EVALUATION AND CLINICAL ASSESSMENT OF THE FUJI AMULET FULL FIELD DIRECT DIGITAL MAMMOGRAPHY SYSTEM

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- Vivienne Jones and Linda Toru of the Medical Physics Department of Northampton General Hospital NHS Trust
- the applications specialists of Fujifilm UK Ltd Medical Systems.

1. INTRODUCTION

The Derby Breast Screening Service covers a population of approximately 77 000 women. The service is delivered via two static units and two mobile screening vans. Its evaluation of the Fuji Amulet Full Field Direct Digital Mammography System (hereafter Fuji Amulet) took place at the London Road Community Hospital in the centre of Derby between May 2009 and March 2010.

Screening takes place at the Community Hospital from Monday to Friday, from 0900 to 1615 hours, with a one-hour break for lunch. Screening appointments are booked in alternating 5-minute and 10-minute slots, giving 50 appointments each day. This arrangement was not changed for the evaluation.

The Fuji Amulet was installed in what had previously been the film processing room. The processor was removed and the existing analogue x-ray set was converted to computed radiography. This was to ensure that any problems with the Fuji Amulet during the evaluation period would not give rise to cancelled clinics or disrupt the screening round.

A magnification table was available at the time of the evaluation. It was not included in the evaluation, however, as no assessment clinics are undertaken at the site. No stereotactic biopsy attachment was available during the evaluation.*

*Fuji have since launched a stereo biopsy attachment for the Amulet. For details see http://www.fujifilm.com/products/.

2. OBJECTIVES OF THE EVALUATION

The objectives of the evaluation were

- to establish whether the image quality produced by the Fuji Amulet in a clinical setting, and the radiation dose required, meet the recommended NHS Breast Screening Programme (NHSBSP) standards. (A full technical evaluation of the Fuji Amulet system was published in 2009.[1])
- to test the reliability of the Fuji Amulet system over a prolonged period in a full screening environment
- to report radiographers' experience of using the Fuji Amulet system with receptor tables of 18 cm × 24 cm and 24 cm × 30 cm
- to establish whether the Fuji Amulet system would integrate fully into the Royal Derby Hospital's GE Centricity™ Picture Archiving and Communication System (PACS).

3. SYSTEM DESCRIPTION

The Fuji Amulet comprises the following

3.1 Mammographic x-ray stand and controller

The Fuji Amulet is supplied with either an 18 cm × 24 cm or a 24 cm × 30 cm direct digital receptor (Figure 1). A high frequency generator delivers up to 35 kV and the tube offers three target–filter combinations: molybdenum (Mo)/Mo; Mo/rhodium (Rh); and tungsten (W)/Rh. The multichamber automatic exposure control (AEC) system has normal, small and large modes.

The Fuji Amulet stand has several features to facilitate its use. They include automatic compression/decompression and autocollimation (depending on the paddle used), and all movements are motorised. The stand comes with two sets of foot switches, one controlling height and the other compression.

The Fuji Amulet has been ergonomically designed to make it as comfortable as possible for both patient and operator. Examples of these design features include the arm rests, the trapezoidal detector housing and the disposable chest wall/axilla pads.

Figure 1 Fuji Amulet x-ray stand and controller.

3.2 Amorphous selenium flat panel detector

The Fuji Amulet features a dual-layer amorphous selenium direct-conversion flat panel detector. Its dual-layer design allows optical switching, which is more efficient than the electronic switching used in traditional thin-film transistor systems. This innovative technology offers enhanced detected quantum efficiency (DQE) and modulation transfer function (MTF). It produces images of 50 µm resolution in under 10 seconds, with under 15 seconds between exposures.

3.3 X-ray protection stand

The stand is designed to hold the Fuji Amulet's acquisition workstation (AWS), exposure control and monitors, and to provide radiation protection. It has a lead glass screen and an optional storage unit.

3.4 Acquisition workstation

The Fuji Amulet's DICOM-compatible AWS (Figures 2 and 3) features a Windows Vista PC with a 21-inch high resolution colour monitor (1600 × 1200 pixels) fitted as standard. The optional high resolution 3 MP monochrome companion monitor allows rapid confirmation of the acquired image. The AWS also functions as a generator control unit, thus combining and simplifying the acquisition and x-ray functions. Its other functions include patient identification, terminal quality control and reject analysis, and quality assurance, using Fuji's own image processing software.

Figure 2 Workstation with colour monitor showing the worklist for the session (right) and monochrome monitor that displays the image on acquisition (left).

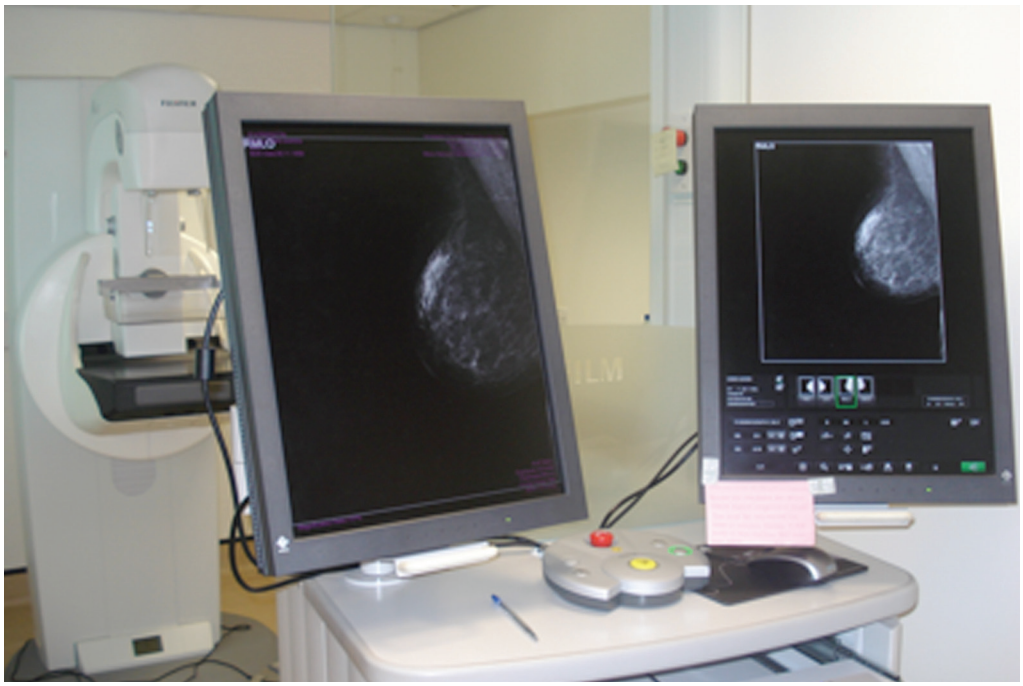

Figure 3 Workstation showing the monochrome monitor (left) and standard acquisition monitor (right), with the Fuji Amulet in the background.

3.5 Accessories

The Fuji Amulet also has a magnification stand and a selection of compression paddles. Neither was included in this evaluation, however.

4. INSTALLATION AND ACCEPTANCE TESTING

Some weeks before the Fuji Amulet was installed a rigorous site survey was carried out. It included all building requirements and a workflow analysis.

The Fuji Amulet's pre-installation requirements were broadly similar to those of a standard analogue mammography machine. As with all digital units, however, adequate air conditioning and constant power were needed.

A schedule of work was drawn up and plans were made for positioning the equipment. Data points were installed by the Trust's IT department.

Initially a Fuji Amulet with an 18 cm × 24 cm detector was installed and tested; this was later replaced by a 24 cm × 30 cm detector. Both are evaluated here.

Following installation, the Fuji Amulet underwent a critical examination to ensure that all aspects were functioning correctly. A key part of the commissioning process involved integrating the Fuji Amulet with the Trust's GE Centricity™ PACS and the National Breast Screening Service (NBSS) system.[2] Close liaison between Fuji engineers, applications specialists and the Trust's IT department was essential during this phase.

Fuji then performed its own commissioning tests. Before clinical use the Fuji Amulet (with the 18 cm × 24 cm detector) was tested by the Trust's medical physics team against current standards for digital mammography systems.[3–5]

When the new x-ray unit, including the larger 24 cm × 30 cm receptor table, was installed in September 2009 the acceptance tests were repeated. The results of both evaluations appear in Appendix 1. It should be noted that in the time that elapsed between the two installations an updated version of the reference document, *Commissioning and Routine Testing of Full Field Digital Mammography Systems*, was published.[6] Both systems met or exceeded the performance standards set out in the relevant version of this document for the normal dose mode, which was the mode to be used clinically.

Once staff had become accustomed to using the two systems, dose data for 50 women were collected from each system.

5. IMAGE QUALITY AND RADIATION DOSES

5.1 Image quality

Image quality was assessed using the Nijmegen contrast detail mammography (CDMAM) test object.† Eight images were acquired for each configuration and the threshold gold thicknesses were obtained using automated software.[5,7] In normal mode both systems produced images above the minimum acceptable standard. Results for other modes are included in Appendix 1.

5.2 Dose survey

In July 2009 a survey of 50 women was undertaken to establish the average dose required by the Fuji Amulet with the 18 cm × 24 cm detector. The results showed an average dose for 50–60 mm breasts of 1.09 mGy for a mean thickness of 57 mm.

In October 2009 another survey was undertaken, with 50 more women, to determine the average dose required by the Fuji Amulet with the 24 cm × 30 cm detector. The results showed an average dose for 50–60 mm breasts of 1.36 mGy for a mean thickness of 55 mm.

The diagnostic reference level (DRL) is 3.5 mGy per view. (For full details see Appendix 2.)

†Department of Diagnostic Radiology, University Hospital, St Radboud, Nijmegen, Netherlands.

6. STAFFING AND TRAINING

Each day's screening clinics are staffed by two people. This usually comprises one mammographer and one assistant practitioner or, occasionally, two mammographers. During the evaluation period, however, they were joined for several sessions by a trainee assistant practitioner.

Training in the use of the Fuji Amulet was by the cascade method: four mammographers were trained by Fuji and then relayed what they had learnt to colleagues. Staff in the Breast Unit were already familiar with the Fuji computed radiography mammography system and, as much of the software for the Fuji Amulet is very similar, the training was straightforward. Staffing schedules were rearranged to ensure that members of the team who had benefited from the initial supplier training were available to support colleagues who had not. Applications specialists were accessible either over the telephone or in person throughout the first week of use to resolve any problems.

7. TIMING ISSUES

7.1 Delays

The evaluation took place between May 2009 and March 2010. This included some delays, resulting from the following

- additional software upgrades were added to the equipment during the period
- the 24 cm × 30 cm receptor table was not available for installation until October 2009. This led to some downtime as a whole new mammography machine was installed, requiring fresh critical evaluation and physics checks
- the Derby screening programme was ahead of schedule, so screening stopped for several weeks during the evaluation period.

7.2 Time audit

Staff were asked to undertake a time audit to establish how long each examination took using the Fuji Amulet. This took place over a period of four weeks in August 2009. Clinics comprised 50 appointments per day. Appointment slots alternated between 5 and 10 minutes, giving an average duration of 7.5 minutes.

All women changed in the x-ray room, during which time personal details were checked and questions were asked regarding any problems with their breasts. The women included in the audit were from seven GP practices with very different uptake rates, as shown in Table 1.

Table 1 Uptake (%) of breast screening in the seven GP practices (Source: Statistics and Tables, NBSS.)

60%
62%
73%
82%
75%
78%
82%
Average: 73.1%

Radiographers were asked to note the time taken for each examination, from when the woman entered the mammography room to when she left. The time was recorded in minutes and seconds, using a stopwatch. The clinics were a combination of first-time and subsequently screened women and also included some women aged over 70 years who had self-referred.

- The shortest time taken to complete an examination was 3 minutes 3 seconds.
- The longest time was 9 minutes 30 seconds.
- The average time was 5 minutes 6 seconds.

Radiographers were also asked to add comments where necessary. Typical responses explained why some examinations took longer: for example ‘large lady; eight images’ or ‘back and shoulder problems; difficult to position’. In all the examinations undertaken and commented on during the audit, however, only two respondents attributed the fact that an examination took over 6 minutes to machine error. In both cases the error was corrected by the radiographer and the machine was out of service for only a few minutes.

8. QUALITY CONTROL

Quality control procedures were based on the NHSBSP's *Guidance Notes for Equipment Evaluation. Protocol for User Evaluation of Imaging Equipment for Mammographic Screening and Assessment*.[8] Mammography staff were already familiar with those procedures as direct digital equipment has been in use at the Derby Breast Unit since 2005.

Quality assurance testing of the Fuji Amulet took no longer than that of other direct digital machines installed at the breast unit. A sample of these tests was sent to the regional physics team, using Forms 7a, 7b and 7c from the *Guidance Notes*.[8] (See Appendix 3.)

Calibration of the Fuji Amulet took place automatically each morning after the machine was switched on. It lasted approximately 20 minutes – a period of time that was factored into the working day.

9. EQUIPMENT RELIABILITY

During the period of the evaluation clinics were booked with 50 appointments each day. The average number of women attending varied between 30 and 41, with an average of 37. Some clinics were cancelled by the breast unit because it was ahead of its screening schedule; during this downtime, Fuji made any necessary adjustments and upgrades to the equipment.

Engineers were called out on two occasions to deal with breakdowns. The first was caused by a communication error between the mammography machine and the workstation. The second related to a loss of power to the Fuji Amulet. This was caused by a loose wire in the isolator box and so was not strictly an equipment error.

All other calls to engineers arose from operator error and were corrected over the telephone, either by the engineer or by an applications specialist.

10. OBSERVATIONS OF THE MAMMOGRAPHY TEAM

All members of the mammography team were asked to record their comments on the equipment and its operation, using the NHSBSP's Digital Equipment Evaluation Form 6.[8] A summary of their comments appears below.[‡] The 15 respondents comprised 10 mammographers, four qualified assistant practitioners and one trainee assistant practitioner. Some respondents did not answer all questions.

10.1 Evaluation

Practitioners were asked to evaluate each aspect of the Fuji Amulet and its use as poor, satisfactory, good or excellent, and to support their evaluation with a comment. The results are shown in Table 2.

Table 2 Comments of the mammography team

	Responses			
Question	Poor	Satisfactory	Good	Excellent
How good was the operator's manual?		7	8	
How good was the user training?		1	9	4
How do you rate unit's ease of use/minimising fatigue?	1	4	7	3
Were x-ray times acceptable?		1	10	3
Setting for radiographic views/rotation of support arm/visibility of set angle?	2	6	6	
Setting position of support table/facility for positioning the height of the support table?		1	10	3
Range of movements?	1	1	9	3
Effectiveness of brakes/locks?		2	6	5
Effectiveness of compression/visibility of compression force from support table?	1	4	7	3
Comfort for women		1	6	7
Range of controls				
(a) Was full range of controls present?	Yes (15)			
(b) How easy were they to find and use?		3	8	2
How do you rate the time for the image to appear on the workstation?			2	12

[‡]Two questions on Form 6 were not relevant to this evaluation and were omitted. One relates to assessments, which were not undertaken on the Fuji Amulet. The other covers the ease with which images were transferred to the reporting workstation: digital images generated in the Derby Breast Unit are transferred automatically to the integrated NBSS/PACS system, however, and the practitioner is required only to close the examination.

Table 2 continued

Question	Responses			
	Poor	Satisfactory	Good	Excellent
How do you rate the image handling and processing facilities on the AWS?			2	12
Overall image quality on AWS?			1	14
What was your level of confidence in the machine with regard to good results?		1	7	6
Were any hazards identified for either you or the women?	One radiographer reported hitting her head when positioning for mediolateral oblique (MLO) views			
	No other hazards were identified			
Cleaning				
(a) Was the equipment easy to clean?	Yes (15)			
(b) Were cleaning instructions in the manual?	Yes (15)			
Patient exposure data and post exposure print out facility?	Yes, facility available (15)			
Did the system limit patient throughput?	No (14)			
	'Only when the machine went down' (1)			

10.2 Additional comments

Five practitioners each offered an additional comment.

1. 'Easy to use, smooth movements, needs pre-sets for angulation.'
2. 'The introduction of the new large monitor made assessing the image even better; however it was very good before. I loved this machine, its design aids positioning, as the ladies just fall into position. They feel supported in the oblique position as the elbow and arm are supported. I think this makes the pectoral positioning easier.'
3. 'The machine has a nice new tactile surface to place the women against. I wonder how durable this will be? The image acquisition is very quick. The large bucky was very good for larger ladies and aided keeping the tummies back! In the MLO position the women are able to rest their arms across the top of the machine. Small ladies can be a bit more difficult with the large bucky.'
4. 'There are limitations to this machine depending on the size and shape of the ladies. Reasonably tall ladies with average amount of breast tissue are fine. Short ladies with little breast tissue or short obese ladies are difficult on this machine. I find I bump my head quite a lot!'
5. 'It's quiet!'

Some radiographers also added comments. (The number of respondents in each case appears in brackets.)

1. 'Rotation should stop automatically at an angle of 45 degrees.'[§] (11)
2. 'Women being examined commented on how comfortable it was.' (6)

[§]This function is now available on the Derby equipment, following a recent software upgrade.

3. 'The image was acquired very rapidly, with no waiting time between the first and second craniocaudal views.' (5) [This has not been our experience with other direct digital machines used in Derby.]
4. 'Small breasted ladies were difficult to image using the 18 cm × 24 cm paddle on the 24 cm × 30 cm table. Manufacturers should be asked to design a more suitable paddle.' (3)
5. 'Angled corners made examination more comfortable for women.' (5)
6. 'The warm up/calibration time [about 20 minutes] is too long.' (1)

A single large monitor was installed in December 2009, along with the Precise Enlargement function. This enables the radiographer to view a single image on a second high resolution monitor. Two radiographers noted the improved visualisation of the image.

1. 'The introduction of the new large monitor made assessing the image even better; however it was good before!' (1)
2. 'Very good image quality. Instant acquisition. No waiting time between each view.' (1)

11. IMAGE QUALITY AUDIT

The evaluation of the Fuji Amulet's performance included an audit of its image quality (Figure 4), carried out in April–May 2010. Radiologists and film readers were asked to assess the quality of selection of images using a form based on NHSBSP's Digital Equipment Evaluation Form 8.[8] The results appear in Table 3 in section 11.2.

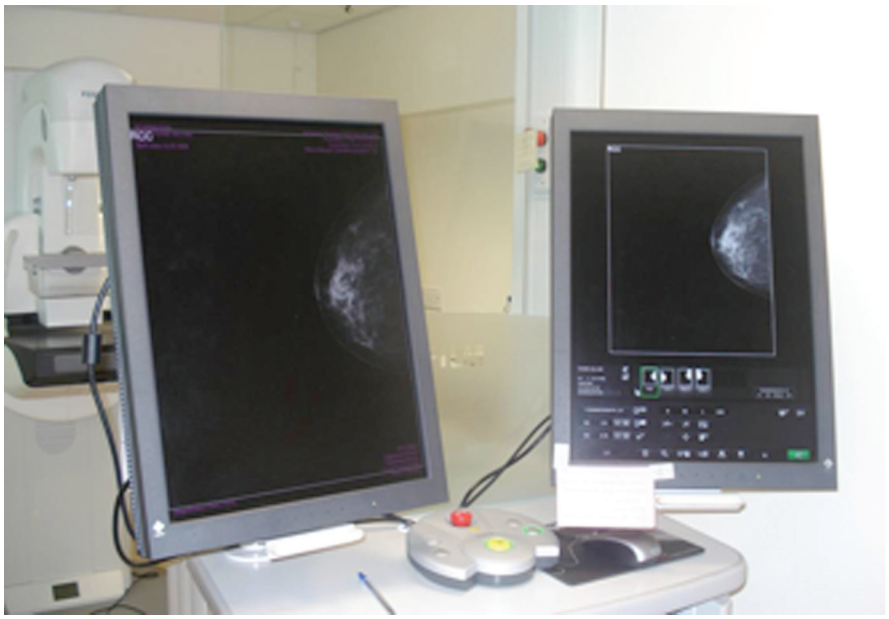

Figure 4 The monochrome monitor on the left shows a larger image on acquisition, making it easier for practitioners to identify blurring.

11.1 Method

One consultant radiologist and two experienced mammography film readers each reviewed 25 different sets of images of women who had attended for routine screening as part of the NHSBSP. Reviewers' opinions were recorded manually on a specially-designed form (see Appendix 4).

In addition, 25 different sets of images produced by two other direct digital machines in the breast unit were reviewed by the same people in the same way. This was designed to highlight any significant differences when compared with the Fuji Amulet.

11.2 Results

Table 3 Image quality audit results

Images/tissue types reviewed	
Fatty	22 (29.4%)
Mixed	39 (52.0%)
Dense	14 (18.6%)
Overall contrast (–3, very low; 0, acceptable; +3, very high)	
+1	4 (5.3%)
0	68 (90.7%)
–1	3 (4.0%)
Absolute diagnostic value	
Excellent	25 (33.3%)
Good	49 (65.3%)
Satisfactory	1 (1.3%)
Poor/inadequate	0

11.3 Discussion

Overall the results are very good, with 98.6% of all examinations rated as excellent or good and only one as satisfactory. The spread of background patterns in the selection audited is fairly typical, with 52% of mixed type and smaller percentages of fatty (29.4%) and of dense (18.6%) types.

Subdividing the number of excellent and good examinations revealed very similar assessments of absolute diagnostic value across all three background tissue types.

Fatty: excellent (36.4%); good (63.6%)

Mixed: excellent (30.8%); good (66.7%)

Dense: excellent (35.7%); good (64.3%)

Although the sample is small, this appears to demonstrate the flexibility of the direct digital image across the tissue types – a particular strength of digital images when compared with analogue examinations.

The comparison between the Fuji Amulet and other existing direct digital units demonstrated very similar results. When combining the excellent and good examinations the total for the Fuji Amulet was 98.6% and for the other two units was 95% and 92%.

In summary, this audit shows that the quality of the digital screening mammograms acquired from the Fuji Amulet mammography unit, across all tissue types, is very good.

12. INFORMATION SYSTEMS AND SOFTWARE

NBSS and PACS are fully integrated at the Derby Breast Unit.[2] The GE PACS system runs RA1000 version 3.0.5.3. The reporting workstations have

1. an HP xw6600 workstation with NEC 20-inch LCD monitor
2. two Barco MFGD 5120 5 megapixel monitors

The local interface enabled the images of all screened (asymptomatic) and symptomatic women to be sent directly from the Fuji Amulet to PACS. The images for each individual woman were in a single PACS jacket.

Screening appointments were made on NBSS and worklists for each clinic were sent directly to the Fuji Amulet. As each appointment was made on NBSS a file was opened in PACS. Details of the day's clinic appeared on the mammography machine. The names of the women attending appeared on the local worklist and were selected as their examination was performed.

Close cooperation between the Fuji applications specialists and the Trust's IT team during the evaluation enabled all this to be managed without difficulty.

13. CONCLUSION

The Fuji Amulet performed very reliably during the whole of the evaluation period. There was little significant downtime, none of it resulting from machine breakdown. The only extended downtime occurred when the entire machine was replaced during the installation of the 24 cm × 30 cm receptor table.

The majority of practitioners found the Fuji Amulet a very easy and fast machine to use. This is essential for a busy screening clinic.

When the 24 cm × 30 cm receptor table was installed, some practitioners initially found it difficult to position smaller breasted women. This was mainly because the 18 cm × 24 cm paddle was fixed in the middle of the receptor table. The manufacturer is currently exploring the possibility of developing a compression paddle to address this. A modification that allowed the rotation to stop automatically at pre-set positions (eg 45°) would further enhance workflow.[¶]

Overall, the practitioners' comments indicated that women being screened found the machine very comfortable.

Linking the system to the hospital's PACS was straightforward. The Fuji Amulet and its local interface needed to be fully tested before use, however, and the cooperation of engineers, applications specialists and the local IT team was essential throughout.

The image quality of mammograms acquired via the Fuji Amulet proved to be very good across all tissue types.

[¶]This modification has since been introduced. (See p.13.)

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APPENDIX 1: PHYSICS REPORTS

A. May 2009 (18 cm × 24 cm system)

Safety checks

Mechanical and safety function	All acceptable
Radiation safety	All acceptable
Thickness gauge accuracy	Within 5 mm
Maximum compression force	195 N
Accuracy of indicated compression force	Within 9 N

Tube and generator

Accuracy of tube voltage (25–35 kV)	Within 0.4 kV
Tube output at 50 cm (Mo/Mo 28 kV)	242 µGy/mAs
Output repeatability, Mo/Mo 28 kV, CP[#] in	0.1%
Variation with tube voltage	Linear relationship with kV for all target–filter combinations
Variation with mAs – broad focus	0.4%
HVL[**], MoMo, 30 kV, CP out	0.31

Alignment

Alignment of x-ray field to the light field	Within 5 mm for all edges, both targets
Alignment of x-ray field to imaged field/detector	With tolerances for all edges, both targets
Size of imaged field	17.3 cm × 23.0 cm
Separation: image edge and chest wall edge of support	5 mm

Detector performance

Uniformity	Maximum deviation in pixel value of 3%, tested in all modes and target–filter combinations
Artefacts and dead pixel dropout	Acceptable
Detector response (4.5 cm Perspex)	Logarithmic response
Clinically representative target pixel value, PV_{clin}	2050
Detector reference air kerma to produce PV_{clin}	132.7 µGy (4.5 cm Perspex, W/Rh, 29 kV)
Detector resolution – square wave contrast transfer factor	0.29 (1 lp/mm), 0.15 (4 lp/mm)
Spatial discontinuity	None seen
Image retention factor	0.04

[#]CP, compression plate.
**HVL, half value layer.

AEC

AEC repeatability – mAs	2%

AEC performance – automatic mode L

Perspex	Equivalent breast thickness	TFkV[††]	mAs	CNR	MGD (mGy)	Exposure time (s)
2	2.1	WRh26	39.4	16.3	0.58	0.76
3	3.2	WRh26	76.1	15.7	0.89	0.76
4	4.5	WRh28	85.9	12.8	1.13	0.77
4.5	5.3	WRh29	86.1	11.6	1.20	0.76
5	6	WRh30	102	11.2	1.47	0.88
6	7.5	WRh31	143.4	10.1	2.04	1.19
7	9	WRh32	203.6	8.98	2.85	1.61

AEC performance – automatic mode H

Perspex	Equivalent breast thickness	TFkV	mAs	CNR	MGD (mGy)	Exposure time (s)
2	2.1	MoMo26	29.2	–	0.96	–
3	3.2	MoMo27	41.7	18.1	1.23	0.77
4	4.5	MoRh28	66.4	14.7	1.58	0.76
4.5	5.3	MoRh29	74	13.3	1.88	0.83
5	6	MoRh30	88.9	12.5	2.34	0.97
6	7.5	WRh30	238.9	11.9	3.10	1.76
7	9	WRh30	422.4	11.6	4.90	3.00

AEC performance – automatic mode W

Perspex	Equivalent breast thickness	TFkV	mAs	CNR	MGD (mGy)	Exposure time (s)
2	2.1	WRh26	26.3	13.9	0.39	0.76
3	3.2	WRh26	49.9	13.2	0.58	0.76
4	4.5	WRh28	56.9	10.6	0.75	0.77
4.5	5.3	WRh29	55.5	9.04	0.77	0.76
5	6	WRh30	66.8	9.03	0.96	0.88
6	7.5	WRh31	94.8	8.20	1.35	1.19
7	9	WRh32	128	7.38	1.79	1.61

[††]Target–filter, kV.

Image quality

Threshold contrast visibility was measured with CDMAM test object.[3–5]

Predicted average threshold gold thicknesses for detail diameters 0.1 to 1mm using automatic beam selections

Detail diameter (mm)	L mode W/Rh 30 kV 1.35 mGy	H mode Mo/Rh 30 kV 2.01 mGy	W mode W/Rh 30 kV 0.88 mGy	Acceptable	Achievable
0.1	1.13	0.88	1.23	1.68	1.10
0.25	0.297	0.248	0.340	0.352	0.244
0.5	0.146	0.129	0.170	0.150	0.103
1.0	0.080	0.079	0.094	0.091	0.056

Baseline images were taken for regular IQ tests using TORMAX and TORMAM test objects.

B. October 2009 (24 cm × 30 cm system)

Safety checks

Mechanical and safety function	All acceptable
Radiation safety	All acceptable
Thickness gauge accuracy	Within 5 mm
Maximum compression force	195 N
Accuracy of indicated compression force	Within 15 N

Tube and generator

Accuracy of tube voltage (27–35 kV)	Within 0.8 kV
Tube output at 50 cm (Mo/Mo 28 kV)	243 µGy/mAs
Output repeatability, Mo/Mo 28 kV, CP in	0.2%
Variation with tube voltage	Linear relationship with kV for all target–filter combinations
Variation with mAs – broad focus	0.8%
HVL, MoMo, 30 kV, CP out	0.30

Alignment

Alignment of x-ray field to the light field	Within 4 mm for all edges, both targets
Alignment of x-ray field to imaged field/detector	With tolerances for all edges, both targets
Size of imaged field	23.6 cm × 29.6 cm
Separation: image edge and chest wall edge of support	5 mm

Detector performance

Uniformity	Maximum deviation in pixel value of 5%, tested in all modes and target–filter combinations
Artefacts and dead pixel dropout	Acceptable
Detector response	Logarithmic response
Clinically representative target pixel value, PV_{clin}	2050
Detector reference air kerma to produce PV_{clin}	71 µGy (4.5 cm Perspex, compression plate, W/Rh 29 kV)
SNR at detector reference air kerma	151
Detector resolution – square wave contrast transfer factor	0.32 (1 lp/mm), 0.13 (4 lp/mm)
Spatial discontinuity	None seen
Image retention factor	0.07

AEC

AEC repeatability – mAs	2%

AEC performance – automatic mode L (24 cm × 30 cm compression paddle)

Perspex	Equivalent breast thickness	TFkV	mAs	CNR	MGD (mGy)	Exposure time (s)
2	2.1	WRh26	40.9	15.9	0.54	0.76
3	3.2	WRh26	82.8	15.3	0.80	0.76
4	4.5	WRh28	95.1	12.6	0.91	0.80
4.5	5.3	WRh28	91.8	10.3	0.96	0.78
5	6	WRh30	102.4	10.2	1.21	0.89
6	7.5	WRh31	150.2	9.4	1.75	1.27
7	9	WRh32	208	8.3	2.11	1.59

AEC performance – automatic mode L (18 cm × 24 cm compression paddle)

Perspex	Equivalent breast thickness	TFkV	mAs	CNR	MGD (mGy)	Exposure time (s)
2	2.1	WRh26	41.3	15.7	0.52	0.76
3	3.2	WRh26	75.5	15.0	0.83	0.76
4	4.5	WRh28	86	12.1	0.97	0.77
4.5	5.3	WRh28	90.6	10.3	0.96	0.77
5	6	WRh30	103.9	10.4	1.18	0.89
6	7.5	WRh31	157.4	9.9	1.74	1.29
7	9	Wrh32	203.6	8.3	2.17	1.61

AEC performance – automatic mode H (18 cm × 24 cm compression paddle)

Perspex	Equivalent breast thickness	TFkV	mAs	CNR	MGD (mGy)	Exposure time (s)
2	2.1	MoMo26	33.7	23.8	0.93	0.76
3	3.2	MoMo27	48	18.7	1.19	0.76
4	4.5	MoRh28	69.6	14.3	1.46	0.77
4.5	5.3	MoRh28	94.9	13.5	1.75	0.96
5	6	MoRh30	90.4	12.0	2.22	0.97
6	7.5	WRh29	269.3	11.8	2.49	1.91
7	9	WRh30	389.5	11.6	3.48	2.78

AEC performance – automatic mode W (18 cm × 24 cm compression paddle)

Perspex	Equivalent breast thickness	TFkV	mAs	CNR	MGD (mGy)	Exposure time (s)
2	2.1	WRh26	26	12.2	0.35	0.76
3	3.2	WRh26	52.3	11.9	0.55	0.77
4	4.5	WRh28	57.3	9.6	0.46	0.77
4.5	5.3	WRh28	59.2	7.8	0.62	0.76
5	6	WRh30	66.8	7.8	0.77	0.76
6	7.5	WRh31	102.4	7.4	1.12	0.91
7	9	WRh32	134.2	6.5	1.39	1.11

Image quality

Threshold contrast visibility was measured with CDMAM test object.[3–5]

Predicted average threshold gold thicknesses for detail diameters 0.1 to 1mm using automatic beam selections

Detail diameter (mm)	L mode W/Rh 30 kV 1.15 mGy	Acceptable	Achievable
0.1	1.09	1.68	1.10
0.25	0.301	0.352	0.244
0.5	0.144	0.150	0.103
1.0	0.081	0.091	0.056

Baseline images were taken for regular IQ tests using TORMAX and TORMAM phantoms.

APPENDIX 2: DOSE SURVEY (1) 18 CM × 24 CM

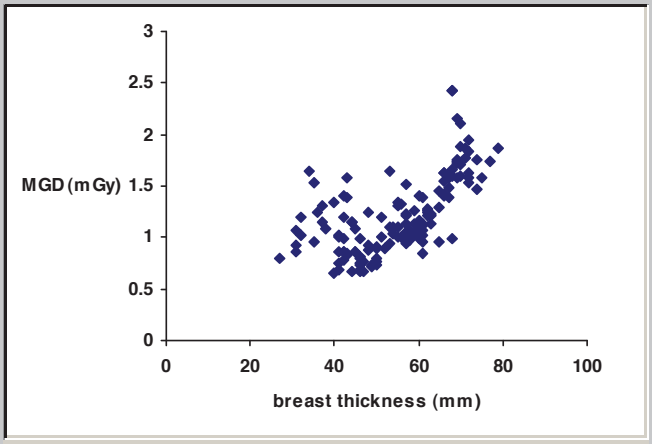
NHSBSP Breast Dose Survey

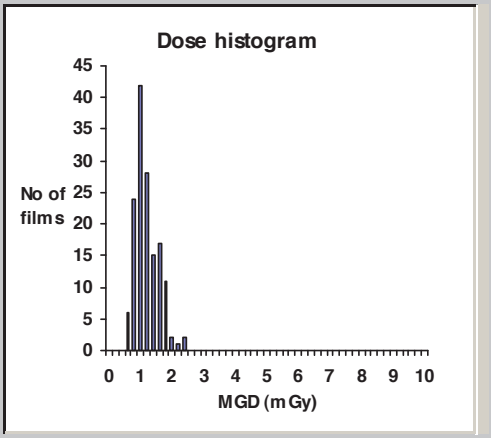
Survey No:	400
Centre:	Derby
Date of first exam:	
Date of last exam:	
X-ray make	Fuji
Model:	Amulet (18x24)
Local id:	DBDA
Installation:	fixed
kV mode:	auto
standard kV:	0
Routine/age trial:	routine screening
24x30 cassettes available:	☐
Block mAs:	
Block density:	
physics service	Northampton
Physicist	V Jones

Processor make:	DR
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:		HVL:	
target:		MGD:	
filter:		film density:	





Count of films

view	main films	Extra films
CC	74	
OB	74	

Summary of X-ray factors selected

Anode	Filter	kV	films
W	Rh	26	2
W	Rh	27	9
W	Rh	28	49
W	Rh	29	16
W	Rh	30	60
W	Rh	31	12

Average doses for main films

view	No of films	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	74	0.66	2.42	1.12	54
OB	74	0.68	2.42	1.28	56

Average doses per screening examination

	No of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
Two view	37	1.43	4.55	2.40

Average dose for 50-60mm thick breasts

View	No of films	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
OB	24	1.09	0.06	57

APPENDIX 2: DOSE SURVEY (2) 24 CM × 30 CM

NHSBSP Breast Dose Survey

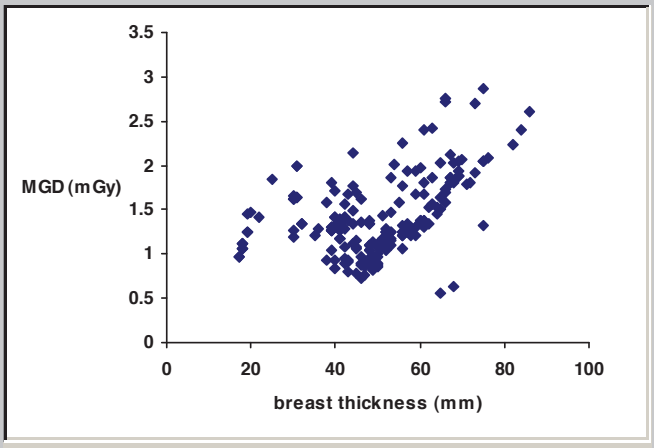
Survey No:	507	Processor make:	DR
Centre:	Derby	Processor ID:	
Date of first exam:		Developer:	
Date of last exam:		Fixer:	
X-ray make	Fuji	Dev Temp (deg C):	
Model:	Amulet (24x30)	Proc time (s):	0
Local id:	dbda	Cassette make:	
Installation:	fixed	Film make:	
kV mode:	auto	Screen make:	
standard kV:	0		
Routine/age trial:	routine screening		

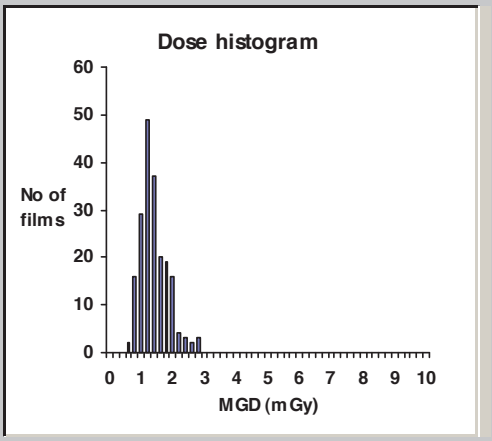
24x30 cassettes available: ☑

Block mAs:	
Block density:	
physics service	Northampton
Physicist	V Jones

MGD to standard breast

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





Count of films

view	main films	Extra films
CC	100	
OB	100	

Summary of X-ray factors selected

Anode	Filter	kV	films
W	Rh	26	14
W	Rh	27	8
W	Rh	28	76
W	Rh	29	28
W	Rh	30	59
W	Rh	31	14
W	Rh	32	1

Average doses for main films

view	No of films	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	100	0.72	2.72	1.36	49
OB	100	0.57	2.86	1.46	52

Average doses per screening examination

	No of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
Two view	50	1.55	4.87	2.82

Average dose for 50-60mm thick breasts

View	No of films	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
OB	25	1.36	0.12	55

APPENDIX 3: DIGITAL DATA COLLECTION SPREADSHEETS

Digital data collection spreadsheet (7A)

Date	Monitors: visual check and screen clean	Flat field correction (DR only). May be less frequent depending on manufacturer's instructions	4 cm Perspex, mAs	kV	Target	Filter	ROI mean pixel value	ROI standard deviation	SNR	Visual artefact and uniformity check
03.08.09	Y		127	28	W	Rh	8463.4	20.2	418.98	Y
04.08.09	Y		128	28	W	Rh	8411.6	20.5	410.3	Y
05.08.09	Y		122	28	W	Rh	8245.2	21.9	376.4	Y
06.08.09	Y		128	28	W	Rh	8365.3	20.5	408	Y
07.08.09	Y		127	28	W	Rh	7270.7	27.1	433	Y
10.08.09	Y		128	28	W	Rh	8576.4	19.8	433.1	Y
11.08.09	Y		122	28	W	Rh	8045	23.2	346.7	Y
12.08.09	Y		128	28	W	Rh	7381.9	28	263.6	Y
13.08.09	Y		127	28	W	Rh	8349.4	20.3	411.3	Y
14.08.09	Y		128	28	W	Rh	7868.4	23.5	334.8	Y
17.08.09	Y		122	28	W	Rh	7836.1	22.7	345.2	Y
18.08.09	Y		128	28	W	Rh	7795.8	23.5	331.7	Y
19.08.09	Y		127	28	W	Rh	8280.8	20.2	409.9	Y
20.08.09	Y		128	28	W	Rh	8470.8	19.7	429.9	Y
21.08.09	Y		122	28	W	Rh	8600.3	19.5	441	Y
24.08.09	Y		128	28	W	Rh	8277.3	20.3	407.7	Y
25.08.09	Y		127	28	W	Rh	8409.5	19.9	422.5	Y
26.08.09	Y		128	28	W	Rh	8409.5	19.5	431.2	Y
27.08.09	Y		122	28	W	Rh	8429.4	19.9	423.5	Y
28.08.09	Y		128	28	W	Rh	8325.1	20.4	408	Y
26.07.09	Y		128	28	W	Rh	8076.9	22.7	355.8	Y
29.07.09	Y		127	28	W	Rh	8269.2	21.1	391.9	Y
23.07.09	Y		128	28	W	Rh	7871.2	23	342.2	Y
21.07.09	Y		122	28	W	Rh	8419.7	20.7	406.7	Y
20.07.09	Y		128	28	W	Rh	8591.3	18.8	456.9	Y
16.07.09	Y		127	28	W	Rh	8040.7	26.7	301.1	Y
15.07.09	Y		128	28	W	Rh	8404.4	19.8	242.4	Y
19.07.09	Y		122	28	W	Rh	8646.3	19.2	450.3	Y
10.07.09	Y		128	28	W	Rh	8316.1	20.5	405.6	Y
09.06.09	Y		128	28	W	Rh	8617	20.2	426.5	Y

ROI, region of interest; SNR, signal-to-noise ratio.

Digital data collection spreadsheet (7B)

Date	Quantitative uniformity check if possible	Mean pixel value, 4 cm Perspex	Mean pixel value, Perspex + aluminium	Standard deviation, Perspex	CNR	TORMAM filaments	TORMAM particles	TORMAM low contrast objects	TORMAM total score
03.08.09	1.85	8460.8	8187.3	20.7	13.21256039	34	12.5	32	78.5
11.08.09	2.48	8045	7776	23.2	11.5	37	14	30	81
17.08.09	1.59	7836.1	7544.7	72.7	12.8	41	14	30	85
23.07.09		7871.2	7586.7	23	12.3	40	12	30	92
21.07.09		8419.7	8075.6	20.7	16.6	41	12	30	93
20.07.09		8591.3	8300.1	18.8	15.4	44	11	30	85
16.07.09		8040.7	7759.2	26.7	16.5	47	12	27	86
15.07.09		8404.4	8114.2	19.8	14.65	41	12	34	97
19.07.09		8646.3	8314.2	19.2	17.2				
28.08.09	1.77	7954.8	7660.5	23.2	12.6				
24.08.09		8277.2	7985.9	20.4	14.2				
19.08.09		8345.4	8050.3	19.8	14.9				

CNR, control-to-noise ratio.

Digital data collection spreadsheet (7C)

Date	2 cm Perspex, mAs	Mean pixel value, 2 cm Perspex	Mean pixel value, Perspex + aluminium	Standard deviation, Perspex	SNR	CNR	4 cm Perspex, mAs	Mean pixel value, 4 cm Perspex	Mean pixel value, Perspex + aluminium
21.07.09	38.9	8225.8	7985.7	22.5	365.59	10.67	136	8163.4	7868.6
28.07.09	40.1	8499.1	8163.1	19.1	444.98	17.59	129	8377	8182.6
11.08.09	38.4	8523.6	8173.5	20.1	424.06	17.42	127	8790.1	8477.9
28.08.09	39	8523	8195.5	19.5	437.08	16.79	115	7955.7	7659.6

Date	Standard deviation, Perspex	SNR	CNR	7 cm Perspex, mAs	Mean pixel value, 7 cm Perspex	Mean pixel value, Perspex + aluminium	Standard deviation, Perspex	SNR	CNR
21.07.09	21.8	374.47	13.52	337.8	8207.5	7909.5	21.6	380	13.8
28.07.09	20.1	416.77	9.672	368	8306	8049.4	21.3	390	12.05
11.08.09	18.6	472.59	16.78	327	8275.4	8031.3	21.7	381.4	11.25
28.08.09	23.1	344.4	12.82	338.3	8215.7	7968.1	22.8	360.3	10.86

CNR, control-to-noise ratio; SNR, signal-to-noise ratio.

APPENDIX 4: IMAGE EVALUATION FORM

IMAGE EVALUATION FORM					
Number	Digital unit	Breast composition	Overall contrast	Absolute diagnostic value	Comments by radiologist/film reader
	Fuji Amulet				
	Fuji Amulet				
	Fuji Amulet				
	Fuji Amulet				
	Fuji Amulet				
	Fuji Amulet				
	Fuji Amulet				
	Fuji Amulet				
	Fuji Amulet				
	Fuji Amulet				
	Fuji Amulet				
	Fuji Amulet				
	Fuji Amulet				
	Fuji Amulet				
	Fuji Amulet				
	Fuji Amulet				
	Fuji Amulet				

Breast composition	
Fatty	F
Mixed	M
Dense	D

Overall contrast	
Very high	3
High	2
Slightly high	1
Acceptable	0
Slightly low	–1
Low	–2
Very low	–3

Absolute diagnostic value	
Excellent	E
Good	G
Satisfactory	S
Poor	P
Inadequate	I