

**EVALUATION AND CLINICAL ASSESSMENT OF THE SIEMENS
NOVATION FULL FIELD DIGITAL MAMMOGRAPHY SYSTEM**

**NHSBSP Equipment Report 0711
December 2007**

Enquiries

Enquiries about this report should be addressed to:

Barbara Knighton
Superintendent Radiographer
Cambridge University Hospitals NHS Foundation Trust
Cambridge Breast Unit
Box No. 97
Addenbrooke's Hospital
Cambridge
CB2 0QQ

Tel: 01223 216333

Fax: 01223 217886

Email: barbara.knighton@addenbrookes.nhs.uk

Published by

NHS Cancer Screening Programmes
Fulwood House
Old Fulwood Road
Sheffield
S10 3TH

Tel: 0114 271 1060

Fax: 0114 271 1089

Email: info@cancerscreening.nhs.uk

Website: www.cancerscreening.nhs.uk

© NHS Cancer Screening Programmes 2007

The contents of this document may be copied for use by staff working in the public sector but may not be copied for any other purpose without prior permission from the NHS Cancer Screening Programmes. The report is available in PDF format on the NHS Cancer Screening Programmes' website

Typeset by Prepress Projects Ltd, Perth (www.prepress-projects.co.uk)

Printed by Charlesworth

CONTENTS

	Page No
EXECUTIVE SUMMARY	1
1. INTRODUCTION	2
2. OBJECTIVES OF THE EVALUATION	2
3. SYSTEM DESCRIPTION	2
4. ACCEPTANCE TESTING	3
4.1 Safety and function	3
4.2 Mammography x-ray system	3
5. QUALITY CONTROL	7
6. DATA ON SCREENING AND MODE OF CLINICAL OPERATION	8
7. DATA ON ASSESSMENTS	10
8. EQUIPMENT RELIABILITY	10
9. RADIOGRAPHERS' OBSERVATIONS AND FINDINGS	10
10. RADIOLOGISTS' COMMENTS AND OBSERVATIONS	12
10.1 Image quality	12
10.2 Film evaluation	15
10.3 Comparison of digital with analogue examination	17
10.4 Workstation	17
11. ERGONOMIC EVALUATION	18
12. INFORMATION SYSTEMS	19
13. CONFIDENTIALITY	19
14. SECURITY	19
15. TRAINING	19
16. CONCLUSIONS AND RECOMMENDATIONS	20
REFERENCES	21
APPENDIX 1: EQUIPMENT EVALUATION FORM 6 – USER FEEDBACK	22

ACKNOWLEDGEMENTS

The NHS Breast Screening Programme is grateful to the staff at the Cambridge and Huntingdon Breast Screening Unit based at the Cambridge University Hospitals NHS Foundation Trust for undertaking the clinical assessment of the Siemens Novation full field digital mammography system. Particular thanks to:

Mrs Barbara Knighton (superintendent radiographer)

Dr Peter Britton (clinical director of breast screening)

Dr Sue Barter, Dr Alan Freeman, Dr Matthew Gaskarth, Dr Ruchi Sinnatamby and Dr Ruth Warren (consultant radiologists)

Mr Oliver Morrish and Mr David Goodman (Radiation Protection Service)

Mrs Mary Ward (ergonomist).

EXECUTIVE SUMMARY

The Siemens Novation full field digital mammography system provided excellent clinically diagnostic images with a significantly lower radiation exposure dose than the current film–screen systems used in the NHS Breast Screening Programme (NHSBSP).

The system fulfilled the technical image quality and dose requirements of the NHSBSP.

The system demonstrated acceptable levels of reliability after the initial problems but it is questionable whether the levels of client throughput would be acceptable for a mass screening service.

The system will be more efficient with the development of a NHSBSP radiology information system (RIS).

Owing to the need for a lower temperature and environmental stability than conventional analogue systems, careful attention must be given to environmental control systems.

Technical recalls, previously $\geq 3\%$, were eliminated and technical repeats were reduced significantly compared with analogue systems.

The repetitive action of film cassette handling was eliminated, giving improved ergonomics compared with the current film–screen system.

The elimination of film processors and processing chemicals provides an improved working environment.

The overall estimation of soft copy reporting time was felt to be in the region of three times longer than standard hard copy roller viewing reporting. An integrated RIS would have improved the reporting process.

1. INTRODUCTION

Since the move to digital radiography and picture archiving and communication systems (PACS) in general radiology, progress towards the use of digital mammography has accelerated. In order to preserve the concept of quality and consistency in the NHSBSP, any new technology must be evaluated to ensure clinical and technical integrity. This technology must provide a performance that is at least as good as that available with the current film–screen systems.

This report covers an evaluation and clinical assessment of the Siemens Novation full field digital mammography (FFDM) system for the NHS Breast Screening Programme (NHSBSP) in accordance with NHSBSP guidance notes.¹

2. OBJECTIVES OF THE EVALUATION

The equipment was evaluated with the following objectives:

- to conduct acceptance tests to ensure that the equipment used in the evaluation met the standards required by the NHSBSP.² The detailed results of a full technical evaluation are contained in a separate report.³
- to evaluate the unit in terms of workflow and practical use for screening
- to assess the ergonomics of the x-ray unit, acquisition workstation and reporting workstation
- to compare the ergonomics and environmental conditions with those of analogue systems.

3. SYSTEM DESCRIPTION

The mammography unit is very similar to the Siemens Nova Mammomat 3000 analogue x-ray set in footprint and design. The digital unit was installed in a room which had previously housed an analogue x-ray set and therefore the mammography unit, control console and radiation shield were installed to correspond to the analogue positions to simplify workflow for the radiographers. Figure 1 shows the installed unit.

The original electrical installations for the analogue unit were used for the digital unit. An additional network point was installed. A ‘comfort cooling’ unit was already installed in the room.

The acquisition workstation, which consisted of a freestanding monitor and keyboard, was placed on an existing bench at right angles to the console, giving easy access for the radiographers, although this meant that the monitor screen was visible to the patient, which caused some consternation to the radiographers.

The workstation for the RIS was placed on the bench facing the console for easy access for the radiographers.

The unit was provided with the following accessories:

- a large format, 24 × 29 cm amorphous selenium detector
- 18 × 24 cm compression plate with a high edge
- 24 × 30 cm compression plate with a high edge
- detail compression plate collimator format for 9 × 9 cm radiation field
- enlargement add-on 1.5 magnification table with compression plate.



Figure 1 Siemens Novation installed at the Cambridge and Huntingdon Breast Unit.

4. ACCEPTANCE TESTING

The Siemens MAMMOMAT Novation^{DR} was installed in the Cambridge and Huntingdon Breast Unit based at Addenbrookes Hospital, Cambridge, and tested on 24 February 2006 and 30 August 2006. Performance testing of this equipment was carried out using the *European Guidelines for Quality Assurance in Mammography Screening* (3rd edn) published by the European Commission⁴ and *The Commissioning and Routine Testing of Mammographic X-Ray Systems* (IPEM Report 89) published by the Institute of Physics and Engineering in Medicine.⁵ Commissioning tests were carried out upon installation and routine tests were carried out six months later.

4.1 Safety and function

Checks of mechanical and radiation safety and function were carried out and were found to be acceptable in all respects including accuracy of breast thickness indicator, compressive force, x-ray tube filtration and leakage and the supplied protective screen.

4.2 Mammography x-ray system

Tests of x-ray unit performance were carried out including alignment checks, assessment of the focal spots size and measurement of kVp, output and half-value-layer. Tests of the automatic exposure control (AEC) system were also performed. All tests were found to be satisfactory. The results are shown in Table 1.

Table 1 Acceptance test results

Alignment of detector, radiation field and light field	All alignments were within tolerance
Leakage radiation	Negligible leakage was measured
Compression and breast thickness indication	Compression was within 5 N of that indicated at all compressive forces and was maintained over 30 s; thickness was within 2 mm of that indicated at 100 N
Focal spot dimensions	Measured by star-test pattern (mm) Molybdenum: 0.42×0.42 and 0.09×0.11 Tungsten: 0.48×0.45 and 0.08×0.11
Accuracy of tube voltage	Within 0.3 kV at all available tube voltages
Half-value-layer (HVL) and filtration	Mo/Mo HVL at 28 kVp measured to be 0.34 mm Al with a derived filtration of 0.61 mm Al with compression plate
Tube output	Radiation output was repeatable and varied appropriately with variations in kVp and mAs. Specific output of $192.8 \mu\text{Gy/mAs}$ at 50 cm, 28 kVp Mo/Mo, broad focus
Automatic exposure control (AEC)	Exposures were repeatable and varied appropriately in all three AEC area positions. The guard timer operated satisfactorily

4.3 Digital detector

Tests were carried out to assess the performance of the digital detector. Some of these tests were carried out using a 4 cm Plexiglas block supplied with the unit. Designed to slot onto the x-ray tube head, this block was very easy to use, handle and store (Figure 2).

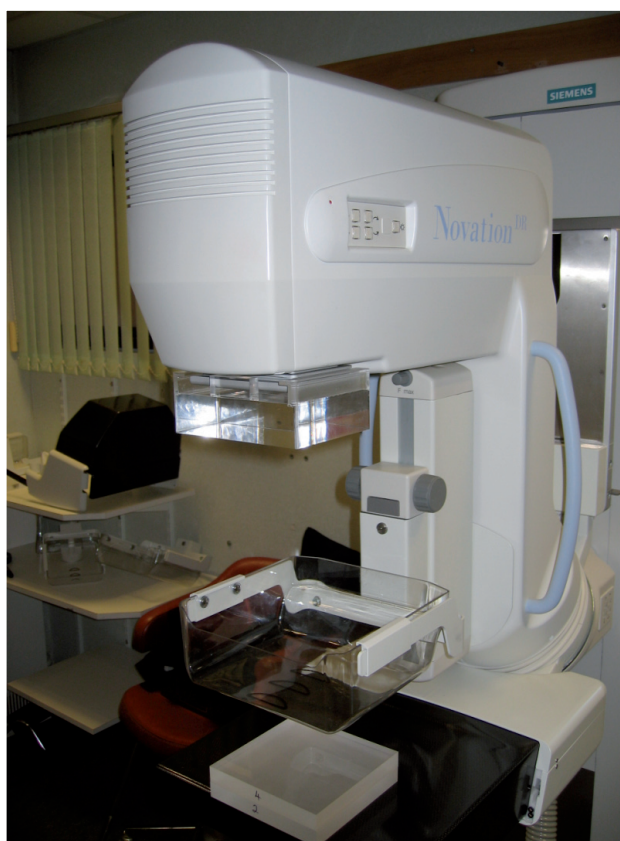


Figure 2 Siemens 4 cm Plexiglas block mounted onto tube head for quality assurance and calibration.

The Novation's digital detector was found to have a linear response to x-ray exposure up to 1.4 mGy and requires a flat field calibration to be carried out using a particular target-filter combination. The manual suggests using the combination that is used in the majority of clinical cases. It then uses this calibration for all target-filter combinations. This means that the assessed image uniformity – while satisfactory for the flat fielded target-filter combination – is not acceptable for other combinations due to the variation in the anode heel effect for different targets and filters. In practice, this is not a problem as the automatic exposure programs select only one target-filter combination: tungsten-rhodium.

Table 2 and Figure 3 shows the results taken under the clinically selected exposures under automatic exposure control using the four available programmed exposure modes. Perspex blocks were compressed to 100 N and contrast to noise ratios (CNRs) were evaluated by placing a 0.2 mm thick aluminium sheet on the Perspex 2 cm above the breast support platform, outside the AEC's dominant region of the detector. Pixel values and standard deviations are given for a region of interest over Perspex on the midline 6 cm from the chest wall edge. NHSBSP Report 0604 shows CNR calculation.²

Table 2 Performance of digital detector

Perspex (mm)	kVp	Target/filter	mAs	Mean pixel value	Standard deviation	CNR
20	25	W/Rh	26.4	288.4	6.4	6.3
30	27	W/Rh	32.0	275.6	6.3	5.7
40	27	W/Rh	54.9	287.1	6.5	5.5
45	28	W/Rh	59.4	277.2	6.4	5.1
50	28	W/Rh	77.6	283.1	6.5	5.1
60	32	W/Rh	74.0	294.8	7.0	4.1
70	32	W/Rh	120	297.3	7.1	4.0

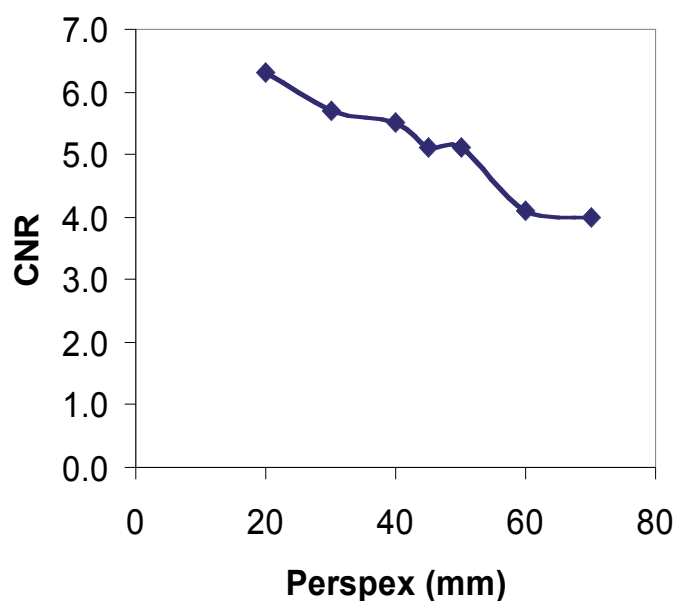


Figure 3 Variation of CNR with Perspex thickness under clinical exposure conditions.

4.4 Image quality

Image quality was assessed by means of a TORMAX Leeds test object viewed on the supplied reporting workstation.

Results for an exposure on a 4 cm Perspex block using 28 kVp Mo/Mo and AEC exposure are shown in Table 3.

Table 3 Image quality results

High contrast spatial resolution (perpendicular and parallel to anode–cathode axis)	8.9 lp/mm
Low contrast spatial resolution	4.5 lp/mm
6 mm detail threshold contrast	0.58%
0.5 mm detail threshold contrast	4.1%
0.25 mm detail threshold contrast	6.9%

Further tests using a resolution grid in contact with the breast support platform at 45° to the anode–cathode axis showed the maximum resolution of the detector to be 10.6 lp/mm. This was an expected result given the 70 µm pixel pitch of the detector.

4.5 Dose audit

An audit of exposures to 101 consecutive women undergoing mammograms was carried out. Details of the exposures were collected and inputted into the NHSBSP software version 2.0 from the National Coordinating Centre for the Physics of Mammography. The Siemens MAMMOMAT Novation^{DR} has four programmed settings for clinical use, selected according to compressed breast thickness. Available target–filter combinations and tube potential are shown in Table 4 along with the number of films from the audit taken using these settings.

Table 4 Dose audit results

Target material	Filter material	Tube voltage (kV)	Number of films
W	Rh	27	46
W	Rh	28	139
W	Rh	29	169

The average mean glandular breast dose for the 37 oblique films taken of breast thicknesses 50–60 mm was 0.78 ± 0.09 mGy (two standard errors of the mean). This is much lower than the national diagnostic reference level for mammography of 3.5 mGy and is due to the use of the tungsten target with the rhodium filter. The mean dose for two view mammography was 1.49 mGy with minimum and maximum doses of 0.36 mGy and 4.68 mGy respectively. The mean results for each view are shown in Table 5.

Table 5 Mean dose results

Radiographic view	Mean MGBD (mGy)	Mean breast thickness (mm)	Number of films
Craniocaudal	0.77 ± 0.03	59 ± 1.0	176
Oblique	0.80 ± 0.03	61 ± 1.3	169

5. QUALITY CONTROL

The unit was left in standby mode overnight and requires a warm up time of 1 hour, which necessitated a member of staff being available to switch on 1 hour prior to the start of the working day. This 'warm up' time is also necessary should the unit be switched off during the day, eg due to unexpected power failure.

Quality control tests were performed by radiographers at the start of each day and were in accordance with NHSBSP guidelines⁶ and after consultation with the local physicists. A quality control manual was provided with the unit and tests were demonstrated by the application specialist. The actual test procedures were as follows:

Daily QC

- Monitor checks for dust and cleaning if necessary.
- Artefact detection – to determine whether monitor is dusty, damaged or has other artefacts. This test uses a compression plate simulator and collimator mounted 40 mm Plexi-phantom.
- AEC long term reproducibility – to measure the AEC image reproducibility and signal to noise ratio (SNR). This test uses the 24 × 30 compression plate with a 40 mm Perspex block. The SNR is calculated from a 10 × 10 mm region of interest selected on the image. An Excel program was devised to enable easy calculation of the SNR.

Weekly QC

- AEC long term reproducibility was performed as above with 2 cm, 6 cm and 7 cm Perspex blocks.
- SMPTE pattern – radiographer evaluation of the monitor was carried out weekly using the SMPTE incorporated in the unit.
- Calibration of the unit – this was carried out prior to the QC tests every 2 weeks. A warning message alerts the user to perform this test to prevent automatic shutdown.

Initially, daily and weekly quality control tests took in excess of 30 minutes to perform. This time became less with radiographer familiarity with the unit but daily QC test times still exceeded time taken for analogue tests.

6. DATA ON SCREENING AND MODE OF CLINICAL OPERATION

Imaging of patients commenced with training on 24 March 2006. A total of 370 two view mammograms were performed for the evaluation.

As the Cambridge static unit does not operate screening clinics, special clinics were set up to replicate the mobile screening clinics. These consisted of three hour sessions with women booked at six minute appointment intervals as on the mobile units. The waiting area in the static unit is remote from the x-ray room so the women were escorted by a radiography department assistant (RDA), or another radiographer, to wait immediately outside the x-ray room in order to replicate the work flow on the mobile units. This radiographer also entered the client data from the clinic list onto the RIS in order that the client details would appear on the work list when the radiographer was ready to x-ray the woman and therefore making best use of the examination time.

Screening sessions were set at six minute appointments. This is necessary in this unit to comply with the NHSBSP requirement for a 36 month screening round length. Two clinics were timed to evaluate the average length of time required to image each woman. This was labour intensive, requiring a member of staff to operate a stopwatch for the entire clinic. The stopwatch was started when the woman went into the room and stopped when she exited. It became apparent during the clinic sessions that it was not possible to run a full clinic at six minute appointment intervals in our centre as clinics began to run so far behind that it became necessary to image some of the women on the analogue system to enable the clinic to finish within working hours.

The operator using the equipment worked alone in the x-ray room and completed the whole examination. All operators were experienced mammographers.

Timings for the two clinics are shown in Table 6.

The data show that two women took an excessively long time to image – one woman had eight images and another had implants, which resulted in an error code on the unit.

Data from the rest of the group show that the longest time taken to image a woman was 13 min 42 s. The radiographer's comments made on the client form suggested that this woman presented some positioning difficulties. The shortest time was 7 min 22 s. A woman with a mastectomy took five minutes. Of the remaining 31 women in the group, 12 took between seven and eight minutes, four took between eight and nine minutes, seven took between nine and 10 minutes, six took between 10 and 11 minutes and one took between 11 and 12 minutes and one took between 13 and 14 minutes.

The number of non-responders for the screening session on 30 May 2006 was four, giving an acceptance rate of 90.5%. In this session the clinic began to run behind schedule and so only 22 women were imaged on the digital unit, with 16 imaged on the analogue unit, to comply with appointment times. The number of non-responders for the screening session on 5 July 2006 was 7, giving an acceptance rate of 80.5% and, again to comply with appointment times, 16 women were imaged on the analogue unit. Acceptance rates on the analogue mobile unit were at that time 75%.

These clinics were timed using the original software on the x-ray unit, which required a minimum time between exposures of 70 s. Since then the unit has been upgraded to have a minimum time between exposures of 55 s. It is estimated that this will result in a shortest examination time of approximately 6 min 30 s.

Clinical Assessment of the Siemens Novation Full Field Digital Mammography System

Table 6 Timings for two screening clinics

Date	First screen	Imaging time		Mammographer comments
		min	s	
30 May 2006	Yes	10	11	No comment
30 May 2006	Yes	7	4	Previous mammo
30 May 2006	No	13	42	Walks with stick
30 May 2006	No	10	17	Walks with stick
30 May 2006	No	8	45	No comment
30 May 2006	Yes	17	11	Implants/error code
30 May 2006	No	9	4	Implants
30 May 2006	No	9	7	Implants
30 May 2006	No	9	27	No comment
30 May 2006	No	21	49	Eight images
30 May 2006	Yes	10	32	Discussion clinical signs
30 May 2006	Yes	7	27	No comment
30 May 2006	No	10	39	No comment
30 May 2006	No	7	22	No comment
30 May 2006	No	8	10	No comment
30 May 2006	No	7	58	No comment
30 May 2006	No	9	37	Wheelchair user – two radiographers
30 May 2006	No	8	36	Painful back
30 May 2006	No	7	14	No comment
30 May 2006	No	7	10	No comment
30 May 2006	No	9	3	No comment
30 May 2006	No	5	0	Mastectomy
5 July 2006	No	7	15	No comment
5 July 2006	No	7	44	No comment
5 July 2006	No	11	40	Discussion
5 July 2006	No	10	35	No comment
5 July 2006	No	7	38	No comment
5 July 2006	No	9	25	No comment
5 July 2006	No	10	25	No comment
5 July 2006	No	9	20	No comment
5 July 2006	No	8	10	No comment
5 July 2006	No	13	15	Discussion
5 July 2006	No	7	25	No comment
5 July 2006	No	7	38	No comment
5 July 2006	No	7	35	No comment

7. DATA ON ASSESSMENTS

This unit does not have a stereo attachment and therefore the evaluation as an assessment tool was limited to imaging with magnification. These views were carried out when the woman for recall had been imaged on the analogue mobile unit and therefore had hard copy film. If the woman had been screened on the digital unit, electronic magnification using the software tools on the workstation gave sufficient detail to avoid further imaging, saving an additional exposure.

8. EQUIPMENT RELIABILITY

During the evaluation period there were several issues relating to reliability:

1. There was an initial failure of the detector. It took two days for a replacement detector to arrive because it had to travel overland from Germany as the air carrier refused to transport the unit as it contained hazardous material. No subsequent evidence or verification for this was given by the manufacturers. The new detector incurred limited physics acceptance testing, and further delay to training, resulting in the application specialist from Germany returning without giving training to staff. The total equipment downtime for this was four days.
2. In one case, for one client, images were lost, ie could not be retrieved from the reporting workstation or PACS. Neither the PACS manager, the Siemens engineer nor the application specialist was able to offer an explanation for this. The examination was repeated using an analogue film–screen system.
3. On acquisition screen during QC procedure a gross artefact resulted in the error message ‘detector conditions not fulfilled’. The environmental conditions for the unit are stringent and the unit will not function if the room temperature increases. This error was thought to be due to increased room temperature. The equipment was down for two days. This happened on a further two occasions, once when the power supply was interrupted for a few seconds and once for an unexplained reason. This error was remedied by switching off the unit for an hour and then rebooting the system. Downtime for each error was two hours.
4. Failure of bulb in light beam diaphragm – no downtime.
5. Exposure was disabled on two occasions. This was caused by the grid remaining in the back position after using the magnification technique. This required an engineer visit to free the grid retainers. The unit was down for two half days.

9. RADIOGRAPHERS’ OBSERVATIONS AND FINDINGS

All radiographers were involved in the equipment evaluation and all hold the Certificate of Competence in Mammography.

The NHSBSP radiographer evaluation forms were used to collect views from individuals regarding use of the equipment. A total of 10 were returned and Appendix 1 shows a summary of the results.

Specific comments on the equipment were as follows:

- operator manual not very user friendly
- user training by supplier was adequate for basic mammography
- unit ease of use and minimising fatigue – the absence of cassette handling is very beneficial
- the ‘prep’ and exposure times were too long, as was the time between exposures (this was based on use before the upgrade, but even after the upgrade the radiographers were still unable to screen at six minute appointment intervals)
- good rotation movement of the support arm and good visibility of the set angle
- good facility for positioning the height of the breast support table
- fully adequate range of movements
- effective brakes/locks
- effective compression system
- good visibility of compression force indicator
- all the expected controls were present and easy to find and use with the exception of the green ‘exposure ready’ indicator, which was difficult to see
- one spot compression plate was supplied with the unit, which was sufficient for use
- the time taken for the image to appear at the acquisition workstation (AWS) was too long, timed at 70 seconds
- the image handling and processing facilities at the AWS were found to be cumbersome when changing view sequence
- the overall image quality at the AWS was found to be very good
- the images were automatically transferred to the reporting workstation (RWS). The unit was set to default to automatic transfer as this was felt to be a safer option than manual transfer. The images were available to view on the RWS almost immediately.

Comfort of women

- Women who had undergone previous axillary surgery found it very uncomfortable.
- Short women were difficult to position and found it uncomfortable due to the large detector plate and fixed automatic exposure control (AEC).
- The compression time is too long and causes discomfort.
- The digital x-ray system performance was found to limit client throughput due to exposure/acquisition times being too slow for six minute appointment intervals at average 76% attendance rate; the communication between the RIS and digital unit was slow, which meant that the mammographers felt that the woman remained compressed for too long.

Radiographer confidence was low early in the evaluation period when one client’s images were lost and had to be repeated on the analogue unit. This was during the early stages of use and may have been due to a training issue. The images were not subsequently found.

No potentially hazardous areas accessible to either woman or radiographer were identified.

Cleaning instructions for the unit were provided in the operator manual and were adequate.

Magnification techniques

- The quality of images obtained using magnification techniques was excellent. However, the magnification table was unstable when in position, resulting in occasional disconnection of electrical contacts and disabling of the exposure.

10. RADIOLOGISTS' COMMENTS AND OBSERVATIONS

10.1 Image quality

All the radiologists involved in the evaluation are experienced NHSBSP breast radiologists. Images were evaluated according to NHSBSP protocols. A total of 370 digital examinations were evaluated for image quality. When available, digital images were compared with previous analogue examinations. Film quality was assessed in similar fashion. A comparison of film and digital image quality was then made between the current digital examination and any previous film examination. The limitation of this was that some of the film examinations were performed three years prior to the digital examination.

Of the 370 examinations, 164 were in symptomatic patients or those undergoing breast cancer follow up, 139 were in women undergoing NHSBSP screening, 13 were in women undergoing NHSBSP assessment, 16 were in women undergoing family history screening and 38 were not specified (Figure 4).

The background parenchymal pattern was assessed for breast density and is shown in Figure 5.

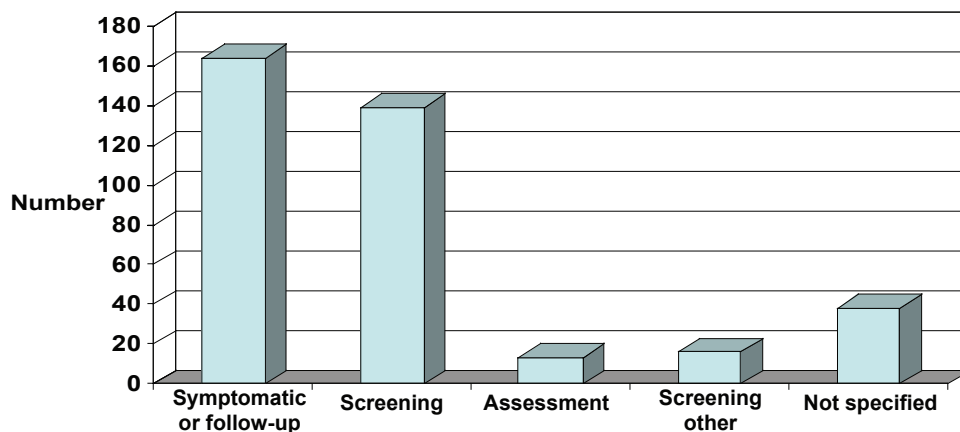


Figure 4 Examination type.

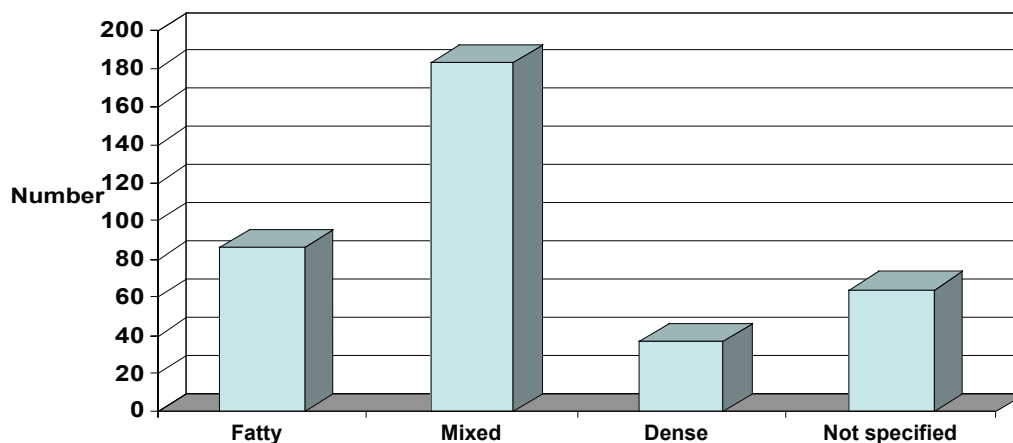


Figure 5 Breast composition.

Figure 6 shows that the overall digital exposure was evaluated and 96.5% of examinations were deemed OK.

Figure 7 shows that the overall digital contrast was evaluated and 96% of examinations were designated as OK.

Figure 8 shows that when digital sharpness was evaluated 97% of examinations were designated OK.

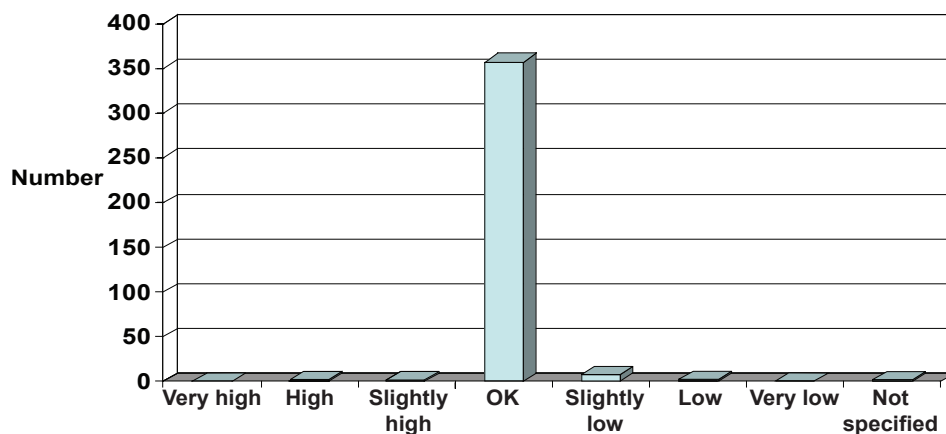


Figure 6 Digital overall exposure.

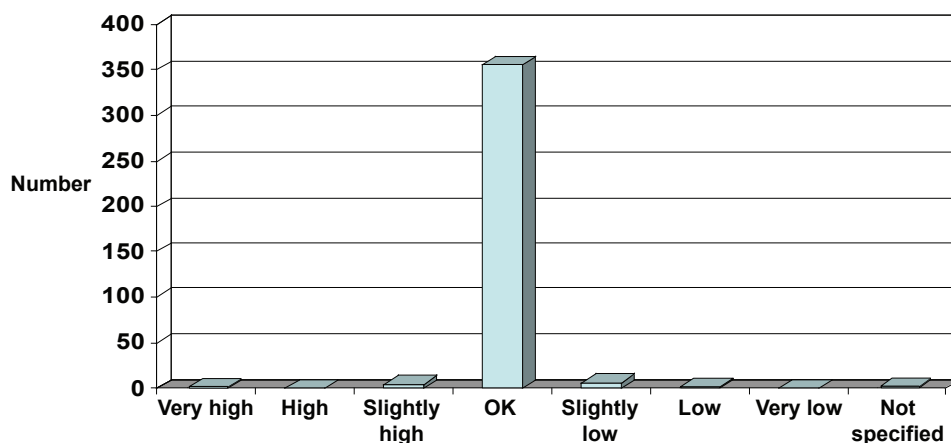


Figure 7 Digital overall contrast.

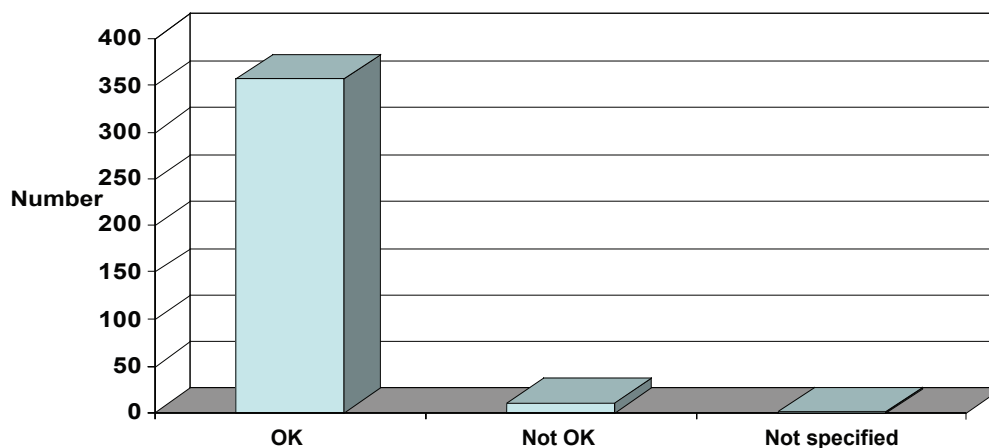


Figure 8 Digital sharpness.

Figure 9 shows that when digital noise was evaluated 99% of the examinations were designated OK.

Digital absolute diagnostic value was evaluated and overall 86.5% of examinations were designated as either good or excellent (Figure 10).

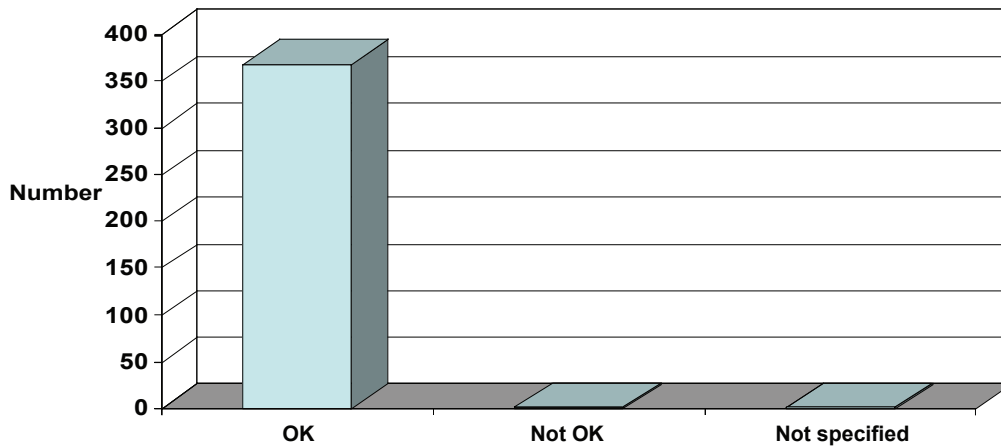


Figure 9 Digital noise.

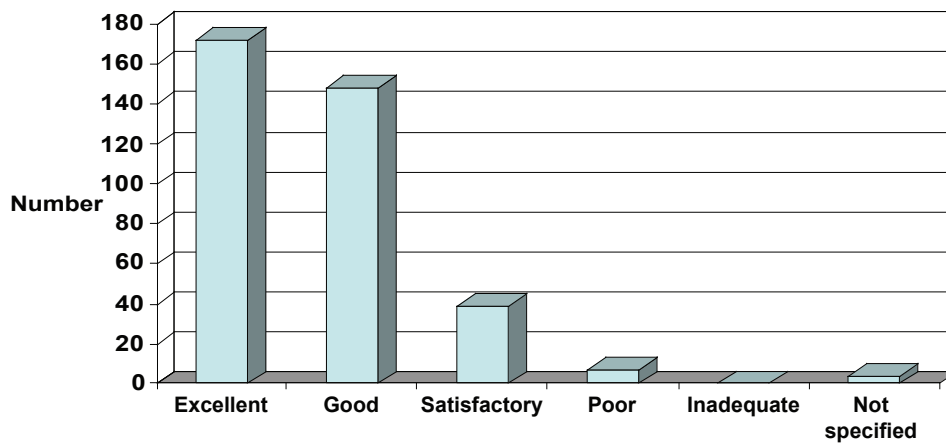


Figure 10 Digital absolute diagnostic value.

10.2 Film evaluation

Of the 370 examinations 146 patients also had previous analogue examinations available for comparison. Overall film exposure was evaluated and 93% of examinations were deemed to be OK (Figure 11).

Overall film contrast was evaluated and 93% of examinations were designated OK (Figure 12).

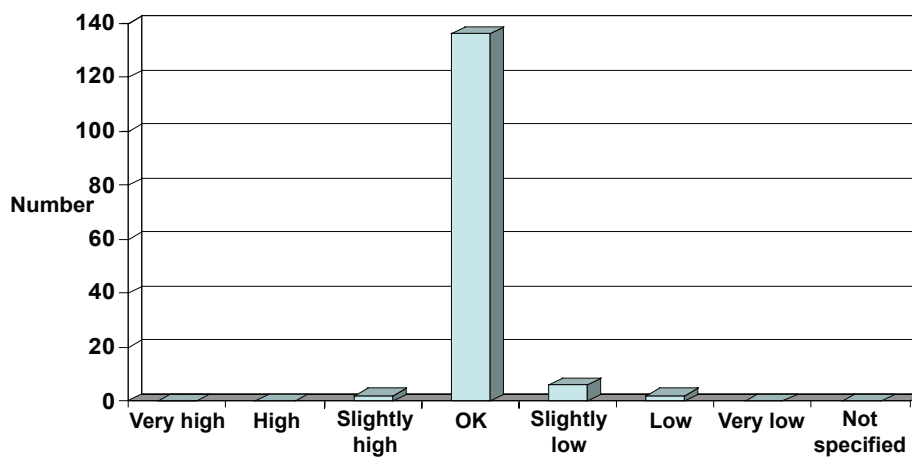


Figure 11 Film overall exposure.

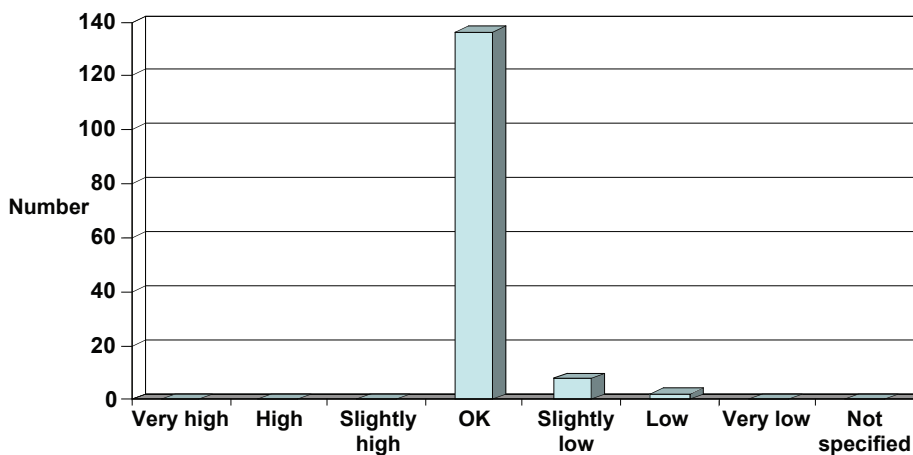


Figure 12 Film overall contrast.

Clinical Assessment of the Siemens Novation Full Field Digital Mammography System

Film sharpness was evaluated and 92% of examinations were designated OK (Figure 13).

Film noise was evaluated and 98% of examination were designated OK (Figure 14).

Film absolute diagnostic value was evaluated and overall 57% of examinations were designated as either good or excellent (Figure 15).

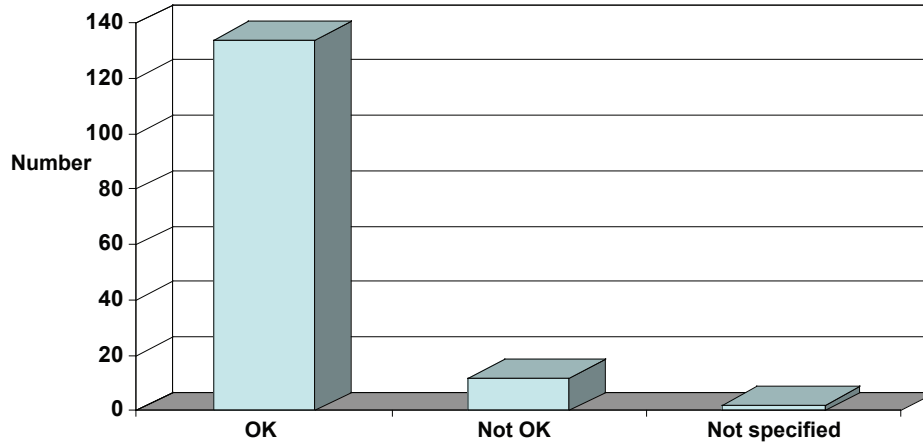


Figure 13 Film sharpness.

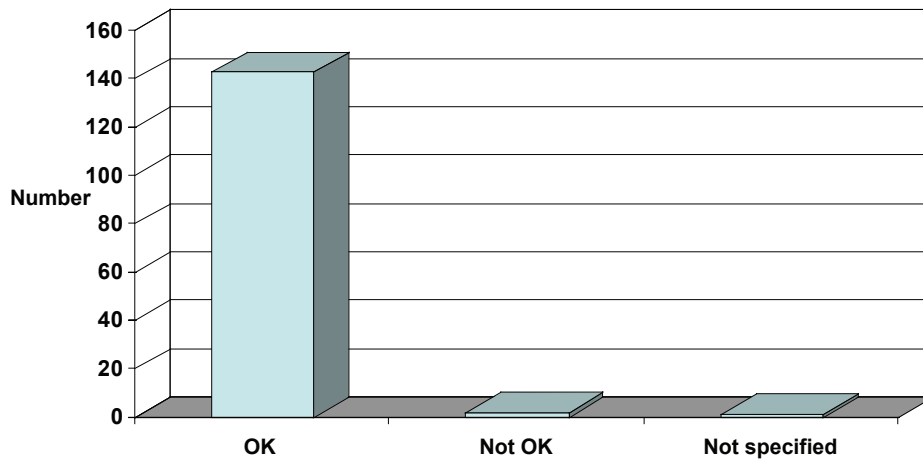


Figure 14 Film noise.

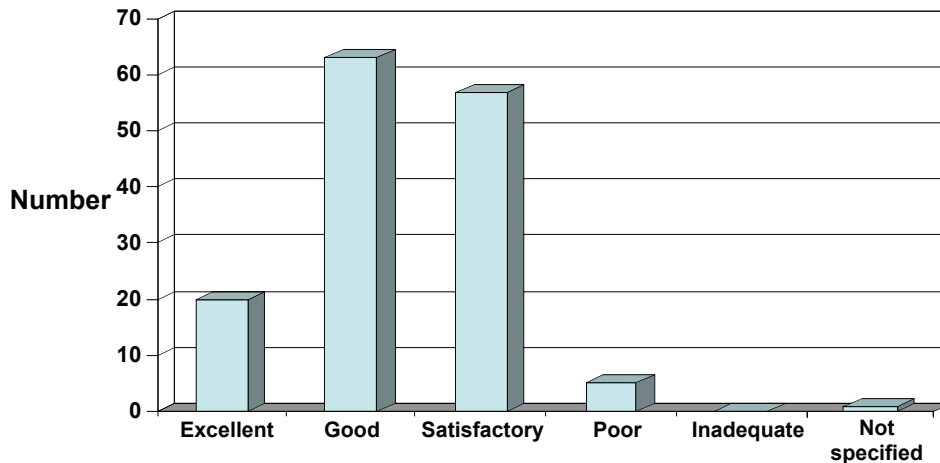


Figure 15 Film absolute diagnostic value.

10.3 Comparison of digital with analogue examination

Radiologists were asked to give a relative diagnostic value to the digital examination and film (Figure 16). No digital examination was determined to be markedly worse than film but 1.4% of digital examinations were considered to be slightly worse than film, 26% the same as film, 52.5% slightly better than film and 16% markedly better than film; in 4% of digital examinations, relative diagnostic value was not specified.

The conclusion of the evaluation is that overall the radiologists were extremely satisfied with the image quality, which was generally felt to be outstanding and a substantial improvement over analogue examinations in the same patients.

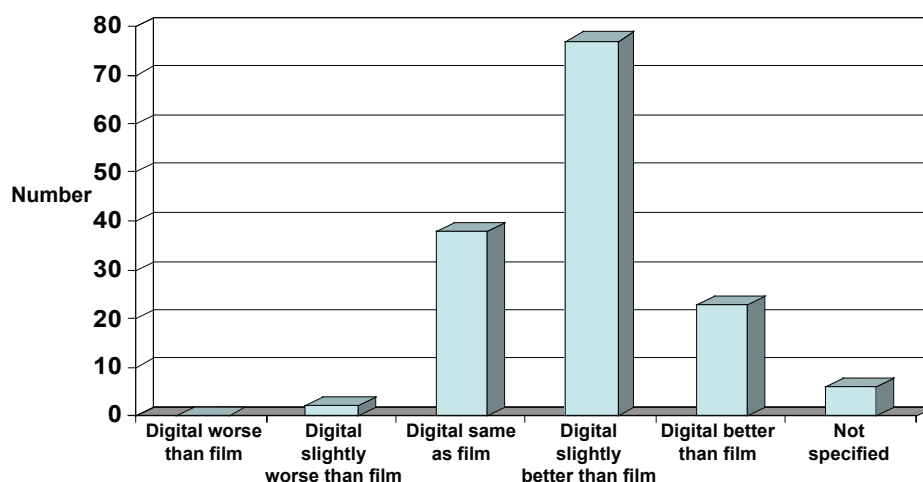


Figure 16 Digital relative diagnostic value.

10.4 Workstation

The workstation was positioned in a reporting room that is also used as a working area for multidisciplinary team clinics. Working conditions were therefore not ideal as background light is required to be of a sufficient level for others to work in the room. Each radiologist was trained on the system and individual 'hanging' protocols were developed. The patients were listed in alphabetical order, and this necessitated scrolling up and down the browser list to find the appropriate patient, which was time consuming and had the potential for error (ie two patients named Smith etc.). All digital examinations were sent both to the reporting workstation and to the hospital PACS. Initially, however, digital mammogram images could not be retrieved from PACS for review on the workstation. Until this problem was fixed with a software upgrade, no examinations were deleted from the workstation as they would not have been able to have been retrieved. The large number of cases on the workstation impeded its speed of use and also slowed reporting. Once the link with PACS was remedied then older examinations could be deleted from the system. However, some of the examinations could not be deleted as they were apparently 'protected' although no protection had apparently been placed on a particular examination by a radiologist.

Overall estimation of radiology reporting time was felt to be in the region of three times longer than standard roller viewing reporting. It was felt that integration with the radiology information system would have speeded the reporting process by automatically retrieving unreported examinations. There was no integration with the National Breast Screening System (NBSS), which does not yet have an interface with digital systems.

11. ERGONOMIC EVALUATION

Three mammographers were observed performing a mammogram using the digital mammography unit and their postures recorded using a rapid entire body analysis (REBA) tool.⁶

The aim was to provide a score that could be used in evaluating the unit and to compare it with others. As each mammogram comprised two views (two craniocaudal and two oblique views), each was given a REBA score. The mammographer's posture was recorded as she positioned the patient and the unit ready for the image to be recorded. Consideration was not given to the use of the computer screens/keyboards, or operating the controls to take the image. One mammographer was observed performing a mammogram using the analogue unit. The unit was very similar and the score was the same. However, the process of inserting and removing the films was not evaluated. This process is eliminated with the digital unit.

The scores are shown in Table 7. Table 8 shows the REBA action levels.

The scores for the craniocaudal image range from 3 to 5, low to medium risk, and the scores for the oblique image range from 7 to 8, medium to high risk (only one score of 8/high risk). For all mammographers the score was higher for the oblique image.

Table 7 REBA scores

		Digital unit				Analogue unit (excluding loading/unloading/processing film)			
		Craniocaudal		Oblique		Craniocaudal		Oblique	
		Left	Right	Left	Right	Left	Right	Left	Right
Radiographer 1	Score	4	3	7	7				
	Risk	Medium	Low	Medium	Med				
	Action level	2	1	2	2				
Radiographer 2	Score	5	5	8	7	5	5	8	7
	Risk	Medium	Medium	High	Medium	Medium	Medium	High	Medium
	Action level	2	2	3	2	2	2	3	2
Radiographer 3	Score	3	3	7	7				
	Risk	Low	Low	Medium	Medium				
	Action level	1	1	2	2				

Table 8 REBA action levels

Action level	REBA score	Risk level	Action (including further assessment)
0	1	Negligible	None
1	2-3	Low	May be necessary
2	4-7	Medium	Necessary
3	8-10	High	Necessary soon
4	11-15	Very high	Necessary now

REBA is a tool for analysing postures that may pose a risk of musculoskeletal injury. As it provides a score it can be useful for making comparisons (eg between different techniques/equipment) and evaluating the impact of any changes. As a risk assessment tool it has its limitations, as there are many other factors associated with the development of musculoskeletal disorders, such as duration of exposure to hazards, individual differences, work environment and psychosocial/work organisation factors, that it does not take into account. For example, it does not take into account what the mammographer is doing between screens or the differences between patients and screening or diagnostic images. However, the results above do suggest a risk of poor postures.

12. INFORMATION SYSTEMS

The unit was integrated with the hospital PACS. However, retrieval of images from PACS to the SYNGO reporting workstation was not possible for most of the evaluation. This resulted in images being retained on the hard drive and therefore considerable slowing of functions. The fault was remedied at the end of evaluation period and was found to be due to an incorrect port number.

Patient episodes were registered on the hospital CRIS prior to imaging to provide an acquisition number for PACS. The time from data entry on CRIS to the patient registration appearing on the AWS scheduler was variable and when very slow could result in time being wasted.

The absence of an NHSBSP RIS necessitates double entry of patient data, once on the CRIS and once on the NHSBSP computer system. This, in turn, involves post-processing of data on both systems.

13. CONFIDENTIALITY

Confidentiality of patient data was maintained through the hospital systems as the unit was only used on the hospital site.

14. SECURITY

Both the AWS and the RWS were password accessible.

15. TRAINING

Training was provided by the Siemens application specialist. All radiologists and radiographers present at the time received training.

16. CONCLUSIONS AND RECOMMENDATIONS

When moving to digital image acquisition and soft copy reporting the learning curve should not be underestimated. Evaluation of this unit took place alongside use of two remaining analogue units. Therefore, there was initial reluctance on the part of some staff to use the new technology. Both good training and support are paramount.

It is essential that IT systems are synchronised with digital systems to enable efficient use of equipment and staff, especially development of an NHSBSP/RIS integrated system.

The exposure to exposure time on this unit was too long to enable comfortable screening at six minute appointment intervals.

Automatic deletion of images from the RWS after reporting of cases would prevent slowing of the system and manual deletion would not be necessary.

The equipment was generally reliable during the period of evaluation. However, when problems did occur company support was sometimes slow.

The long 'warm up' time presents a problem, especially when the unit is switched off inadvertently during the working day. It may be possible for the manufacturer to provide an automatic timer system to switch on the unit prior to staff arrival. This facility would be especially useful for a unit installed on a mobile mammography unit.

All tests performed were within accepted standards. However, routine QC tests take longer to perform than those performed on an analogue unit but can be evaluated instantly on the acquisition work station. A dedicated QC programme, providing procedure instructions and automatic evaluation of results, incorporated within the unit system would be extremely beneficial.

REFERENCES

1. *Guidance Notes for Equipment Evaluation. Protocol for User Evaluation of Imaging Equipment for Mammographic Screening and Assessment*. NHS Cancer Screening Programmes, 2007 (NHSBSP Equipment Report 0703).
2. *Commissioning and Routine Testing of Full Field Digital Mammography Systems*. NHS Cancer Screening Programmes, 2006 (NHSBSP Equipment Report 0604).
3. *Technical Evaluation of the Siemens Novation Full Field Digital Mammography System*. NHS Cancer Screening Programmes, 2007 (NHSBSP Equipment Report 0711).
4. *European Guidelines for Quality Assurance in Mammography Screening*, 3rd edn. Luxembourg: European Commission, 2001
5. *The Commissioning and Routine Testing of Mammographic X-Ray Systems*. Institute of Physics and Engineering in Medicine, 2005 (IPEM Report 89)
6. *Quality Assurance Guidelines for Mammography*. NHS Cancer Screening Programmes, 2006 (NHSBSP Publication No 63)
7. Hignett S, McAtamney L. Rapid entire body assessment (REBA). *Applied Ergonomics* 2000, 31: 201–215.

APPENDIX 1: EQUIPMENT EVALUATION FORM 6 – USER FEEDBACK

Question	Excellent	Good	Satisfactory	Poor	Comments
1 Operator manual	0	3	6	1	Not a very user friendly format
2 User training by supplier	0	1	5	4	Training was adequate for basic mammography
3 Unit					
3.1 Ease of use	0	4	4	1	Absence of repetitive handling of cassettes is very beneficial
3.2 Unit's help in minimising fatigue	0	3	1	3	Absence of repetitive handling of cassettes is very beneficial
4 Acceptability of exposure times	0	0	2	8	Exposure times were too long. 'Prep' time was too long. Time between exposures was too long. Note that this was based on use before the upgrade but after the upgrade the radiographers felt they were still unable to screen at six minute intervals
5 Setting for radiographic views					
5.1 Rotation of the support arm	0	10	0	0	
5.2 Visibility of the set angle	1	9	0	0	
6 Setting of breast support table: facility for positioning height	0	10	0	0	
7 Range of movements – adequacy of range	0	10	0	0	
8 Effectiveness of brakes/locks	0	10	0	0	
9 Compression					
9.1 How effective was the compression system?	0	7	2	0	
9.2 Visibility of compression force indicator	0	9	1	0	
10 Comfort of women		1	1	5	Women having had axillary surgery found it very uncomfortable. Short women are difficult to position and find it uncomfortable. Compression time is too long and causes discomfort
11 Range of controls and indicators					
11.1 Were all the expected controls present?	0	9	1	0	
11.2 Were they easy to find and use?	0	9	1	1	Green exposure ready indicator light difficult to see
12 How do you rate the choice of collimators supplied for spot compression?		2	8		Only one supplied

Clinical Assessment of the Siemens Novation Full Field Digital Mammography System

Question	Excellent	Good	Satisfactory	Poor	Comments
13 How do you rate the time for the image to appear at the work station?	0	0	0	10	Slow. Too long. Unsuitable for disabled/ elderly/anxious women
14 How do you rate the image handling and processing facilities at the AWS?	0	3	4	3	Very fiddly trying to change views
15 Overall image quality at AWS	3	7	0	0	
16 How easy was it to transfer images to the RWS (no hard copy printer available)?	0	0	1	0	Auto transfer but images lost on one occasion – necessitated repeat imaging on analogue unit
17 Confidence of good results – what was your level of confidence in the machine?	0	4	6	0	Low confidence early on when a set of images was lost and had to be repeated
18 Hazards: were there any potentially hazardous areas accessible to either you or the woman, eg hotspots?	0	0	0	0	No
19 Equipment cleaning					
19.1 Ease of cleaning the machine					
19.2 Were there instructions in the manual?	1	5	4		Yes
20 Patient and exposure data print out facility					N/A
21 Did the digital X-ray system performance limit patient throughput?					Yes – too slow for six minute appointment interval. Communications between RIS and digital unit slow. Too long under compression
Magnification					
1 Ease with which the magnification equipment may be attached and removed	2	6		2	There is a lot of movement of magnification table when in situ – resulting in occasional disconnection of contacts and disabling of exposure. One radiographer commented that she enjoyed using the unit for magnification techniques as the images were excellent
2 Ease of use of magnification support table	4	6			
3 Removal and insertion of collimators	4	6			
3.1 Range of collimators (only one supplied therefore no comments)	5	5			
3.2 Operation of automatic diaphragms					

