

EVALUATION AND CLINICAL ASSESSMENT OF THE FUJI CR PROPECT ON A BREAST SCREENING TRAILER

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1. INTRODUCTION

The Derby Breast Screening Unit covers a population of approximately 76 000 women. Screening takes place at two static sites and in two mobile screening vans. The screening programme invites one-third of the population each year, and does this by month of birthday. In this way, the mobile vans visit each screening site annually. The static site at the Royal Derby Hospital is the programme's base office. It provides a symptomatic breast service, high risk screening for family history patients, and a surveillance service for previously diagnosed breast cancer patients. One GE Senograph DS full field digital mammography machine has been in place there since 2005. In addition, a GE Essential full field digital mammography machine was installed in December 2007.

Introducing direct digital mammography machines across the Derby Breast Unit would mean purchasing three direct digital machines and two new mobile screening vans. Given the expense of such a strategy, computed radiography (CR) has been adopted as an interim solution.¹

With this in mind, the Derby Breast Unit (DBU) reached an agreement with Fuji to pilot its Profect CR system on a mobile screening van from June 2007 to June 2008 under full screening conditions. This clinical evaluation of the pilot scheme was commissioned by the NHS Breast Screening Programme (NHSBSP) and supplements its two earlier, technical, evaluations of Fuji CR systems.^{2,3}

2. SCOPE OF THE PROJECT

The Fuji Profect CR system was evaluated on a typical mobile breast screening van (Figure 1). The van is 11 m long and was manufactured by CSC Specialised Vehicles. It is approximately seven years old and is fitted with a Siemens Mammomat 3000 Nova mammography machine of the same age.



Figure 1 Derby mobile breast screening unit.

Prior to the CR system's installation, the mobile van was equipped with one Fuji 18 cm × 24 cm film loader, one 24 cm × 30 cm film loader and one Fuji unloader. A combination of Fuji cassettes fitted with fine screens and Fuji UMMA D/L mammography film was used. Patients' films were identified with a Kodak Data Flash ID camera, which also transferred exposure factors onto the films.

The aims of the evaluation were to

- test the robustness of the equipment on a mobile screening van that is regularly moved
- establish whether the NHSBSP's recommended six minute appointment slots could be maintained with the CR system
- assess the impact of its introduction on practitioners' working environment
- determine whether technical recalls and repeats could be reduced, improving service to the clients
- compare the quality of CR images with the established film-screen system
- assess the robustness of image transfer from the mobile van to the static site.

3. EQUIPMENT INSTALLATION AND SETUP

The mobile van was sited at the base office for two weeks in June 2007 in readiness for the installation. A plan of the van's layout was sent to Fuji and a site visit was made by their engineers to determine where the new equipment would be fitted.

The Fuji Profect CS high throughput CR reader was installed on the mobile van in the space vacated by the 18 cm × 24 cm loader and the unloader (Figure 2), and a three megapixel monitor was fitted on the adjacent bench. A three megapixel high resolution monitor was installed at the base office, along with a Fuji 7000 laser printer that had been set up by Fuji to deliver mammography standard images. Staff from Northampton General Hospital's Medical Physics department verified that the image quality met NHSBSP standards.⁴ (Hard copy images were produced as there was no interface between the National Breast Screening Computer System (NBSS) and PACS (Picture Archiving and Communication System) at that time to allow downloading of images to the hospital's PACS system. This has since been addressed: NBSS is now fully integrated and breast screening images are all soft copy read.)

Eight 18 cm × 24 cm CR cassettes and eight 24 cm × 30 cm CR cassettes with imaging plates were provided. Also provided were four fully encrypted 12 cm × 7 cm hard drives with a storage capacity of 320 GB. These were used to download images from the mobile van and take them back for printing at the base office. Approximately 60 women per day are booked into mobile clinics, and one hard drive comfortably stored the images produced by a clinic. (Occasionally during the evaluation images from two clinics were stored, without difficulty, on a single hard drive.)

The automatic exposure control (AEC) on the mammography machine was recalibrated by the Siemens engineer to give an increased dose, as recommended by the medical physics team following their set-up tests.

Strapping was supplied for securing the CR reader before the mobile van moved off.

Part-way through the evaluation, a Fuji x-con interface was installed, allowing all exposure-related information from the x-ray set (such as kV, mAs, filter and compression) to be linked automatically to the mammogram on the CR system. This information was then displayed on printed images or on the PACS system.



Figure 2 CR reader and workstation.

4. TRAINING

Initial training for four practitioners took place at the Fuji headquarters in Bedford. Two senior radiographers, the QA radiographer and an assistant practitioner attended. The training was practical and focused, and included opportunities for hands-on use of the printer, computer and reader. A comprehensive training manual was provided by Fuji. This training was then cascaded through the Derby Breast Unit team, with each Fuji-trained team member introducing a small group of radiographers and assistant practitioners to all aspects of the CR screening process. The mobile van remained outside the base office throughout this period, and staff were allocated time to familiarise themselves with the new equipment.

5. IMPLEMENTATION OF CR

Once the mobile van was back in service a rota was introduced to ensure that each session included one Fuji-trained practitioner to support the other team members. A list of contact numbers for engineers and applications specialists was also displayed in the van. A short guide to the system's basic functions was produced, based on Fuji's comprehensive instruction manual.⁵ (See Appendix 1.)

A Problems Log was introduced in which staff could identify any issues that arose and how they were resolved. (See Appendix 2.) This was a useful resource both for staff who encountered the same problem and for managers giving feedback to Fuji.

Clinic appointments were initially scheduled for every 10 minutes. These longer slots gave staff time to become more familiar with the equipment and adapt to its impact on workflow. At this point in the evaluation the Derby Breast Unit was not using a work-list or the NBSS Daybook program. Clinic lists were being taken out daily to the mobile and, in the absence of an NBSS-PACS interface, all images continued to be printed. Appointments were later scheduled at six minute intervals (see section 7).

6. IMAGE EVALUATION

6.1 Comparison of CR and analogue film

As part of the evaluation of the CR equipment, images produced by the film-screen system were compared with CR laser film images.

6.1.1 Method

One consultant radiologist and three experienced mammographic film readers each reviewed 180 sets of films of women who attended for NHSBSP screening. Only women with previous analogue screening films and current printed CR films were included. All the women were over 50 years of age. The film readers' opinions were noted manually on a form derived from the NHSBSP equipment evaluation document.⁶

A total of 720 films were reviewed and a breakdown of the results appears in Table 1a. In 540 cases sharpness, noise and exposure/contrast were also assessed, with the results shown in Table 1b.

6.1.2 Results

Table 1a Results for four readers reviewing a total of 720 examinations

Pattern		
Fatty	215 (30%)	
Mixed	395 (55%)	
Dense	110 (15%)	
Rating	Analogue images	CR images
5 (excellent)	22 (3.1%)	278 (38.6%)
4 (good)	383 (53.2%)	385 (53.4%)
3 (satisfactory)	291 (40.4%)	57 (8%)
2 (poor)	24 (3.3%)	0 (0%)
Relative diagnostic value of CR, compared with analogue film		
+2	104 (14.4%)	
+1	401 (55.8%)	
0	212 (29.4%)	
-1	3 (0.4%)	

Table 1b Results for four readers evaluating a total of 540 cases for sharpness, noise and exposure grade

Sharp		
No (analogue)	76 (14.1%) (16 fatty, 42 mixed, 18 dense)	
No (CR)	32 (5.9%) (4 fatty, 22, mixed, 6 dense)	
Noisy		
Yes (analogue)	1 (0.2%) (1 dense)	
Yes (CR)	28 (5.2%) (16 mixed, 12 dense)	
Exposure grade	Analogue	CR
+2	6 (1.1%)	0 (0%)
+1	65 (12%)	7 (1.3%)
0	387(71.8%)	513 (95%)
-1	81 (15%)	20 (3.7%)
-2	1 (0.2%)	0

6.1.3 Discussion

Background patterns in over half of the films reviewed were assessed as a mixture of fatty and dense. Comparison of their absolute diagnostic value revealed an equal number of 'good' films (rated 4) in the analogue and the CR groups. However, a significantly higher proportion of CR images were rated as 'excellent' (5), whereas the number rated 'satisfactory' (3) was correspondingly higher in the analogue group. There were few poor or inadequate images among the analogue films and none at all among CR films.

The relative diagnostic value of CR was assessed as significantly higher than analogue: over 70% of the CR films were rated better (+2) or slightly better (+1) than analogue; fewer than 30% were rated as the same as analogue film and under 1% as slightly worse. Absolute diagnostic values were also higher in the CR group, with 92% of the CR images rated as good or excellent compared with 56.3% of analogue images.

A lack of sharpness was noted in both groups but primarily among analogue images. Noise was restricted to mixed and dense patterns and was more common in CR images. Exposure and contrast were assessed as acceptable (0) in the clear majority of both sets of image. Whereas this applied to 95% of CR cases, however, results for analogue cases were more widely spread.

In summary this audit suggests that, overall, printed CR films are at least as good as analogue films for NHSBSP film reading and in a significant number of cases are better.

6.2 Technical recalls

At the time of the pilot the Derby Breast Unit was complying with recommended NHSBSP standards covering technical recalls for women attending for breast screening.⁴ Practitioners believed that using CR would help to cut the number of recalls by avoiding some of the technical problems that called for repeat screening; and that this in turn would free up more appointment slots, reduce women's anxiety levels and enhance job satisfaction among radiographers.

The number of technical recalls was indeed reduced. (See Table 3 and Figure 3.) A comparison was made of technical recall rates over three mobile sites for 2004–2006 (before the introduction

of CR) and 2007 (after its introduction). By enabling practitioners to see images as they were taken, CR reduced the likelihood of women having to return for repeat examinations as a result of poor positioning, because part of the breast was not on the film, or because of major blurring. There were no film handling problems. Minor blurring still hampered interpretation in some cases, but this is expected to improve as practitioners' experience of viewing images develops.

Table 3 Technical recalls for the Ashbourne, Belper and Ripley sites

	2004	2005	2006	2007
Blurring	9	11	7	8
Position	4	22	15	1
Exposure	2	4	10	0
Film handling	4	2	6	0
Not known	1	2	0	0
Total recalls	20	31	38	9

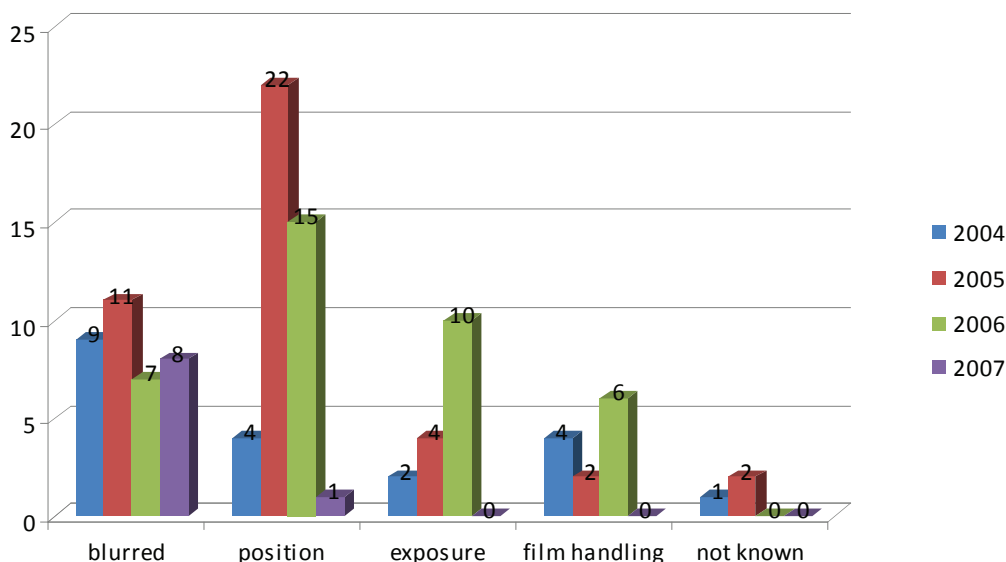


Figure 3 Technical recalls for Ashbourne, Belper and Ripley sites.

7. TIME AUDIT

Ten minute appointment slots were used for the first three months to enable staff to become familiar with the equipment. After this the recommended six minute slots were reinstated and the clinics were audited. A slightly modified version of NHSBSP digital equipment evaluation form 5 (shown at Appendix 3)⁶ was used to record

- the time the woman entered the mammography room
- the number of images taken
- the time the woman left the mammography room
- the comments of radiographers (for example, where extra films were needed or a longer time was taken).

7.1 Results

Table 4 Time audit results

Number of women screened	Average time per woman	Time range	Average number of films per examination	Film range
397	5.93 minutes	15–3 minutes	4.3	6–2

Clinics were scheduled from 0900 to 1200 hours and from 1330 to 1615 hours. There were approximately 60 appointments per day, each scheduled for six minutes.

Clinics generally started and finished on time. The only exceptions to this were when the woman attended late or on the wrong day or when several women attended with mobility problems of which the clinic had not been notified. The take-up rate was 83.7%.

7.1.1 Acceptance testing

Before clinical use the Fuji CR system was tested against current standards for digital mammography systems.^{7–9} It was initially installed with no change to the x-ray system setup, which had previously been used with Fuji AD/UMMA screen-film. This resulted in image quality that lay outside the acceptable range. Tests were repeated with doses raised by 50%, and this time the system met all relevant quality criteria. Medical physics therefore recommended that the system be used at the higher dose level.

Image quality was tested using the Nijmegen CDMAM test object with 2 cm of Perspex above the object and 2 cm below it. The threshold contrasts were obtained using automated software.

The key results of these tests are shown in Tables 5 and 6. Full medical physics test results are given in Appendix 4.

Table 5 Image quality measurements conducted using 28 kV Mo/Rh

Detail size (mm)	Predicted threshold gold thickness (μm)		Acceptable value
	Initial setup	Increased dose setup	
0.1	2.14	1.65	1.68
0.25	0.33	0.26	0.35
0.5	0.16	0.10	0.15
1.0	0.08	0.05	0.91

Table 6 Dose measurements

Dose setting on AEC	Mean glandular dose (MGD) for standard breast (mGy)	Dose limit for standard breast (mGy)
Initial (+3)	1.47	<2.5
Elevated dose (+14)	2.25	<2.5

7.1.2 Radiation doses

Exposure factors used with 50 screened women were recorded and doses calculated using the NHSBSP software for dose surveys.¹⁰ Table 7 shows the average dose for the oblique exposures in the thickness range 50–60 mm, for which the diagnostic reference level is 3.5 mGy.¹¹ The average dose from a previous survey, which used film-screen, is included for comparison.

Table 7 Radiation doses

	Average dose for 50–60 mm breasts (mGy)	Average thickness (mm)
Film-screen	0.86	56
CR elevated dose (+14)	1.46	55

8. COMMENTS FROM RADIOGRAPHERS

Table 8 lists the comments of the mammography practitioners on the advantages and disadvantages of using the equipment.

Table 8 Radiographers' comments

Advantages	Disadvantages
<ul style="list-style-type: none"> • cassettes are lighter, so likely to reduce the risk of musculoskeletal discomfort • practitioners can see images on the mobile van • there are no heavy magazines or films to transport as the hard drive is used to transport images from mobile van to the base office • there were fewer technical recalls • there were no artefacts on the images • there were no processing problems 	<ul style="list-style-type: none"> • significant heat is generated by CR readers; efficient air conditioning is needed • printing continued to be necessary during the evaluation; 24 cm × 30 cm films needed printing separately, which was time-consuming • recording exposure factors was an additional and time-consuming task. This has since been resolved with the introduction of a Fuji X-con interface

The consensus from all radiographers and assistant practitioners was that the CR mobile van provided a much better working environment for staff (who preferred to be sent there) and a better service for the women, as fewer technical recalls were necessary. Proposals were soon put forward to adapt the second mobile van for CR.

9. COMMENTS FROM MEDICAL PHYSICISTS

Standard commissioning tests were undertaken by the medical physics team before the Fuji Profect CR system was brought into service.⁵

This initial testing phase was longer and more challenging than expected, for a number of reasons

- installation work invalidated some of the tests and they had to be repeated
- as this was a new CR installation in a mobile van, Fuji's applications specialist and engineer were still determining the most effective way of saving images for transfer to the base office
- the bar code reader failed part-way through testing
- the medical physics team had to develop new protocols for using the CDMAM object (the phantom recommended for digital testing) to test CR, and also for downloading images off site
- scoring the hard copy CDMAMs was time-consuming, however experienced the reader
- advice had to be sought from other medical physicists on aspects of the commissioning process.

9.1 The performance of the system and quality control

The system was initially set up to match the film-screen system, which required a +3 density setting.

Table 9 Initial setup

	Density setting	MGD (mGy) to the standard breast (NHSBSP remedial level=2.5 mGy)	Image quality Contrast-detail detection with CDMAM
Initial setup	+3 (to match Fuji AD/UMMA film-screen system)	1.47	Below acceptable level for 0.01 and 1 mm details
Recommended (by medical physics)	+14 (an increase in dose of 50%)	2.25	Acceptable

The initial recommendation to work at an increased dose level of +50% was based on images of TORMAX and TORMAM test objects, as there had been insufficient time to complete tests with CDMAM objects across a range of doses. Later tests with CDMAM confirmed that a higher dose was needed to meet acceptable limits for threshold contrast.

This recommendation is in line with the doses required to meet image quality standards for different (CR and DR) digital systems.^{12,13} This comparison indicated that

- the dose to reach minimum image quality standard is higher for CR systems than for typical film-screen
- for Fuji CR, the dose to reach achievable image quality standard is at or just above the limiting value (2.5 mGy)³
- routine quality control test films (TORMAX) show Fuji CR's image quality to be similar to that of the earlier film-screen system when film-screen is used with the (now standard) higher density setting.

9.2 Conclusions and lessons learned from medical physics testing

- Sufficient time should be allowed for testing, especially if experience with CR and the test phantom is limited. (At the time of this evaluation the equipment manufacturers/suppliers themselves had no experience of setting up a CR system in an NHSBSP mobile environment.)
- The test results are consistent with those in the NHSBSP's technical evaluations of digital equipment.

- This process has helped the team to develop protocols for testing CR systems and using the CDMAM automated reader software.
- Although more time than expected was spent resolving quality control issues, the system now performs well.

10. OVERALL CONCLUSIONS

The Fuji CR Project is an excellent interim solution for upgrading a service that is moving towards direct digital imaging, as it avoids the need to buy new mammography machines or new mobile vans. However AEC optimisation is essential if image quality is to be maintained.

During the 12 months of this evaluation no clinics were cancelled as a result of breakdowns in the CR system.

Any problems with the system occurred in the early stage of the evaluation; they were caused mainly by human error arising from unfamiliarity with the equipment. In the later stages of the pilot no problems were logged. Staff are now keen to transfer other mammography equipment to CR. This would allow the department to realise the benefits of a fully digital service.

These benefits include the cost savings to be made by removing the need for processors, chemistry, and film. Enhanced safety and security are also factors. Although the mobile van moved six times during the evaluation the equipment was easily secured and no damage was suffered.

A smooth transition from film-screen to CR depends on close liaison between users, manufacturers and medical physicists.

Optimisation of mammography equipment is essential to ensure the balance between quality and dose.

Earlier access to NBSS interfaces, use of the daybook and soft copy reporting would have enhanced the screening workflow.

Since the pilot ended, both the second mobile unit and the second static unit have been converted to CR and the programme has become fully digital. All images are now sent to Royal Derby Hospital's PACS, and NBSS is fully integrated; breast screening images are all soft copy read, allowing consistent reporting for film readers and enhancing workflow.

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APPENDIX 1: USING COMPUTED RADIOGRAPHY

1 Equipment

Switch on all equipment:

- printer at the base office (note: this takes 20 minutes to warm up)
- Profect CR Reader for cassette input
- viewing monitor and workstation in the dark room
- PC tower unit.

2 Cassettes

2.1 Using cassettes

- Cassettes have an indicator to show which side is the chest wall and they must be placed in the bucky correctly.
- It is advisable to take views in menu order (ie right cc, left cc, right obl, left obl).
- Cassettes will be marked for the views which are needed for correct bar coding; this also ensures correct rotation of cassettes.
- Cassettes are very sensitive to x-rays and background radiation and need to be stored behind the control panel.

2.2 Erasing cassettes

Before using any cassettes at the start of the day, erase background radiation signal

- a blue light indicates when the cassette erasure function is ready for use
- select secondary erasure
- insert cassette into reader
- cassette will be returned when ready for use.

3 Insert hard drive for image storage

- Put **password** in computer.
- This takes you to the first page, the **registration screen**.
- Complete the following process first thing in the morning or the day's work will not be stored and will have to be downloaded at the end of the session:
 - Click on the **media** button, on the top right hand side of screen.
 - Click on DVD option, which brings up three options.
 - Click on **handling start** then **OK**.
 - Click on green exit door to return to registration screen.

4 QA test blocks

4.1 Block tests

These to be carried out as they are now (ie 4 cm daily; 2, 4, 6, 8 cm once a week; phantom once a week).

4.2 4 cm daily block test

- On the registration screen complete patient ID.
- Then patient name and location.
- Then click the **next** button on bottom right of the screen, which takes you to the anatomical menu.
- Choose **daily** or **weekly block test**.
- Click on **start study**; this takes you to the **acquisition screen**.
- Next choose the **EDR** (Exposure Data Recognizer) button.
- Click the **semi-x** button, then highlight **number 2** on the chest wall. This chooses the middle chamber and reads the area nearest the chest wall where the test objects are placed.
- Press **OK**. (This procedure is **not** necessary for routine mammography as the chamber is chosen automatically when 'breast' is selected on the anatomical screen.)
- Next, click back onto **green door**, which returns you to the **acquisition screen**.
- Highlight the 4 cm option and expose.
- Barcode cassette.
- Insert into reader.
- Do not click on the **green door** until all exposures are completed (ie 2, 4, 6, 8 cm).
- Clicking on the **green door** once will take you back to the QA screen and enables you to change contrast (GA) and density (GS) factors. (This is not necessary for block tests.)
- To **end** the study and come out of the **acquisition screen**, click and hold the **green door** button.

5 Ready to start clinic

After switching on the equipment, erasing cassettes, and completing QA tests you are ready to begin the clinic.

- On the **registration screen** all of the demographic details for each woman need to be entered; do not forget **date of birth**.
- Press the **next** button, which takes you to **anatomical menu**.
- Choose **breast bilat**, then **mammo**, then **start study**, which takes you to the **acquisition screen**.
- Select **highlight view**, then **expose woman**, then **barcode cassette**, then **insert cassette into reader**.
- After 40 seconds has elapsed, the image appears on the monitor.
- Check the image quickly for **blurring** and **PEAS** (position, exposure, anatomical markers, sensitivity).
- Then highlight **next view** and proceed as above.
- At the end of the examination, if extra views are needed (eg nipple view), highlight **MLOS** on the **acquisition screen** and press **duplicate menu** to repeat MLO. Barcode and expose as above, or use **add a new menu**. (See page 10 of the Quick Start Guide.)
- When all views appear satisfactory, click on **green door** and hold. This sends images to delivered folder and returns you to **registration screen** ready for the next woman.

6 Changing images

Once images are delivered, demographic errors such as annotations or names cannot be changed, as they have been stored. Information can be changed on the monitor, but these changes are not transferred to the hard drive.

- Changes have to be corrected at the base office before printing. Radiographers and assistant practitioners need to make a note of any anomalies either on the clinical list or on the woman's sheet.
- If the image has not yet been delivered, changes can be made by pressing the **green door** button once; this takes you to the **QA screen**, where details can be changed as necessary. This screen can also change the contrast (GA) and the density (GS); it takes a long time, however, so is not advisable on mobile vans.
- If demographic details need changing, click on the top left of the **acquisition screen** (person, id and pen symbol), which takes you back to the **registration screen**, where the changes can be made.

7 End of day

- Check that the queue is empty on the registration screen.
- Click **queue tab** and press the refresh button. Any images waiting to be downloaded to the portable hard drive must be cleared from the queue before the system will allow the portable hard drive to be closed without losing images. Do not proceed until the list is empty.
- To remove the portable hard drive, select **media** then **handling end** from the DVD options. Wait for the list of patients to clear.
- Check **delivered list** to ensure that the last woman's images have been downloaded.
- Remove the hard drive and return it to the base office.

APPENDIX 2: PROBLEMS LOG

Date	Problem	Comments/action
05.07.07	Printer repeatedly closing down	Reported to engineer, who will increase its memory
06.07.07		Engineer increased memory
06.07.07	Problems printing large films (24 cm × 30 cm)	Print 18 cm × 24 cm images first. Print 24 cm × 30 cm images at the end by selecting each woman separately
10.07.07	Barcode reader failed; system froze Slow communication between keyboard and computer	Suspended procedure, closed down computer, re-booted. (This took 10 minutes)
13.07.07	More problems with barcode reader	Information input manually
13.07.07		Engineer replaced barcode reader PC tower changed. Keyboard to computer speed improved
24.07.07	Hard drive failed to function	Applications support advised how to correct. (Details now available in Troubleshooting file)
11.09.07	Media failure	System was not closed down correctly. Importance of not closing down until all processes are complete. (Images may be retrieved the following day)
25.09.07	Image reader very slow	Engineer increased speed of erasure lamps. Now much faster

APPENDIX 4: MEDICAL PHYSICS TEST RESULTS

kV calibration

Test	Limiting value	Results	Pass/fail
Max. kV error in useful clinical range (25–32 kV)		Broad	
kV with set kV = 28	Remedial: ± 1 kV Suspension: ± 2 kV	Maximum error kV at 28 set 0.4 28.1	Pass –

Tube output

Test	Limiting value	Results	Pass/fail
Output repeatability, Mo/Mo 28 kV, CP in	$> \pm 5\%$ mean	0.4%	Pass
Radiation output rate – Mo/Mo 28V	< 7.5 mGy/s	15.9	Pass
μ Gy/mAs at 50 cm (Mo/Mo 28 kV)	> 120 μ Gy/mAs at 50 cm	197	Pass
Variation with kV – Mo/Mo	The relationship between kV and output should be near linear	OP at 28 kV (CP in): 49.2 μ Gy/mAs at 1 m	Pass
Variation with kV – Mo/Rh		OP at 28 kV (CP in): 40.0 μ Gy/mAs at 1 m	Pass
Variation with kV – W/Rh		OP at 28 kV (CP in): 14.9 μ Gy/mAs at 1 m	Pass
Variation with mAs – broad focus	$\pm 10\%$	3.7%	Pass

Safety checks

Test	Limiting value	Results	Pass/fail
Mechanical and safety function			Pass

Compression

Test	Limiting value	Results	Pass/fail
Maximum Thickness gauge accuracy	< 130 N, > 200 N ± 5 mm	Maximum force = 170 N Indicated (mm) 20 38 58 68 Measured (mm) 20 40 60 70 Difference (mm) 0 2 2 2 Maximum error = 2 mm	Pass Pass

Alignment

Test	Limiting value	Results							Pass/fail
		F	B	L	R				
Alignment of x-ray field to the light field	Remedial: misalignment > 5 mm along any edge						R		
		Mo	-5	-2	-2	-5			Pass
Alignment of x-ray field to imaged field/detector	Remedial: > 5 mm or < 0 mm overlap of image by x-ray field on all sides Suspension: > 10 mm overlap or > 2 mm unexposed border along CW edge with respect to image Suspension: > 10 mm overlap along left or right edge with respect to image	W	-3	-3	-5				Pass
Separation between image edge and the chest wall edge of the breast support platform	Remedial: > 5 mm between edge of the image and front edge of the breast support platform	Mo	0.5						Pass
		W	4.5						Pass
			18 x 24	4.5 mm					Pass

Detector performance

Test	Limiting value	Results	Pass/fail	Notes
Dark noise	Image should be uniform and without artefacts	None seen	Pass	The limiting value in the revised version of NHSBSP0604, (Version 3, April 2009) is pixel value >450.
	Remedial: pixel value >280	429	Fail	
CR reader sensitivity	Remedial: calibrated $S_{cal} > 20\%$ from 120	142	Pass	After recalibration 1/10/07
Image plate (IP) matching and artefacts	Remedial: maximum variation in S-value > 5%	Tested by radiographers/applications specialist	-	
	Remedial: maximum variation in mAs >5%			
Laser function	Remedial: any laser jitter or dropout	None	Pass	
Uniformity	Difference between centre and left/right > 10%		Mo/Mo 28	W/Rh 28
		Centre to left	2%	0%
		Centre to right	5%	2%
	Difference between left and right > 10%	Left to right	4%	1%
Detector response	Remedial:	This test was performed and results will be used as baselines for future tests	Baselines established	
	Detector reference air kerma >20% change from commissioning value			
	Noise standard deviation at any measured level >10% increase from baseline			
	SNR change >10%			
Detector resolution			Bars parallel to a-c	Bars perpendicular to a-c
Square wave contrast transfer factor	Remedial: measured SWCTF(f) > 10% change from commissioning	SWCTF(1)	0.368	0.403
		SWCTF(4)	0.078	0.089
		SWCTF(8)	0.061	0.022
Limiting spatial resolution	<75% of commissioning value		7 lp/mm	Pass
Spatial discontinuity	Any evidence of discontinuities		None	Pass
Image retention	Image retention factor >0.3		Image retention factor = 0.0	Pass
Geometric distortion	Any evidence of distortion		None	Pass

AEC

Test	Limiting value	Results	Pass/fail				
AEC repeatability	Remedial: max. deviation in mAs from mean >5%	Radiographers' daily QC test results acceptable	Pass				
	Suspension: max. deviation in mAs from mean > 10%						
AEC performance – automatic mode	CNR: $\pm 10\%$ baseline		Perspex thickness (cm)	+3	+14	Density setting	Baselines established
			2	13.2	14.8		
			3	11.1	13.1		
			4	10.8	12.7		
			4.5	10.8	12.3		
			5	8.93	10.3		
			6	8.90	10.4		
	7		8.29	9.12			
Exposure times			+3	+14	Density setting		
	4 cm Perspex: < 1 s	Exposure time 4 cm	0.4	0.5		Pass	
	6 cm Perspex: < 4s	Exposure time 6 cm	1.0	1.3		Pass	
	4.5 cm Perspex: acceptable <2s, achievable <1.5s	Exposure time 4.5 cm	0.6	0.9		Pass	

Image quality

Test	Limiting value		Results				Pass/fail	
	Detail size	Threshold gold thickness (µm) Acceptable	+3	Hard copy +14	Mo/Rh 28 Density setting	Soft copy +3		+14
Threshold contrast visibility – CDMAM	2	0.069				–	–	Within acceptable tolerances using +14 density setting
	1	0.091				0.08	0.05	
	0.5	0.150				0.16	0.10	
	0.25	0.352				0.33	0.26	
	0.1	1.68				2.14	1.65	
Regular IQ tests – TORMAX				Hard copy	Mo/Mo 28		Soft copy	Baseline
			+3	+14	Density setting	+3	+14	
	6 mm	Target <0.8%	1.4%	1.4%		0.5%	0.6%	
	0.5 mm	<3%	6%	5%		4%	2%	
	0.25 mm	<5%	11%	11%		7%	6%	
Regular IQ tests – TORMAM	Remedial: visibility of details should be unchanged from baseline			Hard copy	Op dose		Soft copy	Baseline
			+3	+14		+3	+14	
			85	92		92	100	

Dose

Test	Limiting value			Results							Pass/fail	Notes
	Perspex thickness (cm)	Remedial (NHSBSP), acceptable (EU2006)	Achievable (EU2006)	Perspex thickness (cm)	+3 density setting	Acceptable?	+14 density setting	Acceptable?				
Dose to the standard breast	2	1.0	<0.6	2	0.47	Y	0.63	Y	Pass	All doses acceptable at both current and increased density steps		
	3	1.5	<1.0	3	0.63	Y	0.86	Y				
	4	2.0	<1.6	4	1.10	Y	1.47	Y				
	4.5	2.5	<2.0	4.5	1.47	Y	2.25	Y				
	5	3.0	<2.4	5	1.24	Y	1.70	Y				
	6	4.5	<3.6	6	2.15	Y	2.94	Y				
	7	6.5	<5.1	7	3.17	Y	4.32	Y				

The tests were carried out in accordance with:

- Commissioning and Routine Testing of Full Field Digital Mammography Systems, 2006 (NHSBSP Equipment Report 0604)*
- The Commissioning and Routine Testing of Mammographic X-ray Systems, 2005 (IPEM Report No 89)*
- European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis, 4th edn, 2006.*

