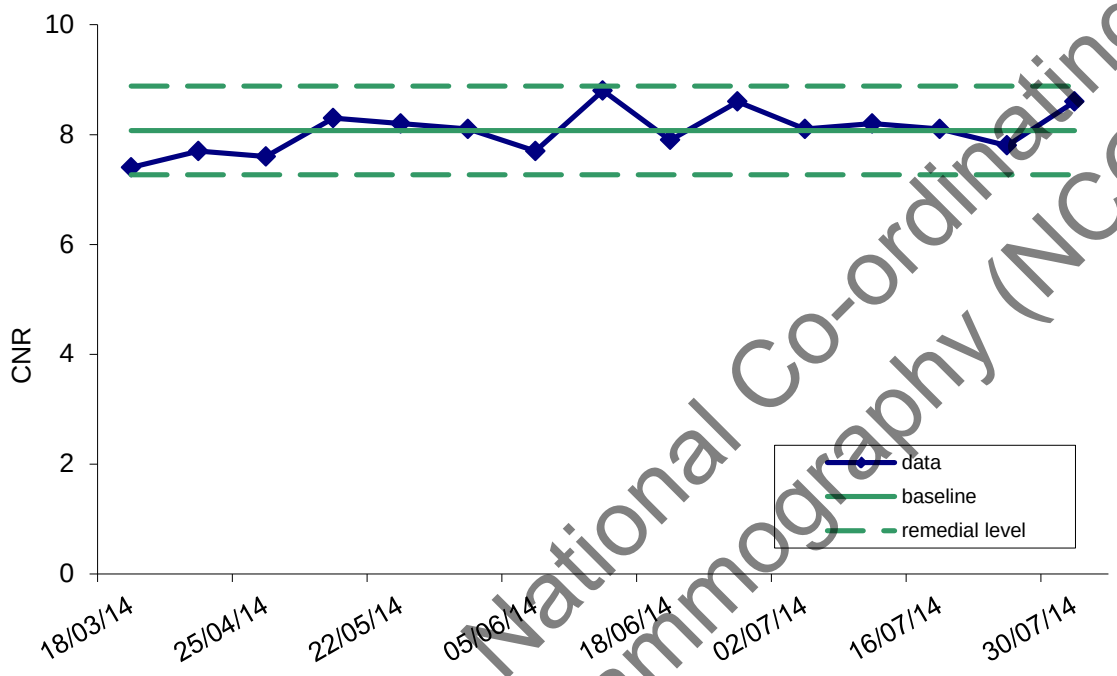

Figure 7. Weekly CNR measurements for 45mm Perspex

Figure 8 shows the results of the weekly uniformity test with some variation throughout the evaluation period, but only one point was just above the upper limit.

The results for image quality measured weekly with a DMAM test object are shown in Figure 9. The figure shows the number of details seen, for a range of detail sizes. There was little variation.

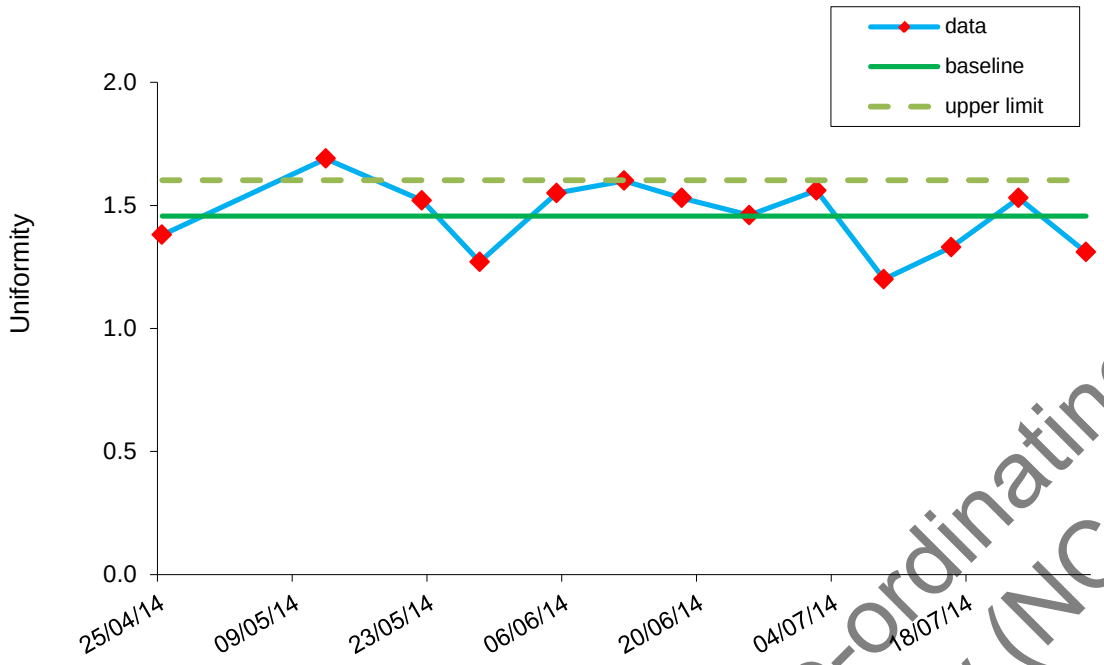

Figure 8. Weekly test of uniformity

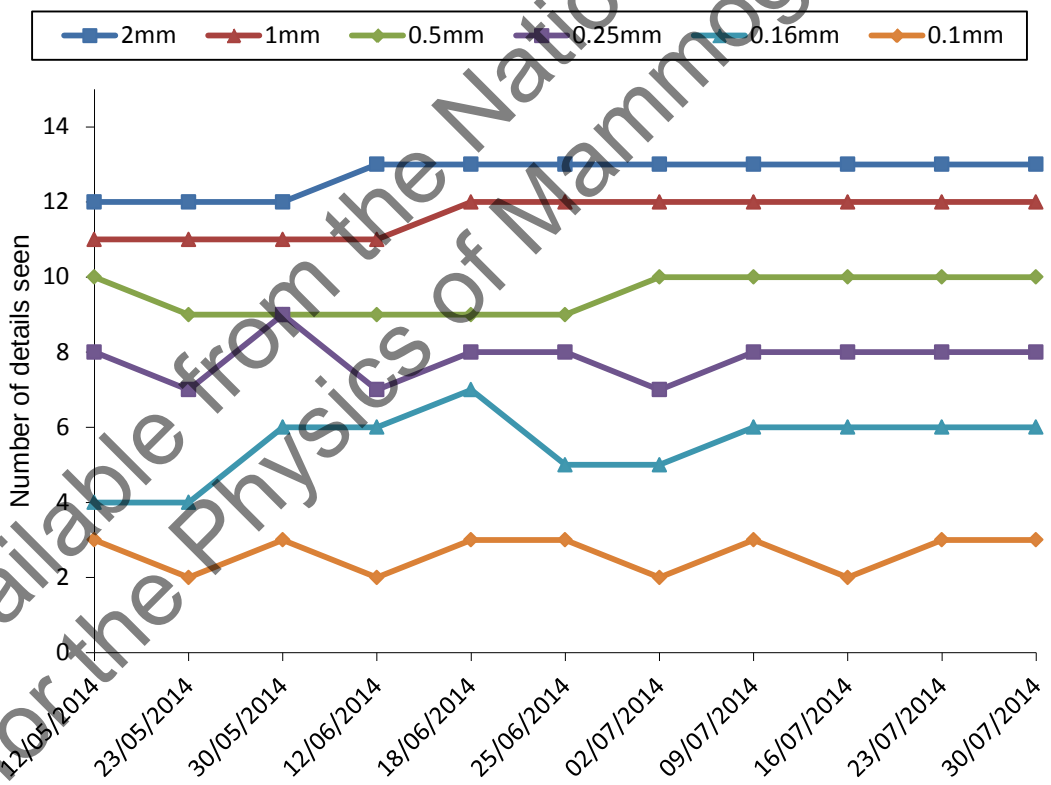

Figure 9. Weekly tests of image quality measured with DMAM test object

3.3 Monthly QC tests

For the monthly tests, Perspex blocks of thickness 20mm and 70mm were exposed under AEC at the H dose setting and the mAs was recorded. The SNR and CNR were also determined for both thicknesses. The results in Figures 10 to 15 show the stability of the system during the evaluation period. All results were within the remedial limits.

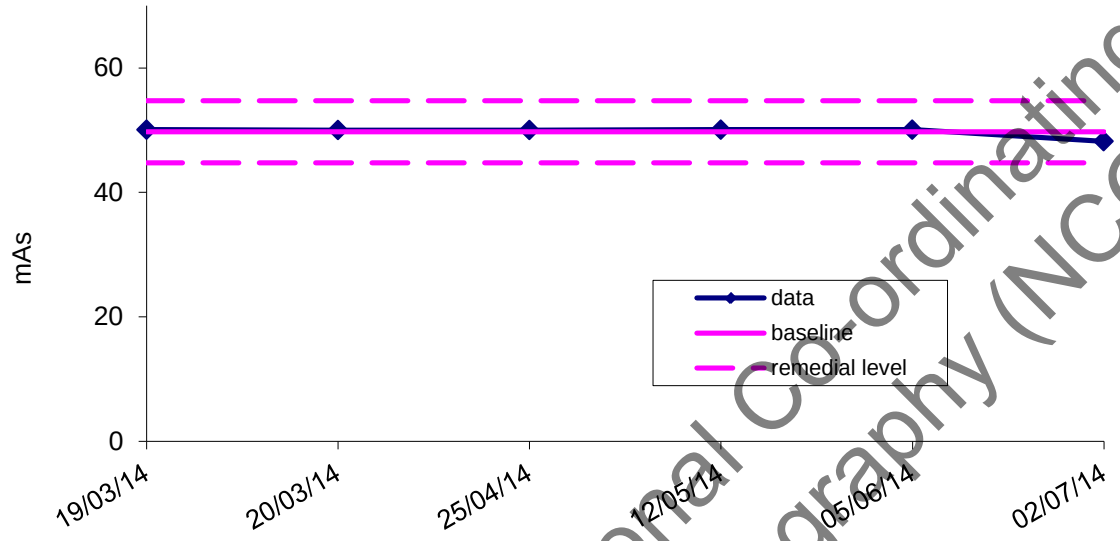

Figure 10. mAs recorded monthly for 20mm Perspex

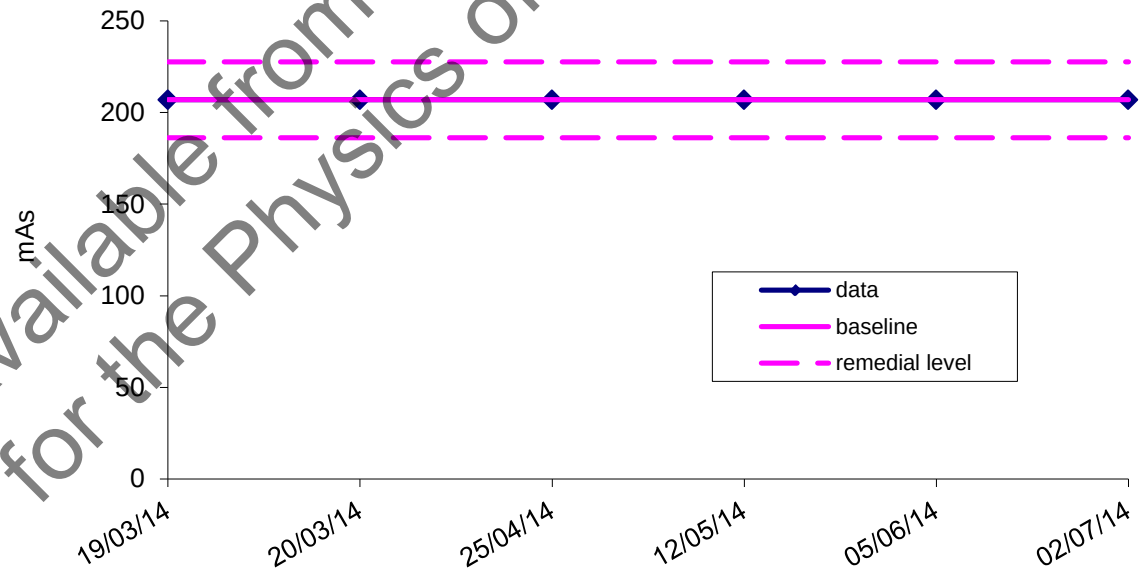

Figure 11. mAs recorded monthly for 70mm Perspex

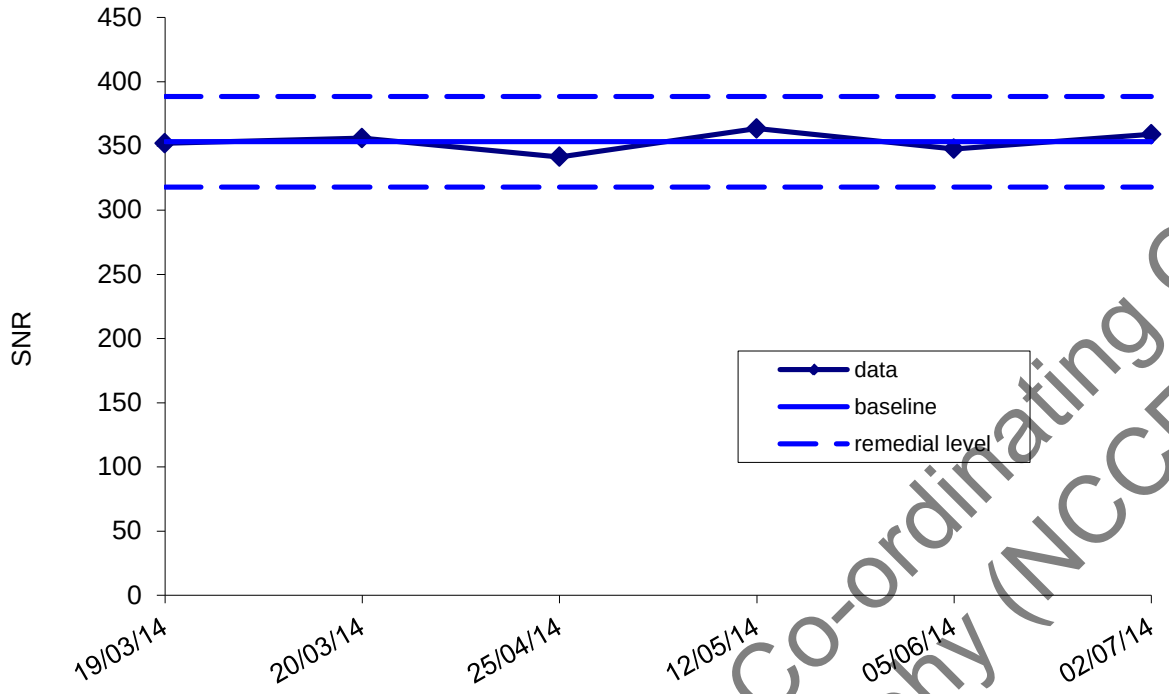

Figure 12. Monthly SNR measurements for 20mm Perspex

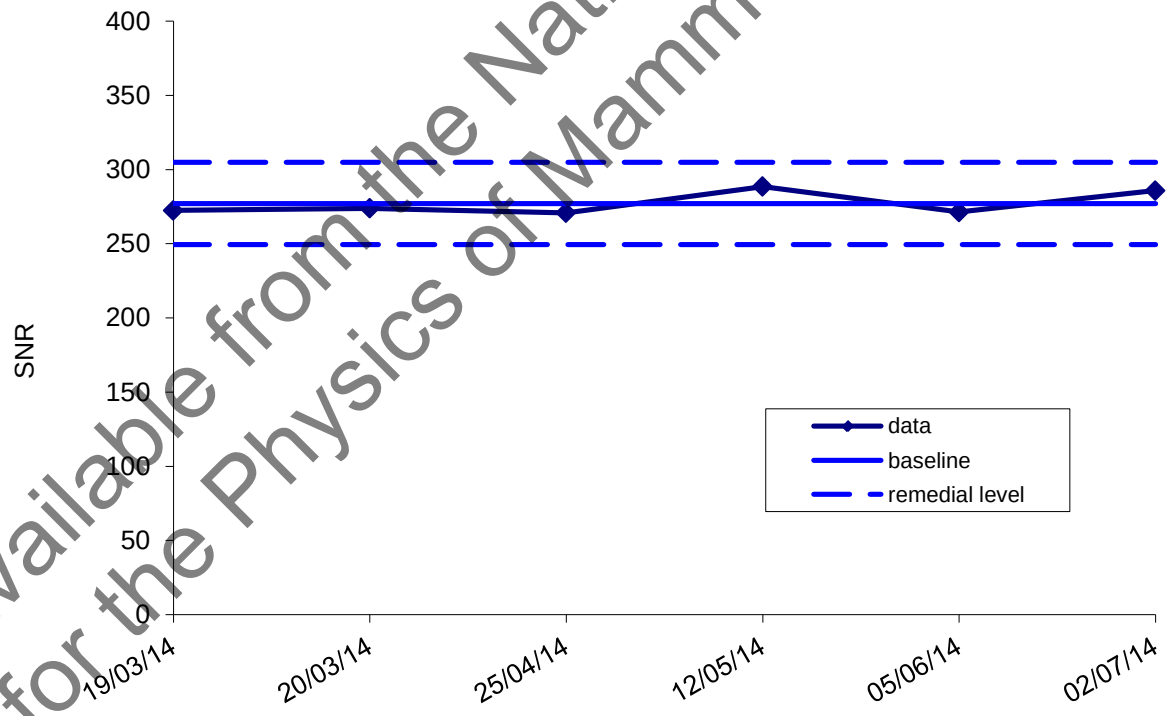

Figure 13. Monthly SNR measurements for 70mm Perspex

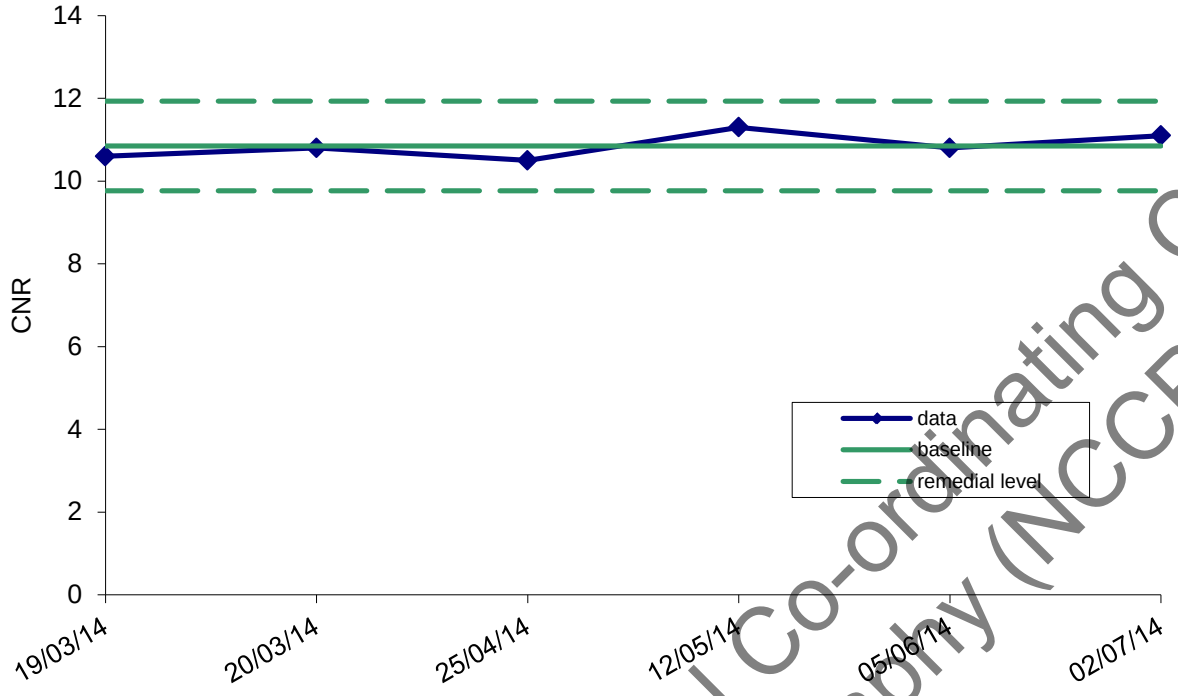

Figure 14. Monthly CNR measurements for 20mm Perspex

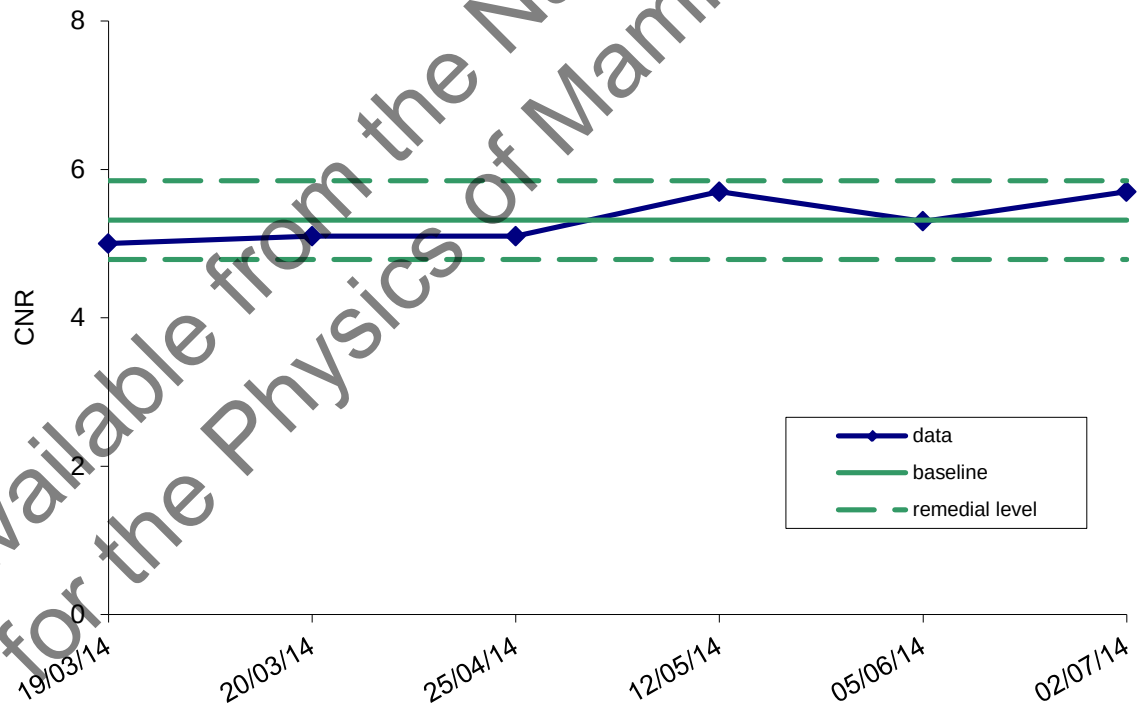

Figure 15. Monthly CNR measurements for 70mm Perspex

4. Data on screening carried out

4.1 Clinic throughput

Full day screening clinics were scheduled on 3 days every week. The daily schedule was from 9am to 5pm with appointments booked at intervals of 5 minutes. Additional appointments were inserted into the schedule when required and screening was continuous throughout the day. The average clinic throughput was approximately 75 to 80 women.

The clinics were staffed by radiographers and assistant practitioners. No one was allocated specifically to the Innovality, and it was used in rotation with other existing equipment.

Every week, there was one full day of assessment for women recalled from screening. The evaluation team used the Innovality as the main imaging system, in preference to the existing equipment, to keep the clinic throughput going.

There were no changing facilities available where the system was located. Women undressed in the room itself after confirming their demographic details. The evaluation team thought that imaging times could have been faster if changing facilities had been attached to the room.

4.2 Clinical dose audit

Exposure details for the images taken for 100 women in June 2014 were recorded for a dose survey. The dose calculator from NCCPM was used to analyse the data and calculate the average mean glandular dose (MGD). This calculator uses data published by Dance et al.[5]

Detailed results for this survey are presented in Appendix 2. The average MGD and compressed breast thickness (CBT) are summarised in Table 1.

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

View	Group of women	Average MGD (mGy)	Average CBT (mm)
CC	all	1.17	52
MLO	all	1.35	58
MLO	CBT 50-60mm	1.18	55

The average MGD for the MLO view of 1.18mGy, for 50-60mm thick breasts, compares favourably with the national diagnostic reference level (DRL) of 3.5mGy.[6]

4.3 Imaging times

Radiographers and assistant practitioners were asked to record the time taken for each screening examination. Times ranged from 4 to 14 minutes.

They reported that the speed of imaging was faster than with the existing AMULET X-ray systems. The time for the acquisition of an image took on average 3 seconds less than the time taken with the existing AMULETs. On average it took 6 minutes from a woman entering the room to completion of the examination.

They were also asked to comment on delays experienced within the examination and if these could be attributed to equipment. Comments were recorded for time durations of over 6 minutes. These included, for example, “kyphosis”, “wheelchair” or “difficulty in positioning”.

There was one comment concerning underexposure of one of the oblique projections, probably due to positioning error. The examination was subsequently completed in one of the other rooms. On this occasion, a series of block tests were undertaken and after evaluation of the data, the system was returned back to service. Minimal downtime was experienced.

A review of the comments concluded that the reasons for the longer examination times were client-related and not due to the system.

4.4 Image quality

An audit of image quality was undertaken during the evaluation period by two experienced film readers and one consultant radiologist. Comments were recorded on NHSBSP Equipment Evaluation Form 8 for user assessment of digital image quality.

Twenty sets of images were selected at random to ensure that a representative sample of the screening clinics were analysed. Both incident and prevalent women were sampled.

The readers were asked to make an estimate of the percentage of breast density for each case within the dataset collected. These cases were classified as fatty (0-33%), mixed (34-66%) and dense (67-100%). The proportions found in the 20 cases considered were:

- Fatty: 5 cases - 25%
- Mixed: 8 cases - 40%
- Dense: 7 cases - 35%

The results are shown in Figure 16.

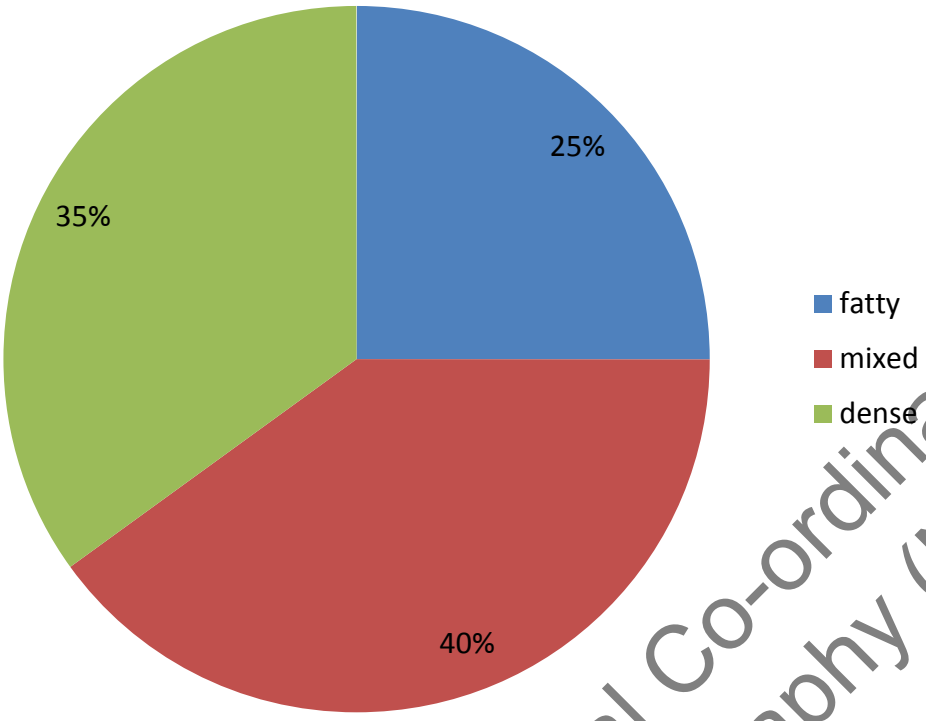

Figure 16. Readers' estimates of breast density

The readers also assessed the contrast for these images. 72% of the cases were rated as satisfactory, with the rest as slightly low contrast or slightly high contrast.

In the assessment of the suitability of image processing, the three readers judged it good or excellent in more than 61% of the cases with another 29% satisfactory. They considered that it was poor for the few remaining cases.

Overall diagnostic value was found to be excellent or good in 74% of cases, with the rest satisfactory. No images were assessed as poor or inadequate.

Diagnostic zoom was rated as good in 92% of cases, and the rest satisfactory.

The results of these assessments are shown in Figures 17 to 20.

Almost all the images were judged to be sharp, with about 3% blurry. None of them were judged to be affected by noise.

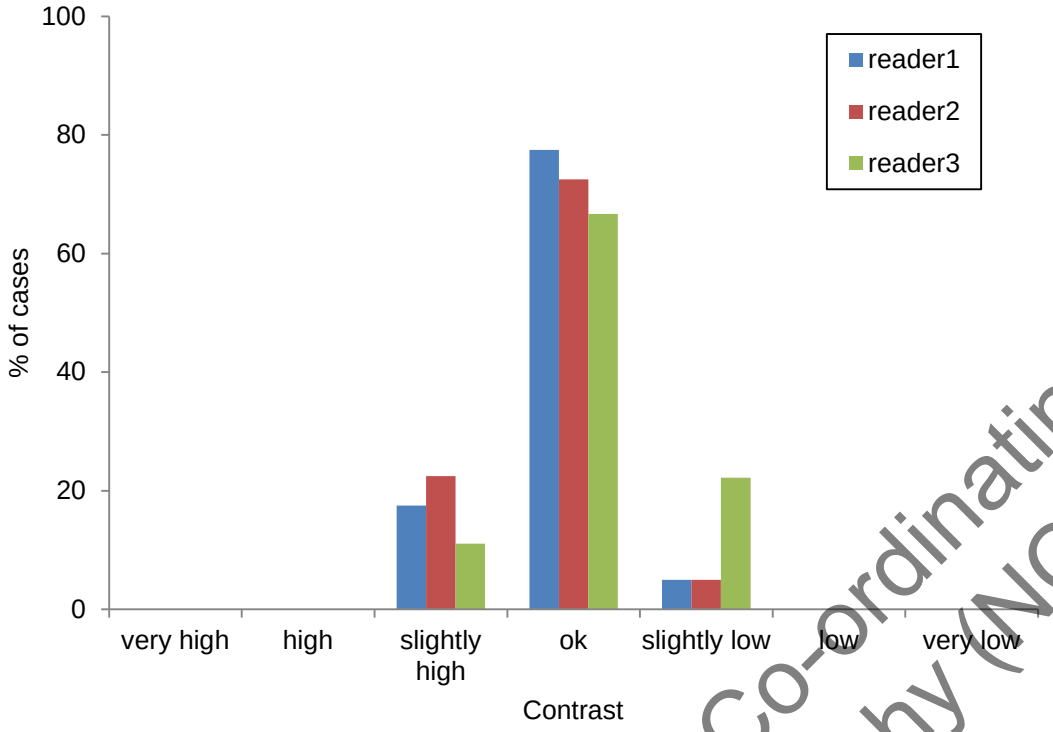

Figure 17. Readers' assessment of contrast

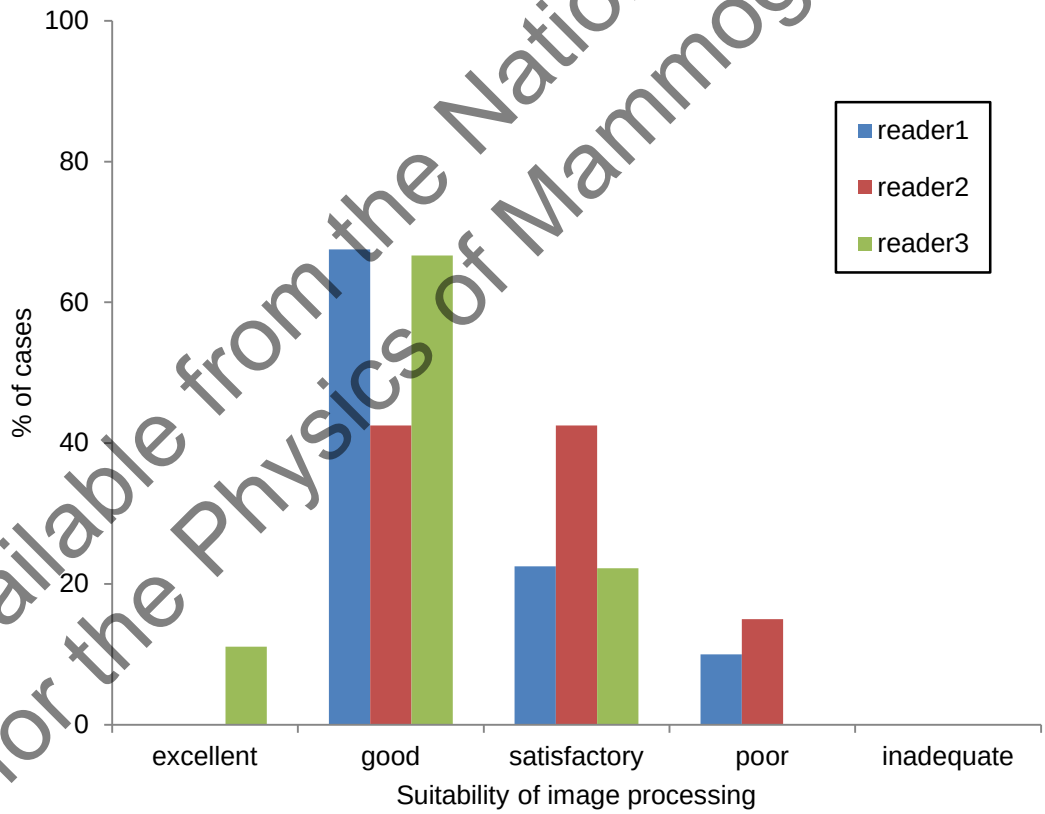

Figure 18. Readers' assessment of suitability of image processing

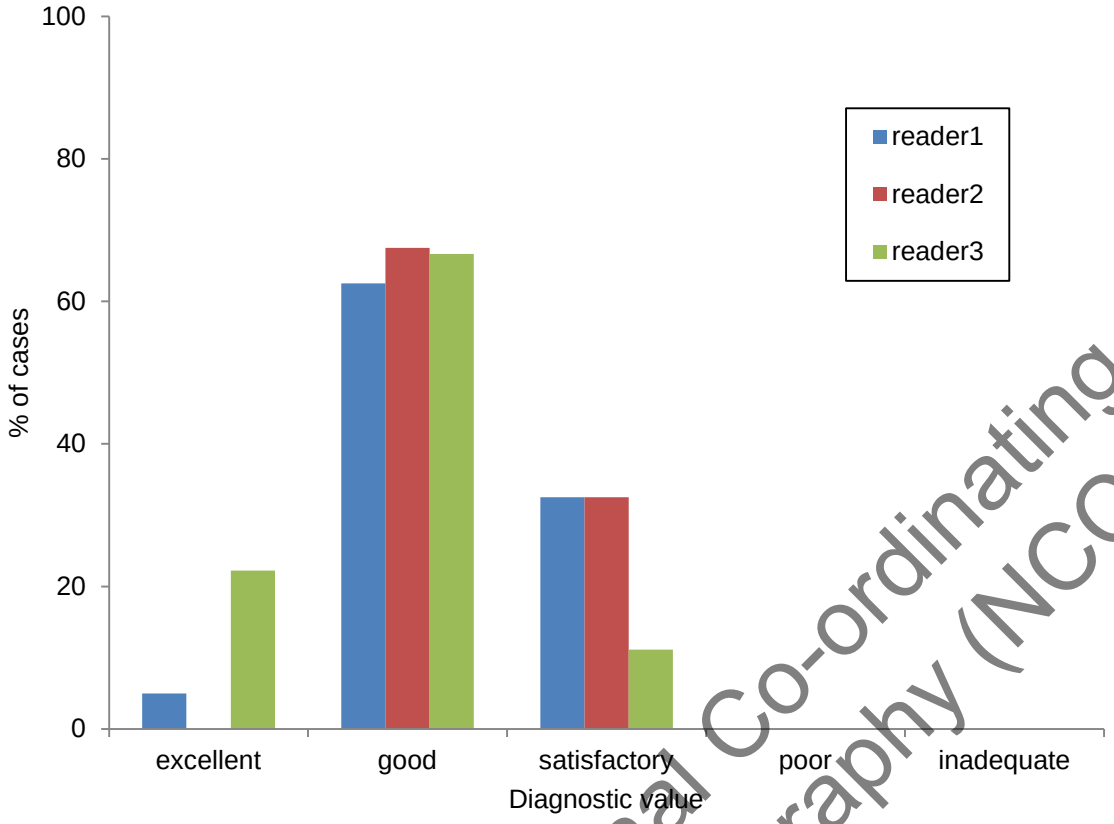

Figure 19. Readers' assessment of overall diagnostic value

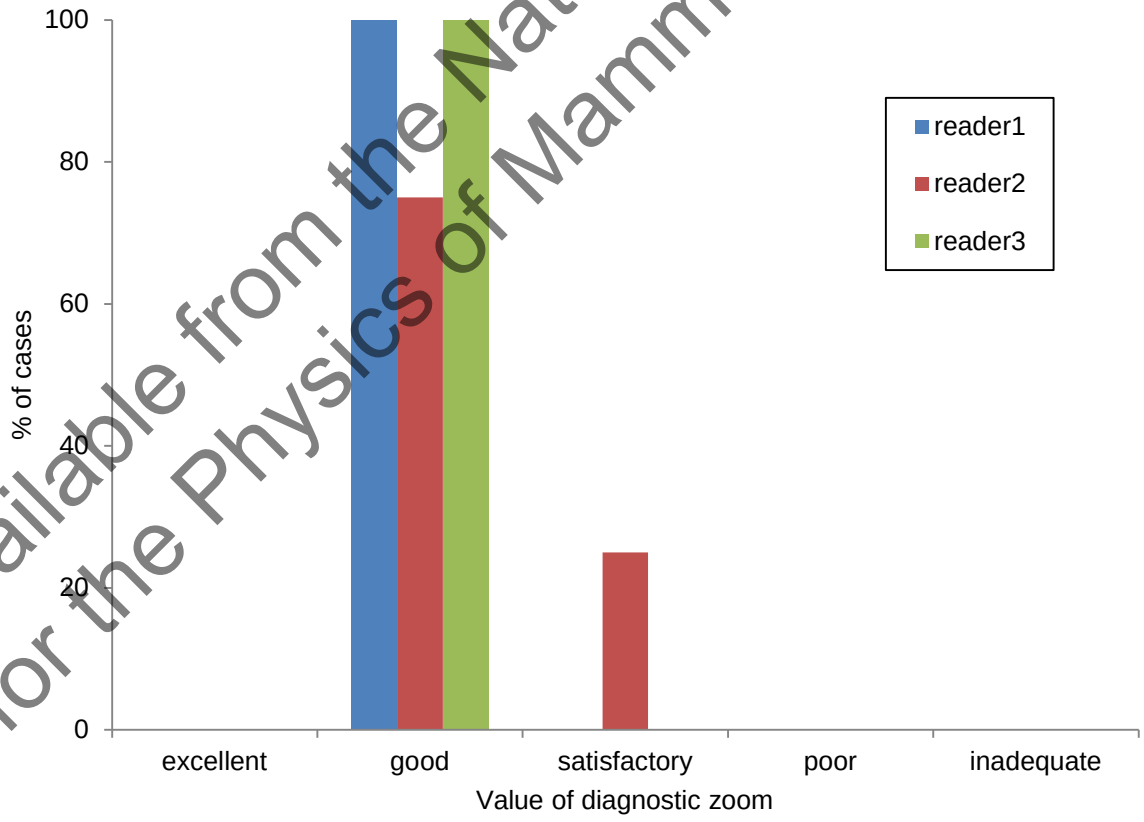

Figure 20. Readers' assessment of diagnostic zoom

5. Data on assessment conducted

Assessments were carried out in the weekly assessment clinic by a radiologist with support from the advanced practitioners. Women recalled to the assessment clinics were imaged according to both national and local protocols.

The assessment images were reviewed by the reporting team. Overall, images that were taken in the clinic were scored as either good or excellent. Attention was given particularly to the sharpness and the overall quality of the images. They were also reviewed using the magnification facility on the reporting workstation.

Typical comments made by the reporting team were “excellent definition”, “good quality” and “better detail”.

None of the images from the assessment clinics were scored as poor.

6. Equipment reliability

The equipment performed reliably during the entire evaluation period. No faults were recorded on the NHSBSP Equipment Fault Report Forms during this period, and there was no downtime.

7. Electrical and mechanical robustness

There were no safety issues, and no electrical or mechanical problems were encountered during the evaluation period.

8. Radiographers' comments and observations

The radiographers and assistant practitioners involved in the evaluation of the Innovality were all asked to record their observations on the NHSBSP Equipment Evaluation Form 6. A summary of their observations is shown below. Full details of the responses can be reviewed in Appendix 3.

Not all questions were answered. One of the questions did not apply to this evaluation as all images generated within the breast unit for screening were automatically transferred to the integrated NBSS/PACS system.

8.1 Operator manual

A user manual in the form of a set of A4 sheets was provided. Only 4 of the 8 respondents saw or reviewed the manual. Of those who reviewed it, 3 thought it was poor with one rating it as average. One commented that it was flimsy.

There was no manual provided for quality assurance of the system.

8.2 Training

One of those who responded to the questionnaire thought that the training for both the modality and the workstation was excellent while 3 thought it was good. Of the remaining respondents, 2 rated the training as average and 2 said that there was no training available to them.

8.3 Ease of use

Respondents rated this as excellent (3), good (4) or average (1). One commented that changing paddles was difficult and it was not easy to do this with one hand. They also said that the storage unit for the paddles was awkward to use. There were two comments about wanting more working space near the AWS.

One comment on the manual start-up of the system was that, unlike with the Fujifilm AMULET, there was no indication of the length of warmup time remaining. One disliked the sleep mode, as it was thought to confuse the software, but another liked the fact that the system came on straight away.

8.4 Exposure times

All respondents found the exposure times acceptable, rating them as excellent (5) or good (3).

8.5 Setting radiographic views

The rotation of the support arm was rated as excellent (5), good (2) or average (1). There was one comment on the rotation being slow.

The visibility of the set angle was found to be generally acceptable and rated as excellent (4), good (3) with one no response.

8.6 Setting the position of the breast support table

The respondents found that there was no issue with the controls for setting the position of the breast support table with 2 finding them excellent and the rest good (6).

8.7 Range of movements

The range of movements was deemed more than adequate, and was rated as excellent (3) and good (5).

8.8 Effectiveness of brakes and locks

Most of the respondents found that the brakes worked well, rating them as excellent (5) or good (2).

8.9 Environmental conditions

The respondents rated the environmental conditions required as either excellent (4) or good (4).

8.10 Compression

The effectiveness of the compression system was rated as excellent (5) or good (2). The one non-respondent did not like the foot pedal as it was “too keen”. Several others also commented that the compression was very “keen” and that they needed some time to get used to it. One explained that compression can jump too quickly, for example from 60N to 90N.

The visibility of the compression force from the breast support table was considered excellent (5), good (1) or average (1). Two commented that the displayed compression

force and the thickness could be easily confused, because the display was the other way round on some other systems and the values are often of the same order.

8.11 Comfort level of women

The level of comfort provided by the system was rated as excellent (6) or good (2). This was based on the respondents' perceptions and on any comments volunteered by the women. One said that it was better than before (with the AMULET) while another said the women were happy with the comfort. Another commented that the Fit Sweet paddle was more comfortable for the women.

8.12 Range of controls and indicators

All the expected controls were considered to be present and the ratings given were excellent (3), good (4) and satisfactory (1). One comment was that the control buttons on the tube head were difficult to push.

The respondents mostly thought that the controls were easy to find and use and answered this question as excellent (2), good (2), average (1) or satisfactory (3).

There were a range of different comments on the positioning of the control buttons. One said additional buttons would be of greater use at a lower level than those on the gantry. Another said that having control buttons on the vertical column would be useful. Another would like control buttons on the side of the C-arm as well as on the tube head, to make it easier when imaging tall women.

8.13 Choice of paddles/collimators for spot compression

Of the 6 respondents who responded to this question, 3 thought it was excellent with the other 3 saying it was good.

8.14 Time elapsed before the image appears at the AWS

This was rated as excellent (5) and good (3). One commented that it was "very speedy".

8.15 Image handling and processing at the AWS

The image handling and processing facilities at the AWS were rated as excellent (1) or good (6) by those who responded to this question.

8.16 Overall image quality at the AWS

The overall image quality was found to be acceptable, being rated excellent (5) or good (2) with one non-respondent. One comment was that, while it was generally good, it was

initially “too harsh” for larger breasts, giving a “halo” effect. This was alleviated by a subsequent upgrade.

8.17 Ease of transfer of images

Most of the respondents said that the facility was not available.

8.18 Level of confidence in the Innovality

The respondents rated their level of confidence as excellent (5) or good (3).

8.19 Hazards

While most of the respondents said there were no hazards to either themselves or to the women when using the system, two had concerns about potential hazards. One said there was a risk of applying more pressure than intended because of the quick compression. The other reported manual handling issues with changing paddles.

8.20 Equipment cleaning

Most of the respondents reported that the system was easy to clean, rating it as excellent (3) or good (4) with one no response. There were no cleaning instructions in the manual, which one of the radiographers described as poor.

All respondents said that the equipment cleaning met the local infection control requirements, rating it as excellent (4) or good (4).

8.21 Patient and exposure data on images

This was rated as excellent (3) or good (4) by those who responded to this section. One person did not respond.

8.22 Did the performance of the system limit patient throughput?

All the respondents agreed that the system did not restrict patient throughput.

8.23 Magnification

Only 3 of the respondents had clinical experience with magnification. They all rated the ease with which the magnification equipment was attached and removed as average. One of them also commented that the attachment could be improved.

All 3 respondents rated the ease of use of the magnification breast support table as average.

8.24 Additional comments on performance

There were a number of comments on aspects of the system that were not covered in the questionnaire. These are included in the sub-sections below.

8.24.1 Paddles

The Fit Sweet paddle was well received by users and blurring was reported to be minimal, less than with existing systems. Some comments were: “I like the flexi paddle – women like this paddle”, “flexi paddles and shifting paddle are excellent”.

The shifting paddle had a low edge, which was ideal for small breasts, but was problematic in some cases, where “overhang“ of breast tissue occurred, and was apparent on the images. A similar comment was made about the 24cm x 30cm paddle.

8.24.2 AEC and implants

The iAEC was reported as an excellent feature of the equipment in the evaluation, as no changes to any of the settings had to be made for women with breast augmentation. The Innovality subsequently became the system of choice for these women during the evaluation period. One respondent commented “I like doing implant women”.

8.24.3 QC tests

- “QA – no tools provided, for example, for uniformity”

8.24.4 General

- “would keep, with a few minor alterations”
- “machine not perfect but could live with it if had to”
- “overall, like the machine”

9. Radiologists’ comments and observations

9.1 Reporting workstation

A reporting station was made available for the evaluation by the manufacturer, but it was not used so no workstation assessment was carried out.

The breast unit already had Visbion 5MP workstations as their main PACS reporting workstations. These workstations were used by the radiologists to report on mammograms from the existing Fujifilm AMULET systems. They, therefore, decided to continue with the existing reporting facilities for the evaluation.

9.2 Image quality

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

9.3 Use in assessment

Screening assessments were undertaken in the weekly assessment clinic by a radiologist, with the support from the advanced practitioners. Women recalled to the assessment clinics were imaged according to both national and local protocols.

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

The reporting team made the following comments "excellent definition", "good quality" and "better detail". No images were scored as poor.

10. Confidentiality

The evaluation complied fully with the NHS Cancer Screening Programmes' Confidentiality and Disclosure Policy[7].

11. Security issues

There were no issues with security as the system was located within a static unit within the hospital.

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

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

12. Training

Application training was provided over a 3-day period by an applications specialist from Fujifilm. Each member of staff had the opportunity to spend time with the applications specialist during that period. In addition, advice was always available over the phone from the Fujifilm applications team.

The screening unit already had a number of Fujifilm systems in operational use. Staff were, therefore, already familiar with many aspects of the system.

13. Discussion

13.1 Equipment and practical considerations

The iAEC mode for AEC allows the system to be used with augmented breast without having to change any settings. This is a feature which was much appreciated by the radiographers. The Fit Sweet paddle was also liked, and was thought to contribute to the women's comfort.

Radiographers were not completely happy with the ease of use of the system. They found the storage system for the paddles awkward to use, as it required the use of both hands, and changing paddles appeared to cause some problems. They also found some issues with the position of the controls. Some of them found the control buttons on the tube head difficult to use and would have preferred a set on the side of the C-arm, to make it easier when imaging tall women.

There was also a comment that the manual start-up did not indicate the length of warmup time as the Fujifilm AMULET did. However the quick start from sleep mode was appreciated.

There were a number of comments about the compression force being “too keen”, that is, it changed too quickly when the foot paddle was pressed. Some staff appeared to confuse the compression force display with breast thickness display.

The system proved reliable during the evaluation period, with no breakdowns. Engineering support was available, either on site, when necessary, or over the telephone.

One practical consideration was the absence of changing facilities in the room where the system was located. This had the effect of increasing the total time involved in screening women.

When the Innovality was used for a longer period of time, most of the difficulties mentioned in this section were overcome, as staff became more familiar with the system. More details are provided in Appendix 4.

13.2 Physics testing and routine QC

Physics tests carried out at commissioning found equipment performance to be satisfactory. A dose survey found the average MGD for MLO exposures of 50–60mm thick breasts to be 1.18mGy. This was well below the DRL of 3.5mGy.

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

13.3 Screening

Despite the non-availability of changing facilities in the room, the screening throughput was 75 to 80 women per clinic. This was within the 6 minute appointment time requirement of the NHSBSP.

13.4 Clinical assessment

A random sample of 20 sets of images was analysed for this evaluation by the team of readers. Overall, the results were assessed as being good. 74% of the images analysed had an overall diagnostic value of excellent or good, and no images were assessed as poor or inadequate.

Although the sample size was small, the analysis showed that the system had the ability to perform well across a range of breast types.

13.5 Radiographers' and radiologists' views

Radiographers and readers were generally satisfied with the training they received. They had some concerns about the manual and its content, and about some of the controls. They found learning to use the Innovality straightforward, partly because of their prior experience with existing Fujifilm AMULET systems.

Overall, they liked using the system and were satisfied with the images produced.

14. Conclusions and recommendations

The system proved to be reliable, with no breakdowns during the evaluation. It met key requirements for throughput of women through screening and assessment clinics, and integrated successfully with the local IT systems.

The Fit Sweet paddle was found to be useful, and seemed to make compression more comfortable for women. Some staff reported difficulty in handling the compression paddles, and in increasing compression slowly enough. Some made suggestions regarding positioning of the control buttons.

The Innovality met the required standard for radiation dose. Image quality was judged to be mainly good or excellent, and imaging augmented breasts was easy because the iAEC automatically produced good images for them.

The evaluation team found the Fujifilm Innovality, used in 2D mode, to be suitable for use within the screening environment of the NHSBSP.

References

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

5. Dance DR, Young KC, van Engen RE. Further factors for the estimation of mean glandular dose using the UK, European and IAEA breast dosimetry protocols. *Physics in Medicine and Biology*, 2009, 54: 4361-4372

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

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Appendix 1: Physics report

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

RADIATION PROTECTION SERVICES
Royal Hallamshire Hospital
Glossop Road
Sheffield
S10 2JF

Ionising Radiations Regulations (I999) - Reg 31 (2)

Critical Inspection to ensure fitness of equipment used for medical exposures to ionising radiation

The following equipment was tested in accordance with the departmental 'Protocol for Acceptance Testing of Diagnostic Radiology Equipment by Medical Physics Staff' and was found to be acceptable for clinical use.

The tests include checks for compliance with the 'Ionising Radiations Regulations 1999' (HMSO 1999), associated 'Approved Code of Practice and Guidance for Work with Ionising Radiation' (HMSO 1999), the related 'Medical and Dental Guidance Notes' (IPEM 2002), and where relevant 'Guidance Notes for Dental Practitioners on the Safe Use of X-Ray Equipment' (NRPB 2001). Consideration was also given to compliance with the 'Technical Requirements for Supply and Installation of Radiological Equipment TRS-89' (Department of Health).

Equipment tested:	**Fuji Amulet Innovality**
Insert Type:	**M-113T**
Insert Serial Number:	**80079-Z3**
Date:	**27/02/2014**
Location:	**BDG Mammography Room 4**

The following observations are made for the supplier's information:

For the smaller paddle (24x30 Small), the x-ray field overlaps the image by approximately 9mm at the nipple edge only. This is unlikely to cause significant issues and the alignment is good for the larger paddle. However, it should be improved if it is practicable to do so without affecting the chest wall alignment. ACTION

The flexi-paddle was not available for testing at the time of this survey. Limited testing will be required when the paddle is delivered to ensure there are no significant differences from the ones already supplied.

The unit, in its current configuration, is a very low dose system with acceptable image quality. The option to increase doses to improve image quality is available if necessary.

All other aspects of safety and performance tested were satisfactory.

Signed:..... Date:.....
Mr. G.D. Morrison - Radiation Protection Adviser

NHS

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

BREAST CANCER SCREENING SERVICE
REGIONAL PHYSICS QUALITY ASSURANCE ASSESSMENT

DATE: 27/02/14

Hospital:	Barnsley District General Hospital			Room:	Barnsley4	Location:	
Generator:	Fuji	Model:	Innovality	Serial No:		Max kV/mAs	35kV/600mAs
Gen Installed:	Det Installed:	Pixel size (µm):		Detector Type		Detector Number	FPD (cm)
Feb-14	Feb-14	50		a-Selenium			63.3

Tube Shield:	B-115
Serial Number:	H80079
Insert Type:	M-113T
Serial Number:	80079-Z3
Installed:	Feb-14
Tube Angle:	
Tube Axis Angulation: BF	
Tube Axis Angulation: FF	
Grid Type:	
Grid Ratio:	06:01
Grid System Exposure Factor:	
Grid Uniformity:	
Line Density:	41
Magnification:	N/a
Meas Mag:	N/a
Light Beam/X-ray Field Alignment:	
X-Ray Field/Bucky (front edge) Alignment	
LBD/Exposure Interlock:	
Exposure Indication:	Control: / Outside:

Movement & Locks:	
Powered movements inhibited with compr of >.. N applied	30
Exposure Cable Length:	

Use:	
Workload:	

FILTRATION (with Paddle)

Filter / Target	W/Rh	Mo/Mo	Mo/Rh
1st HVT @ 24 kV (mmAl):	0.464		
1st HVT @ 25 kV (mmAl):	0.483		
1st HVT @ 26 kV (mmAl):	0.499		
1st HVT @ 27 kV (mmAl):	0.510		
1st HVT @ 28 kV (mmAl):	0.519		
1st HVT @ 29 kV (mmAl):	0.526		
1st HVT @ 30 kV (mmAl):	0.537		
1st HVT @ 31 kV (mmAl):	0.546		
1st HVT @ 32 kV (mmAl):	0.554		
1st HVT @ 33 kV (mmAl):	0.560		
1st HVT @ 34 kV (mmAl):	0.569		
Nominal Added Filtration (mm):			

FOCAL SPOT (L X W)

	Nominal	Star		Ref Angle	Target
Fine	**0.1**			2°	W
Broad	**0.3**			5°	W

COMPRESSION

Compression Force (Max) Ind.	194	N
Compression Change after 30sec:	3	N
Compression Force (As set):		Kgf
Compression Auto-Release:		

OPERATOR'S PROTECTIVE SCREEN

Slate Lead Equivalence	mm @	kV
Transmission of Scattered Radiation		

Leakage	<3	µGy/hr @ 1 metre

COMMENTS

For the smaller paddle (24x30 Small), the x-ray field overlaps the image by approximately 9mm at the nipple edge only. This is unlikely to cause significant issues and the alignment is good for the larger paddle. However, it should be improved if it is practicable to do so without affecting the chest wall alignment. ACTION

The flexi-paddle was not available for testing at the time of this survey. Limited testing will be required when the paddle is delivered to ensure there are no significant differences from the ones already supplied.

The unit, in its current configuration, is a very low dose system with acceptable image quality. The option to increase doses to improve image quality is available if necessary.

All other aspects of safety and performance tested were satisfactory.

Signed: Date:

Checked:

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Digital Mammography X-ray Equipment Survey Report

Hospital:	Barnsley District General Hospital			
X-ray set:	Barnsley4		**Equipment Code:**	BDG4
Reason for Visit:	Commissioning		**Test Equipment:**	Radcal & LTO
Equipment Surveyed:	Generator:	Fuji		
	Tube:	M-113T		
	Installation:	20/02/2014		
Asset/Serial Number(s):	Generator:		**Detector:**	
	Tube:	80079-Z3	**Detector install date:**	20/02/2014
	ID no:			
Survey Date:	27/02/2014		**Conducted By:**	MD Hill
Report Date:	05/03/2014		**Report By:**	MD Hill
Checked Date:	05/03/2014		**Checked By (Name):**	CJ Ogley
Next Test Due:	29/08/2014		**Signature:**	
Report Sent To:	J Clark			
	D Houghton	QARC		

CONCLUSIONS/RECOMMENDATIONS

For the smaller paddle (24x30 Small), the x-ray field overlaps the image by approximately 9mm at the nipple edge only. This is unlikely to cause significant issues and the alignment is good for the larger paddle. However, it should be improved if it is practicable to do so without affecting the chest wall alignment. ACTION

The flexi-paddle was not available for testing at the time of this survey. Limited testing will be required when the paddle is delivered to ensure there are no significant differences from the ones already supplied.

The unit, in its current configuration, is a very low dose system with acceptable image quality. The option to increase doses to improve image quality is available if necessary.

All other aspects of safety and performance tested were satisfactory.

For queries relating to this report please contact: MD Hill - 0114 22 65197 - Matt.Hill@sth.nhs.uk

Actions taken by the unit:

A copy of this sheet must be returned to the issuer, with actions taken and dates

Summary of results and comparison with recommended standards

National performance standards (NHSBSP Report 0604)

	Measured values Current	Baseline	Minimum Standard	Pass/Fail
Date for Baseline measurements		Feb-14		
Measured at Clinical settings				
PV/EI for 4.5 cm block	8320	8320		
Image quality at settings for 5cm PMMA				
Contrast-detail performance (auto-read scores)				
1 mm detail	0.07	0.07	0.091	**Pass**
0.5 mm detail	0.12	0.12	0.15	**Pass**
0.25 mm detail	0.27	0.27	0.352	**Pass**
0.1 mm detail	1.07	1.07	1.68	**Pass**
Beam uniformity and alignment at TF for 4.5cm PMMA				
X-ray beam uniformity	1.66%	1.66%	>10%	**Pass**
Overlap of X-ray beam wrt detector, all edges (mm)				
Broad Focus	9	9	> -0, +5	**Fail**
Magnification	N/a	N/a	> -0, +5	**N/a**
Automatic exposure control (clinical settings)				
Reproducibility of exposure (%)	5.0	5.0	≥ 5	**Pass**
Thickness compensation in clinical mode (CNR)	-	-	>10% from baseline	**-**
Mean glandular dose (MGD)				
TFkV	W/Rh 28	W/Rh 28		
MGD to standard breast at clinical settings (mGy)	0.94	0.94	≤ 2.5 mGy	**Pass**

Other parameters (IPEM Report 89 and IPEM Report 91)

	Measured values Current	Baseline	Remedial Level	Pass/Fail
1. X-ray tube and generator tests T/F 4.5cm clin	W/Rh	W/Rh		
X-ray tube voltage accuracy (kV)	0.6	0.6	≥ ± 1	**Pass**
X-ray tube output consistency with mAs (%)	1.8	1.8	≥ 5	**Pass**
Specific X-ray tube output at 28 kV (µGy/mAs at 50cm)	63.5	63.5	<70% baseline	**Pass**
X-ray tube output rate at focus-detector distance (mGy/s)	2.5	2.5	<70% baseline	**Pass**
Broad focus size on reference axis (mm)	0.50x0.35	0.50x0.35	≥0.66x0.45#	**Pass**
Fine focus size on reference axis (mm)	N/a	N/a	≥0.15x0.15#	**N/a**
Maximum motorised compression force (N)	200	200	150 ≤, ≥ 200*	**Pass**
Breast Thickness Indicator error (mm)	-3	-3	>5mm	**Pass**

These figures apply to 0.3mm BF and 0.15mm FF focal spot sizes. For other sizes see IPEM89

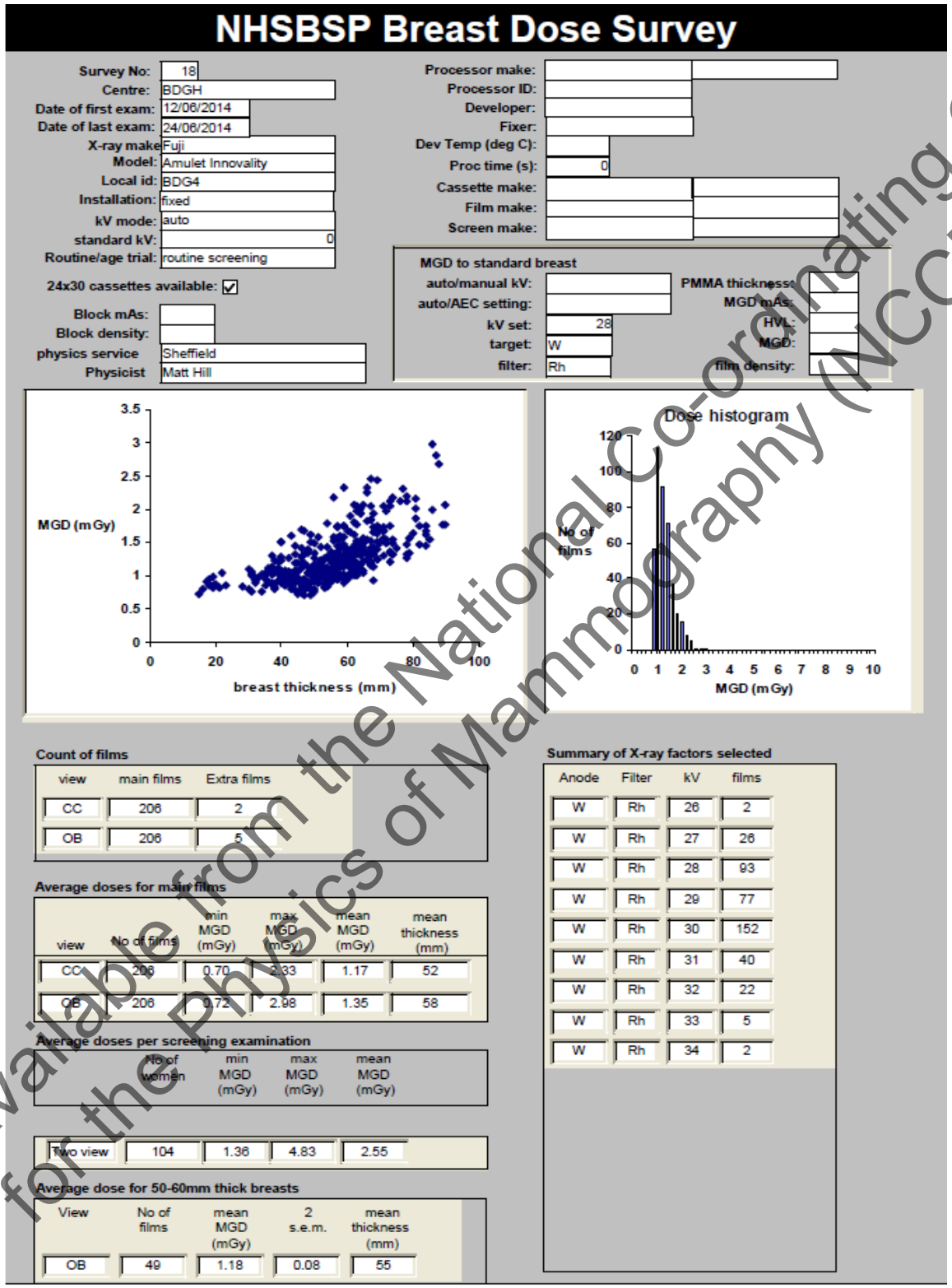
* Suspension level, no remedial level.

N/A - Not applicable to be entered if test not possible, i.e. for Fine Focus tests when there is no fine focus on the set

Not tested to be entered if test not carried out at this survey

Version: Digital Mammo 1.9 Test List NHSBSP Report 0604 v3	Perform on which surveys		Performed this survey		Baseline	Tolerances	Pass/Fail?
	Commissioning	Routine	Tested	Reported			
Misc							
Compression (IPEM 89 5.6.5)	X	X	X	X		Indicated >20N from measured	Pass
			X	X		<150 or >200N for powered comp.	Pass
			X	X		>300N for any comp.method	Pass
			X	X		>20N change in 30seconds	Pass
Focal Spot Size (IPEM89: 5.6.6)	X	X	X	X		BF 0.3mm: 0.66x0.45mm	Pass
			X	X		FF 0.1mm: 0.15x0.15mm	-
Light Beam to X-ray/Image (3.1.1)	X	X	X	X		>5mm	Fail
X-ray to Detector Alignment (3.1.1)	X	X	X	X		>5mm or <0mm	Fail
Chest Wall image to Platform (3.1.3)	X	-	X	X		>5mm	Pass
Size of Imaged Field (3.1.2)	X	-	X	X		<0.95 specified size	Pass
Leakage (IPEM 89: 5.6.4)	X	-	X	X		>1000microGy/h @ 1m	Pass
Detector Tests							
Uniformity (3.2.3)	X	X	X	X	0.2%	>10% max. dev. from mean	Pass
Calliper Calibration (3.2.2)	X	-	X	X	0.0128	>2% error	Pass
Artefacts (3.2.4)	X	X	X	X	-	Dead pixels - See manufacturers spec.	Pass
			X	X	None	None affecting IQ	Pass
Detector Response (3.2.5)	X	X	X	X	83.0	Detector Air Kerma >±20% from baseline	Pass
			X	X	1.9	Noise Stdev >10% increase on baseline	Pass
			X	X	44.4	SNR >±10% from baseline	Pass
Detector Resolution - MTF	X	X					
Spat. Discontinuity & Res. Homogeneity (3.2.7)	X	X	X	X	None	Any regions of blurring or discontinuities	Pass
Image Retention (3.2.8)	X	X	X	X	-0.02	Image Retention Factor >0.3	Pass
AEC Checks							
AEC Repeatability (3.3.1)	X	X	X	X		>5% (>10%) max. dev. from mean mAs	Pass
AEC Performance - Automatic mode (3.3.2)	X	X	X	X		>10% change from CNR baseline	Pass
AEC Variation with Density Control (3.3.3)	X	-				Outside manufacturers spec.	
AEC Variation with Position of Detector (3.3.4)	X	-				Variation in mAs >10%	
Guard Timer (IPEM 89: 5.7.3)	X	X	X	X		Terminates exposure	Pass
Generator Tests							
Output (IPEM 89: 5.6.9)	X	X	X				
kV accuracy (IPEM 89: 5.6.7)	X	X	X		-	>±1kV; >±2kV	
HVL (IPEM 89: 5.6.8)	X	X	X				
Image Quality							
Detail Detection (3.5.1)	X	-	X	X		<"Acceptable" IQ - Table 5	Pass
Regular IQ tests - TOR(MAX) (3.5.2)	X	X	X	X	-	NHSBSP stds; Less than baseline	Pass
Regular IQ tests - TOR(MAM) (3.5.2)	X	X	X			Significantly less than baseline	
Dose							
Dose to the standard breast (3.6.1)	X	X	X	X	-	25% above baseline MGD	Pass
			X	X	-	Acceptable/Achievable from Table 6	Pass
Clinical breast doses (3.6.2)	X	-		X	-	>3.5mGy; > Local DRL	-

Appendix 2: Clinical breast dose survey



NHSBSP Breast Dose Survey

Survey No:	18
Centre:	BDGH
Date of first exam:	12/06/2014
Date of last exam:	24/06/2014
X-ray make	Fuji
Model:	Amulet Innovality
Local id:	BDG4
Installation:	fixed
kV mode:	auto
standard kV:	0
Routine/age trial:	routine screening
24x30 cassettes available:	☑
Block mAs:	
Block density:	
physics service	Sheffield
Physicist	Matt Hill

Processor make:	
Processor ID:	
Developer:	
Fixer:	
Dev Temp (deg C):	
Proc time (s):	0
Cassette make:	
Film make:	
Screen make:	

MGD to standard breast

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

Count of films

view	main films	Extra films
CC	206	2
OB	206	5

Average doses for main films

view	No of films	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	206	0.70	2.33	1.17	52
OB	206	0.72	2.98	1.35	58

Average doses per screening examination

	No of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
Two view	104	1.36	4.83	2.55

Average dose for 50-60mm thick breasts

View	No of films	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
OB	49	1.18	0.08	55

Summary of X-ray factors selected

Anode	Filter	kV	films
W	Rh	26	2
W	Rh	27	26
W	Rh	28	93
W	Rh	29	77
W	Rh	30	152
W	Rh	31	40
W	Rh	32	22
W	Rh	33	5
W	Rh	34	2

Appendix 3: Radiographers' answers to questionnaire

	Comments and observations
1. How good was the operator's manual?	4 N/A, 1 average, 3 poor Looks could be better Never saw one don't remember seeing it Flimsy A4 sheets Not used Not seen No manual provided for quality assurance
2. How good was the clinical applications training provided by the supplier? a. Modality	2 N/A, 1 excellent, 3 good, 2 average None available
b. Workstation.	2 N/A, 1 excellent, 3 good, 2 average
3. How do you rate the unit's ease of use?	3 excellent, 4 good, 1 average Find the exchange of paddles difficult – not easy to do with one hand Storage system for paddles also awkward to use On manual startup – no indication of length of warmup time as on existing AMULETs
4. Were the X-ray exposure times acceptable? (If not, explain – for example, hit backup timer frequently)	5 excellent, 3 good

5. Setting for radiographic views: How do you rate the rotation of the support arm?	5 excellent, 2 good, 1 average slow
How do you rate the visibility of the set angle?	1 N/A, 4 excellent, 3 good
6. Setting position of breast support table: How do you rate the facility for positioning the height of the breast support table?	2 excellent, 6 good
7. Range of movements: Adequacy of the range of movements offered by the unit?	3 excellent, 5 good
8. Effectiveness of brakes/locks: How well did the brakes work? (for example, was there any backlash or movement)	1 N/A, 5 excellent, 2 good Do not like foot compression plate – too keen
9. Suitability of environmental conditions required to use the equipment	4 excellent, 4 good More room behind screen Not had any issues yet – though not had a really cold spell More worktop space required near AWS
10.Compression How effective was the compression system?	1 N/A, 5 excellent, 2 good Very keen until you get used to it Compression is very keen. Needs to be watched at all times Both fixed paddles are very keen – compression can jump from 60N to 90N a little too quick Did not like foot pedal
Visibility of compression force from breast support table?	1 N/A, 5 excellent, 1 good, 1 average Very easy to mix up compression force with tissue thickness,

	especially if values are similar Keep getting mixed up with compression force and thickness – other way round to other machines Time to adjust is required – to get used to compression force Good compression
11.Comfort of women	6 excellent, 2 good Especially with flexible paddle Better than before Liked flexi paddle Women happy with comfort
12.Range of controls and indicators: Were all the expected controls present?	3 excellent, 4 good, 1 satisfactory Additional controls would be of great use at a lower level than the ones on the gantry Found control buttons on tube head difficult to push
Were they easy to find and use?	2 excellent, 2 good, 1 average, 3 satisfactory More visible on side of gantry Having controls on the vertical column would be useful Preferred light switch to be on support arm
13.How do you rate the choice of paddles/collimators supplied for spot compression?	2 N/A, 3 excellent, 3 good Not used
14.How do you rate the time for an image to appear at the acquisition workstation?	5 excellent, 3 good Very speedy

15.How do you rate the image handling and processing facilities at the acquisition workstation?	1 N/A, 1 excellent, 6 good
16.Overall image quality at the acquisition workstation: How do you rate the image quality on this unit?	1 N/A, 5 excellent, 2 good
	Generally good. However, processing programs for larger breasts initially too harsh giving "halo" effect. Has now been updated Had some issues with image quality
17.How easy was it to transfer images for example to reporting station, to an encrypted hard drive?	7 N/A, 1 good
18.Confidence of good results: What was your level of confidence in the machine?	5 excellent, 3 good
19.Hazards Were there any potentially hazardous areas accessible to either you or the woman?	2 yes, 5 no, 1 average
	To apply more pressure due to the quickness on compression Changing paddles Not noticed any
20.Equipment cleaning: Ease of cleaning the machine?	1 N/A, 3 excellent, 4 good
Were there instructions in the manual?	6 N/A, 1 good, 1 poor
Does this meet the local infection control requirements?	No cleaning instructions in manual 4 excellent, 4 good
21.Availability of patient and exposure data on images?	1 N/A, 3 excellent, 4 good
22.Did the digital X-ray system performance limit patient throughput? for example, wait between exposures too long	8 no

23.Magnification	
a. Rate the ease with which the magnification equipment may be attached and removed	5 N/A, 3 average Could improve attachment
b. Rate the ease of use of the magnification breast support table	5 N/A, 3 average
24.Any additional comments on general or imaging performance	The workspace at the control panel is very limited A 24 x 30s flexi paddle would be of great use Paddles are difficult to change – especially one-handed Storage unit for paddles is very difficult to use Keep system especially if 24 x 30s flexi paddle is available Compression force very keen Flexi paddles and shifting paddle are excellent – would like a 24 x 30s flexi paddle 24 x 30s shifting paddle – chest wall height too shallow – giving artefacts from chest wall of women 24 x 30H flexi paddle – can be a bit too heavy and may be dropped when changing paddles 24 x 30s paddle is often too shallow – resulting in overhang 24 x 30s shifting paddle on MLO's – sharper definition and light to see lower edge – so lower edge of breast, not missed off on film Perspex too flimsy Prefer paddle holding socket like on AMULET – changing paddles can be a bit fiddly Angle and vertical controls would be useful on the vertical column as well as tube head No QA tools for example for

	uniformity Not keen on “sleep mode” – it confused the software Keep with a few minor alterations Do not like changing paddles – very user unfriendly (not one handed job) Thickness on small paddle too thin Can get overhang from shoulder Foot pedal too keen Compression force + thickness confusing Don’t like no operator control button on side of column Like it coming on straightaway Like doing implant women Like MLO’s on small paddle shifting up Like flexi paddle – women like this paddle Machine not perfect but could live with it if had to Like displacing of collimation on oblique views Overall, like machine - exchange of paddles awkward, though obviously secure once in place Would like a flexi 24 x 30 paddle The paddle could be a bit higher to prevent overhang Flexi paddles are very good but difficult to change unlike on AMULET QA uniformity not available

Appendix 4: Manufacturer's comment

The manufacturer contacted the Superintendent Radiographer at Barnsley in 2016, asking for an update on some of the difficulties reported by users during the evaluation period. Feedback was provided for appropriate sections of the report.

Section 8.1: The only manual available at the time of the evaluation was a "quick guide" provided by the applications specialist. A full Operators Manual has subsequently been made available.

Sections 8.3 and 8.19: Manual handling of paddles when changing or storing them – this is no longer perceived as difficult now that the users are more familiar with the system. However, one-handed operation is still not possible.

Section 8.10: During the evaluation some users found that the foot pedal changed the compression too rapidly for their liking. By 2016, they had become used to it and this was no longer a problem.

Section 8.17: The radiographers did not need to transfer images, which were sent directly to PACS. The question about "ease of transfer" (the DICOM Study Image Save) would only be of relevance to physicists.

Section 13.1: During the evaluation, some users reported minor difficulties in using the Innovality. By 2016, they had become used to it, and were happy to operate the system. The only remaining issue was that users who were shorter in stature would have preferred the control buttons to be lower on the C-arm, for easier operation.