

**EVALUATION AND CLINICAL ASSESSMENT
OF THE KONICA MINOLTA REGIUS 190
WITH CP-1M CASSETTES**

NHSBSP Equipment Report 0906
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We are especially grateful for the support of Jenny Diffey and colleagues from North Western Medical Physics, based at The Christie NHS Foundation Trust in Manchester. The contribution of the Konica Minolta team, in association with GE and the Trust's Computer Services Department, was also crucial to the success of the project.

1. INTRODUCTION

This clinical evaluation was undertaken between September 2008 and March 2009 at the Breast Unit, Royal Bolton Hospital NHS Foundation Trust. It was commissioned by Konica Minolta and the NHS Breast Screening Programme (NHSBSP). The NHSBSP *Guidance Notes for Equipment Evaluation*¹ and the guidelines for *Routine Quality Control Tests for Full Field Digital Mammography Systems* were followed throughout.²

The centre where the evaluation took place is an NHSBSP unit that screens approximately 26 000 women per year. It meets both relevant national quality standards for breast screening and the criteria for evaluation centres outlined in the *Guidance Notes*.¹ During the evaluation period the centre was chosen as a pilot site for the extension of the breast screening age.

Most of the centre's routine screening takes place either on mobile units or in a static screening unit. To achieve the increased capacity needed for the evaluation, more women were screened on the mobile units and at the static site in Bolton. The base site is used primarily for assessment, with only a limited amount of screening. To ensure sufficient screening numbers for the evaluation, however, additional appointments were made there, including some screening outside normal hours. The resulting staffing and other pressures meant that the static site was not an ideal setting for the evaluation; of those available, however, it was agreed to be the most satisfactory.

The system was supplied by Konica Minolta on a free loan basis for the evaluation. The company indemnified the equipment for the loan period; it also provided technical support and a laser printer and film for hard copy archiving.

The project lead was Claire Mercer, the Breast Screening Programme Manager and an experienced breast screening radiographer. The Director of Breast Screening, Dr Anthony Maxwell, oversaw key clinical decisions. A computed radiography (CR) team was created and its members were the only clinical users of the system under evaluation. The team met monthly for updates on current issues. It comprised

Jeanette Douthwaite	Trainee Advanced Practitioner
Elizabeth Horne	Mammographer
Elizabeth Hough	Advanced Practitioner
Jennifer Pearce	Mammographer
Alison Tuson	Assistant Practitioner

The film readers consisted of six experienced radiologists/film readers

Christine Crook	Advanced Practitioner
Dr Janick Harake	Consultant Radiologist
Elizabeth Hough	Advanced Practitioner
Dr Anthony Maxwell	Consultant Radiologist/Director of Breast Screening
Dr Ann Mills	Consultant Radiologist
Cheryl Waite	Advanced Practitioner

North Western Medical Physics (NWMP) collaborated in the commissioning and regular six-monthly testing of the equipment. It also helped with the analysis of clinical evaluation data.

The Konica Minolta CR was used with a GE Healthcare mammography unit that was already in place. The collaboration of technical staff from both organisations was vital in setting up the automatic

exposure control (AEC) to optimise CR performance. The continuing technical support of the Konica Minolta staff was invaluable at every stage of the evaluation process.

2. OBJECTIVES OF EVALUATION

The aim of the clinical evaluation was to assess the suitability of the Konica Minolta system for use in NHSBSP mammographic screening. The evaluation used soft copy reporting; the laser printer and hard copy images were used only for archiving purposes. The objectives of the evaluation were

- to assess clinical image quality by comparing it with the standard local film-screen system
- to assess the impact on radiation dose of optimising AEC and CR performance
- to assess the impact of user interfaces on workflow
 - the radiographer workstation and CR plate reader
 - the reporting workstation
- to determine whether the system could accommodate typical screening appointment slots of six minutes
- to test the reliability of the system when used for routine NHSBSP screening
- to evaluate user comments.

It was assumed that women's perceptions of the mammography examination would not be affected by the introduction of CR, so these perceptions were not investigated. Radiography questionnaires yielded no comments on the subject.

3. SYSTEM DESCRIPTION

The unit evaluated was the Konica Minolta Regius 190 dual bay CR reader with CS3 console and mammography HQ processing. The mammography processing includes gradation and frequency processing and is supported by Konica Minolta's proprietary 'Hybrid' enhancement processing software. The dimensions of the unit are w580 × d580 × h1230 mm and its weight is 170 kg.

The system uses an RC110M cassette and a rigid CP-1M mammography image plate with two field sizes (18 × 24 cm and 24 × 30 cm). (See Figure 1.) Its capacity is 90 plates per hour. The cassette cycle lasts approximately 40 secs and image review time is 23–27 secs. The nominal pixel size is 43.75 µm, with 12-bit (4096) grey levels. The laser imager (which was excluded from the evaluation) uses SDP Dry Laser Film.

The workstation hardware comprised

- Dell Precision WorkStation T5400
- two Dual Intel Xeon E5410 processors (each 2.33 GHz)
- 4 GB of memory
- two mirrored 146 GB 15K SAS hard drives
- an NVidia Quadro NVS 290 graphics card for the colour LCD monitor
- a Dell 2007FP colour monitor
- a Matrox MDP5MP graphics card for the greyscale monitors
- two Eizo RadiForce G51 greyscale monitors.

The software comprised

- Windows XP Service Pack 3
- Insignia InView Standalone QA v5.10.6.



Figure 1 Konica Minolta Regius 190 dual bay CR reader with CS3 console and mammography HQ processing.

4. ACCEPTANCE TESTING, COMMISSIONING AND PERFORMANCE TESTING

NWMP were responsible for the commissioning and routine six-monthly testing of the equipment. They also collaborated with the Trust in analysing the clinical data. A Konica Minolta representative was available during the trial period to advise on the operation of the equipment, but took no part in the evaluation process.

4.1 Commissioning

NWMP performed commissioning tests on the CR equipment in September 2008. Their report established that

- new cassettes should be irradiated and erased at least three times before clinical use
- if 24 × 30 cm cassettes are to be used, the AEC device must be adjusted for this larger field size
- the equipment had met or exceeded the performance standards and protocols set out in NHSBSP Equipment Report 0604 (Version 2).³

4.2 Six-monthly routine testing

NWMP performed routine tests on the CR equipment in March 2009, after it had been used for six months in the NHS Breast Cancer Screening Programme. Their report established that there had been no significant changes in performance over the period. Owing to the practical constraints outlined in sections 1 and 8, however, the workload achieved with the equipment was somewhat lower than anticipated.

5. ROUTINE QUALITY CONTROL

5.1 Daily and monthly routine testing

The equipment was not used every day, and tests scheduled to be undertaken daily could be performed only when it was in use. The prescribed daily and monthly tests were undertaken by mammographers.

NWMP were provided with the results of AEC consistency tests using 2, 4, 6 and 7 cm thicknesses of Perspex to calculate mAs and sensitivity (S-value), which are inversely proportional. The results were compared with standards set out in NHSBSP Equipment Report 0702.² Using the same target/filter combination, this gives a remedial level of baseline $\pm 10\%$ for the measurement of current-time and detector dose indicator. The results are given in Figures 2–6.

- Figures 2–5 show that some results were at remedial level for both mAs and S-value. With a 4 cm thickness of Perspex, the system selected either the Mo/Mo or Mo/Rh target/filter combination. The results for the two settings have been differentiated in the analysis.
- Figure 6 shows the variation in S-value after normalising for the variation in mAs. After normalisation, only values for the 4 cm block where Mo/Mo was selected remained at the remedial level. As there were few measurement points for this target/filter combination, it was more difficult to define a suitable baseline value for comparisons. In all other cases, the variations in S-value were in the acceptable range. This suggests that the CR system is able to work below the remedial level only if the AEC system operates within smaller tolerances.
- A region of interest (ROI) is used by the CR system to define the S-value for an image. Differences in the positioning of this ROI influence the S-value, and could underlie the variation in results.

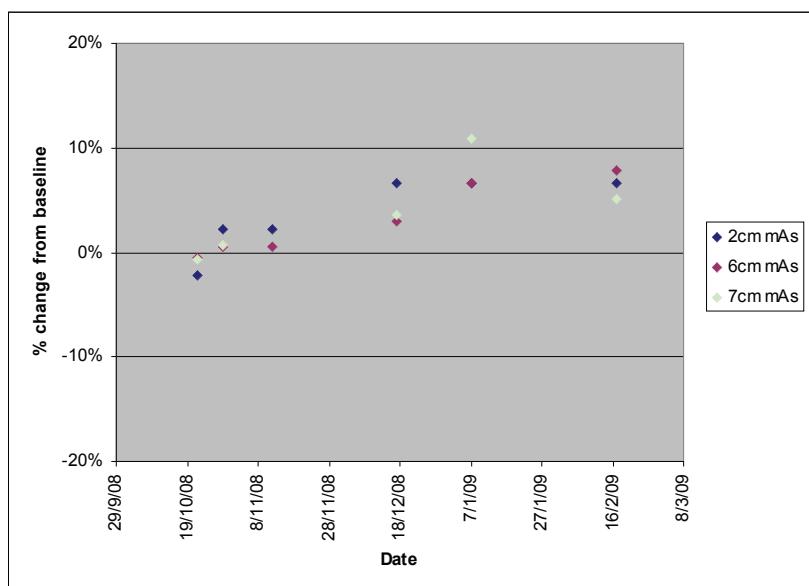


Figure 2 Percentage change in mAs from baseline for 2, 6 and 7 cm of Perspex.

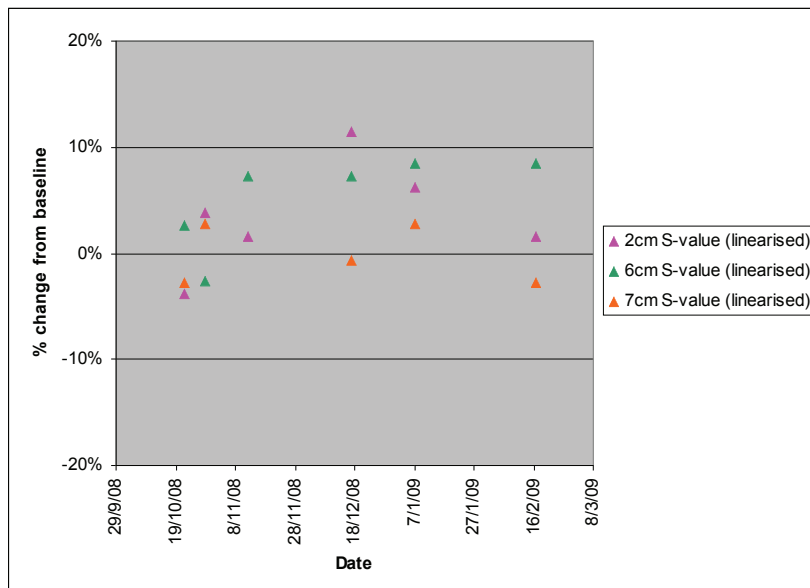


Figure 3 Percentage change in S-value from baseline for 2, 6 and 7 cm of Perspex.

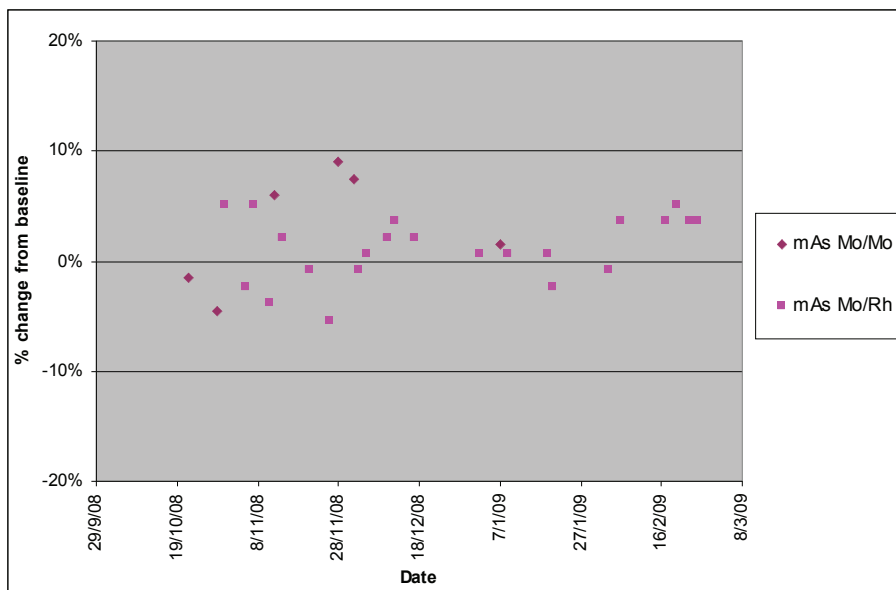


Figure 4 Percentage change in mAs from baseline for 4 cm of Perspex.

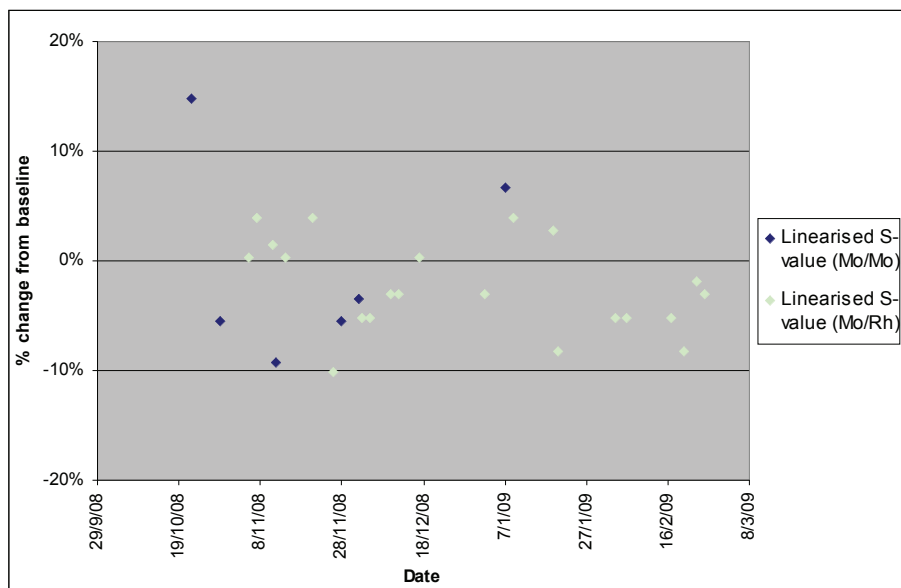


Figure 5 Percentage change in linearised S-value from baseline for 4 cm of Perspex.

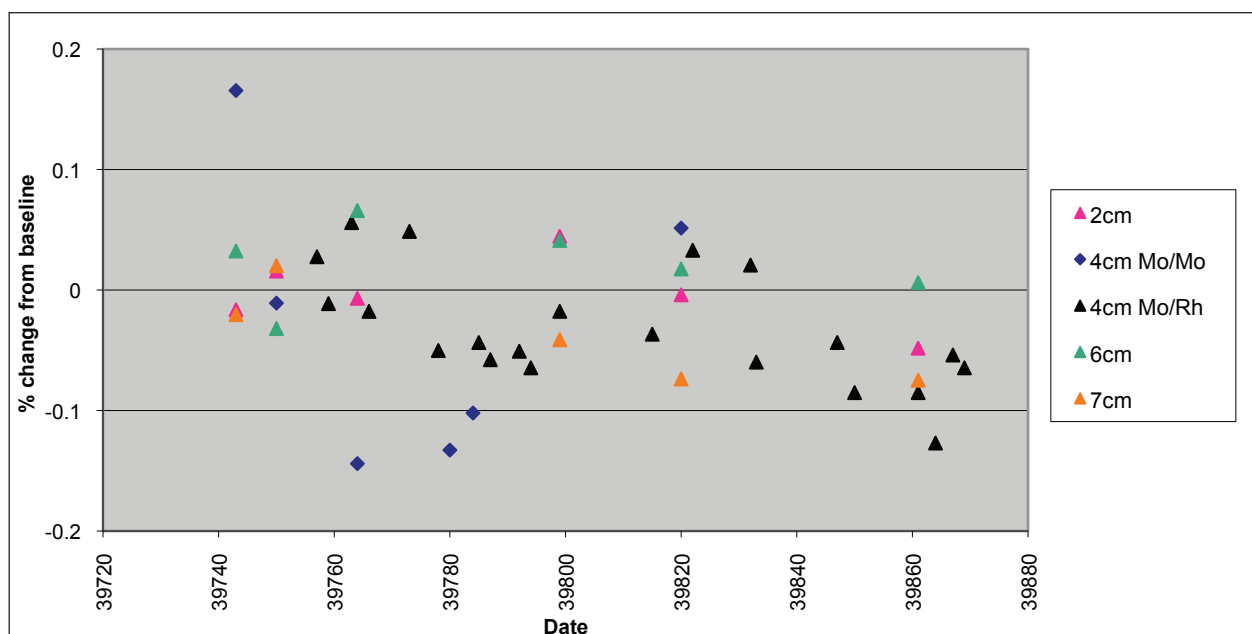


Figure 6 Percentage change in linearised S-value (normalised to baseline value).

6. IMAGE QUALITY ASSESSMENT

Image quality was assessed both objectively, using a test object, and subjectively, using clinical images.

- For the objective assessment of image quality the CDMAM test object was used. The results were consistent with the NHSBSP's technical evaluation of the system (NHSBSP Equipment Report 0806)⁴ and (as Figure 7 illustrates) they fell between 'acceptable' and 'achievable' levels.
- Clinical image quality was tested subjectively by two independent readers. Each assessed 451 images on a five point scale, yielding a total of 902 assessments. The same images were then read and scored by seven advanced practitioners and radiologists.

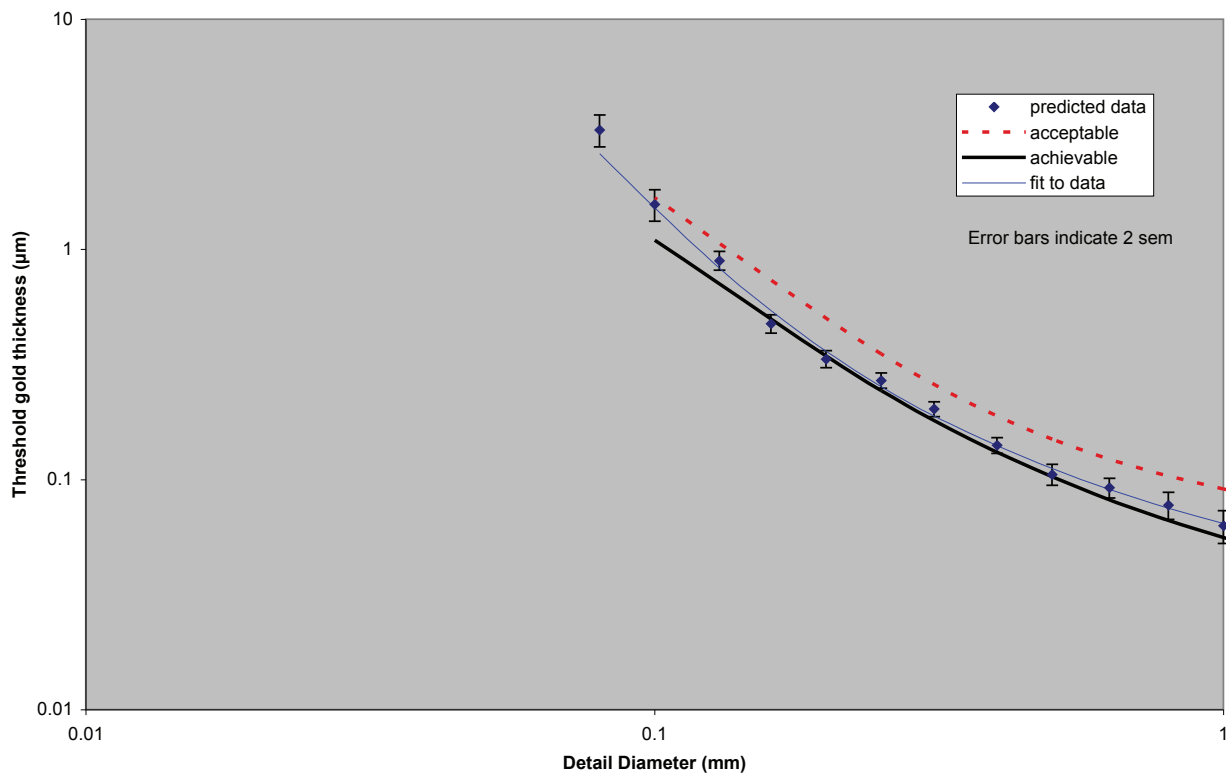


Figure 7 Predicted threshold contrast measurements assessed using the CDMAM test object.

- Exposure, contrast and overall image quality were graded from 1 to 5: 1 = inadequate, 2 = poor, 3 = satisfactory, 4 = good, 5 = excellent. Sharpness was graded from 1 to 5: 1 = blurred, 3 = satisfactory, 5 = sharp. Breast composition was defined as fatty, dense or mixed.
- Three of the images assessed were of patients with implants; four others included unidentified artefacts.
- There was complete agreement between readers in 49% of cases and agreement to within one point on the scale in a further 48% of cases.
- As Figure 8 shows, the majority of images were considered 'good'.
- The sharpness of images was enhanced by the plates' needle crystal structure, which reduced scattered radiation.

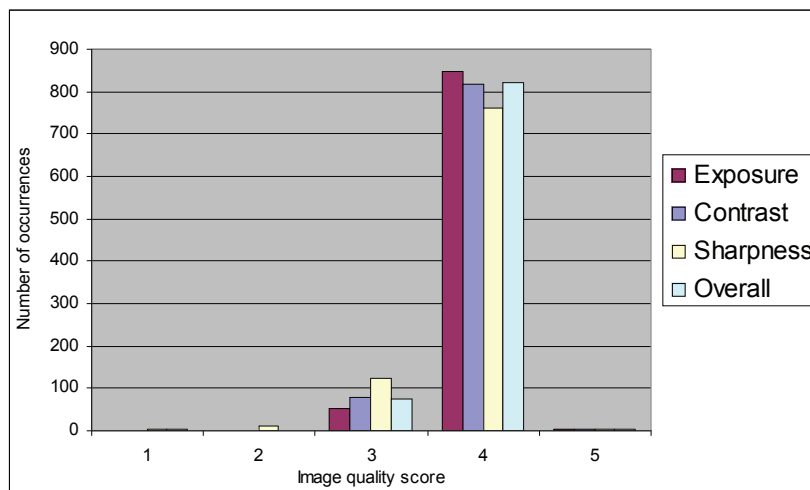


Figure 8 Subjective clinical opinions of screening image quality.

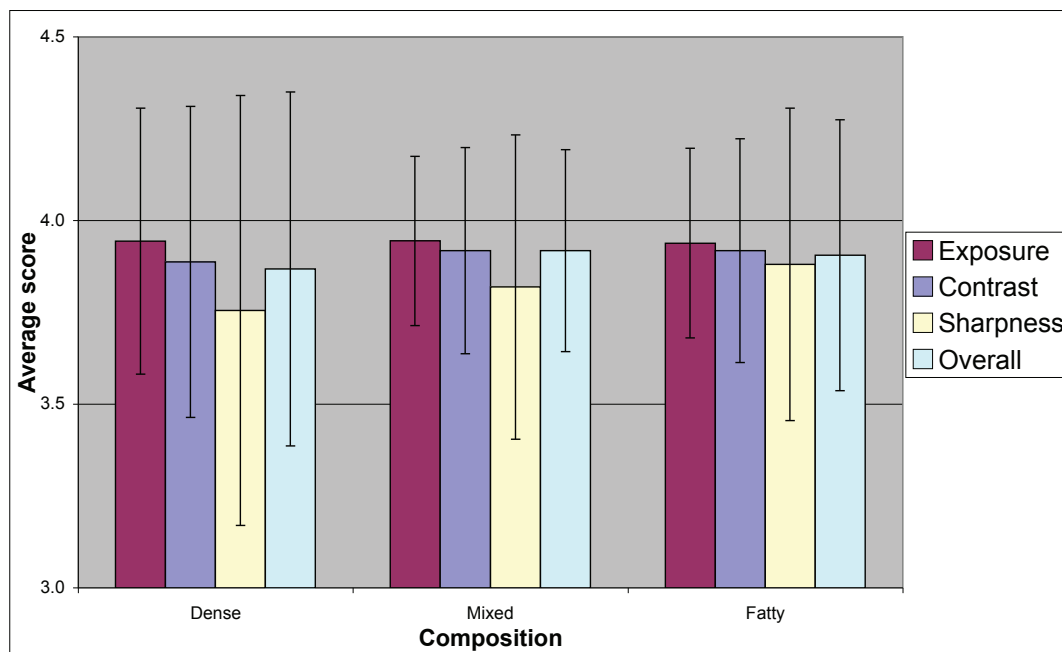


Figure 9 Image quality assessment by breast composition.

- In Figure 9 the data have been differentiated according to breast composition. The average sharpness score is slightly higher for fatty breasts than for dense breasts. However the differences are small when compared with the standard deviation in the results.

7. DATA ON SCREENING CONDUCTED

7.1 Clinical dose audit

A dose audit was completed for the first 100 women imaged with the Konica Minolta system. This was based on records of the exposure factors selected by AEC. Four women were excluded from this sample as they had breast implants. The data were analysed using the *NHSBSP Breast Dose Calculator and Database (Version 2.0)* supplied by the National Coordinating Centre for the Physics of Mammography.⁵

- Figure 10 shows the expected variation in mean glandular dose (MGD) for a range of breast thicknesses.
- Table 1 shows the mean and range of MGD for both craniocaudal (CC) and mediolateral oblique (MLO) views.
- The average MGD for MLO view examinations of compressed breasts of 50–60 mm thickness was 1.98 mGy. The standard error of the mean was 0.03 mGy. The mean compressed breast thickness for this sample was 56 mm (Table 2).
- The average MGD for this sample was well below the national reference level, which is 3.5 mGy for a compressed breast thickness of 55 mm examined in the MLO view.
- In 2007 the average MGD for the same GE Senographe DMR+ system using Kodak Min R2000 film was measured at 1.77 mGy, with mean compressed breast thickness of 56 mm. The increase in MGD is attributable to the adjustment of the AEC for use with a CR system.

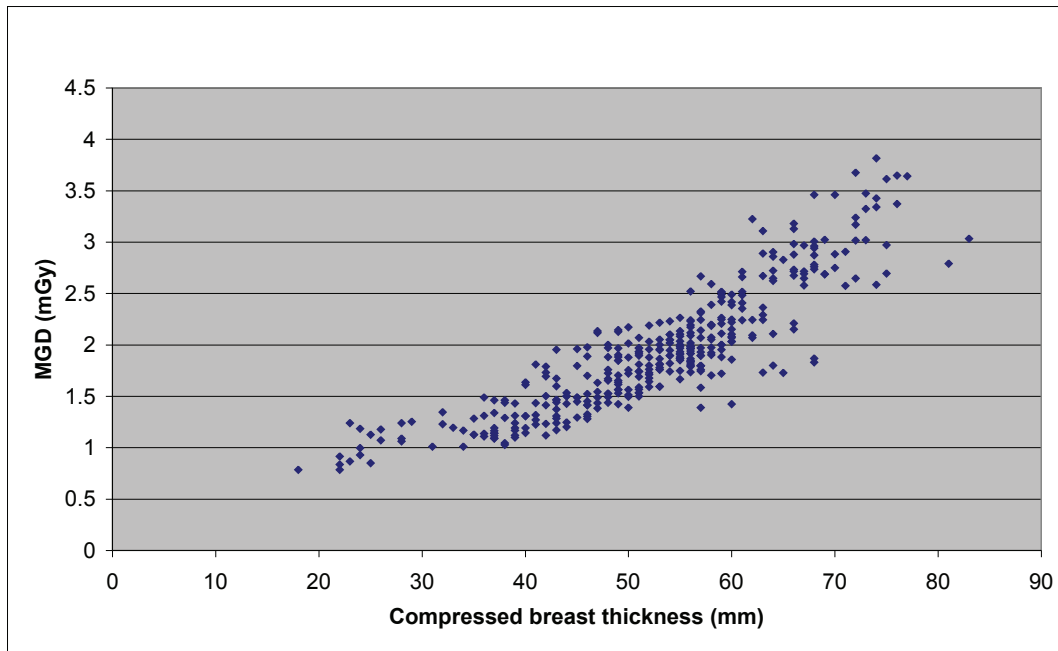


Figure 10 MGD to a range of breast thicknesses.

Figure 10 shows the relationship between MGD and compressed breast thickness. Both CC and MLO views were included in the sample.

Table 1 Average doses for all data in the sample

View	Number of films	Mean MGD (mGy)	Min – max MGD (mGy)	Mean thickness (mm)
CC	190	1.79	0.78 – 3.62	50
MLO	190	2.06	0.85 – 3.82	55

Table 2 Average doses for 50–60 mm thick breasts in the MLO view

View	Number of films	Mean MGD (mGy)	2 × standard error of the mean	Mean thickness (mm)
MLO	76	1.98	0.06	56

7.2 Comparison with existing image quality assessment

To assess the Konica Minolta CR's image quality the TOR(MAM) test object was exposed using 28 kV, Mo/Mo, and AEC. The AEC registered 129 mAs post exposure. This gave a score of 90 on the reporting workstation and 103 on the printed film. By contrast a score of 79 mAs post exposure resulted when Kodak Min R2000 film was used on the same x-ray unit. Although the TOR(MAM) had been exposed under the same conditions, the AEC registered 84 mAs post exposure.

7.3 Conclusions

The average MGD achieved using the GE Senographe DMR+ x-ray set and Konica Minolta's CR equipment (1.98 mGy) was slightly higher than that for the same unit using Kodak Min R2000 film (1.77 mGy). The increased MGD is attributable to the adjustment of the AEC for use with a CR system. However, it lies comfortably below the National Reference Level of 3.5 mGy.⁶

8. CLINIC ORGANISATION AND THROUGHPUT

The system was installed in the base screening and assessment unit. The smallest mammography room was used for the CR evaluation, in order to minimise the impact on workflow in the two main symptomatic treatment, screening assessment and biopsy rooms.

The monitor for viewing images was sited with the CR reader in the mammography room. The laser printer was needed for archiving purposes as there was no means of archiving to the Picture Archiving and Communications System (PACS). (A mini-PACS has since been installed for use by the breast screening service.) Space being limited, the laser printer was housed in the Screening Programme Manager's office. The images were sent to the printer automatically as each examination was completed.

The fact that the Konica Minolta CR system was not connected to PACS made some routine activities more laborious. Work-lists could not be downloaded to the workstation, for example. In some cases, mammographers entered each client's identification details during the course of the clinic: in others, details were entered beforehand on a manual work-list. Radiographers were required to record exposure parameters manually in the x-ray rooms.

Maintaining a steady throughput of women with consistent appointment times was also a challenge when using the Konica Minolta CR system. However the reasons for this are not related exclusively to the system and its configuration.

- There was increased throughput at mobile and static sites (away from the base site) to increase capacity in readiness for the extension of the screening age.
- The base site had not been used every day for screening but kept chiefly for assessment and symptomatic work. Increased screening appointments at the base site demanded more staff, and this had to be achieved without jeopardising the increase in appointments at other sites.
- Pressures on staffing made six minute clinic appointments impracticable. As a result the number of clients attending a clinic in the evaluation period was somewhat lower than anticipated.
- Overall throughput for the system under evaluation may have been compromised where mammographers were still engaged at the workstation and not ready to re-enter the x-ray room. However effective teamwork and individual workflow management could help to minimise these delays. (Throughput, and in particular the time taken to digitise the images following the examination, is discussed further in section 11.)

To summarise, staff at the site cannot comment authoritatively on the performance of a Konica Minolta CR system in a one-roomed department or mobile screening unit as, for the reasons outlined, it was not possible to evaluate the system at its optimum level. Our experience would nevertheless suggest that typical screening appointment times of six minutes could be supported in a one-roomed static department in which two mammographers were working together.

9. DATA ON ASSESSMENTS CONDUCTED

No breast screening assessments were performed with the Konica Minolta CR system.

10. EQUIPMENT RELIABILITY

The Konica Minolta CR equipment was generally very reliable. The main challenges arising from the evaluation, and those entailing most system downtime, related to connectivity problems between the acquisition workstation and the printer or reporting workstation. These were not associated with the Konica Minolta CR system however. Uptime cannot accurately be calculated as a proportion of that expected because the equipment was used sporadically. In the event of downtime film-screen mammography could be used; because this alternative was available, repairs might not have been undertaken with the same urgency.

The faults directly associated with the CR system were few

- problems reading the barcodes of cassettes
- cassettes which occasionally became partly stuck during ejection
- the difficulties NWMP experienced when loading images on the reporting workstation if a large number of images had been acquired with the same identification.

There were also issues after installation with communication errors and links with the laser printer; although internal, these issues were resolved with the help of Konica Minolta's technical staff.

11. MAMMOGRAPHERS' COMMENTS AND OBSERVATIONS

Mammographers' views on the Konica Minolta CR were collected using the relevant form from the NHSBSP equipment evaluation guidelines.¹ A summary of their responses to the applicable sections appears below with the project manager's observations.

Summary of mammographers' responses

How good was the operator's manual?	Satisfactory, although one colleague would have welcomed a printed (as well as the electronic) version.
How good was the training provided by the supplier?	Effective and consistent. The applications specialist was very useful.
How do you rate the unit's ease of use?	It was very easy to use, though repetitive strain injury (RSI) risk remains with the handling of cassettes.
How do you rate the unit's help in minimising fatigue?	RSI risk remains with the handling of cassettes.
Ease of insertion and removal of cassettes	Cassettes were the same size as film cassettes. Generally easy to insert and remove, despite occasional sticking during ejection. (See section 10.)
Were all the expected controls present?	Yes.
What was your level of confidence in the machine?	High. (While some respondents mentioned networking difficulties here, these were caused by internal factors not the CR equipment.)
Did the x-ray set performance limit patient throughput?	At the start of the trial one user noted that throughput was slower as users were working with an unfamiliar system. At the end of the trial the same user noted that it was possible to maintain the six minute appointment time.
How would you rate the image quality of films taken on this unit?	Image manipulation enhances film reading. Image quality improved by lack of processing artefacts. Good edge enhancement.
Additional comments	Useful to have skin surface and parenchymal patterns visible simultaneously.

11.1 Operator manual

The online operator manual was concise and clear. It contained good sequential information and guidance, with recommendations for avoiding potential hazards and system misuse. The Breast Unit received appropriate guidance and support. This included system information to enable us to comply with quality assurance guidelines.

11.2 Training

Training was carried out by an applications specialist from Konica Minolta. This ensured that each mammographer was trained consistently and sufficiently to become competent in all aspects of image acquisition.

11.3 Ease of use

Both 18 × 24 cm and 24 × 30 cm cassettes were used, weighing 400 g and 500 g respectively. Their loading, scanning, erasing and ejecting did not impede the work flow.

11.4 Image acquisition

This was sufficiently quick to cause no delays.

11.5 Acquisition workstation

The conventional keyboard and mouse and the touch screen workstation were all easy to use, both for generating the work-list and for image acquisition. Combined with automatic image rendering (which helped the mammographer to identify each examination projection) this improved productivity and workflow. It also enabled faster throughput than with film-screen by removing the delay between capturing an image and its appearance on screen. In addition the mammographer was able to create settings for image presentation, which in turn reduced the need for film readers to make adjustments.

11.6 Image handling

A hard copy film was produced for archiving purposes. The time delay in sending images from the acquisition workstation to the reporting workstation was insignificant.

11.7 Reporting workstation

The image viewing application was easy to use. The image processing software expands the image presentation options by allowing parameters such as contrast and brightness to be adjusted independently. Other processing features include the facility to magnify and spot zoom images, and to improve the demonstration of microcalcifications and skin line enhancement in the heterogeneously dense breast. Implant examinations were particularly well demonstrated and enhanced using the image presentation tools.

12. RADIOLOGISTS'/FILM READERS' COMMENTS

The radiologists/film readers were pleased with the overall image quality. Subjectively, they felt the images compared favourably with the film-screen system in current use. There were occasional technical problems which resulted in the temporary unavailability of screening images. They usually arose from network issues, however, and would be unlikely to occur in a full PACS environment.

The reporting workstation provided by Konica Minolta met the needs of the evaluation. Although it had not been set up with specific mammographic display protocols this did not significantly affect the reading and evaluation of the limited number of mammograms in the study.

13. INFORMATION SYSTEMS

As noted above, the system was not connected to PACS. Many of the connectivity difficulties experienced would be unlikely to have occurred in a full NBSS/PACS environment.

14. CONFIDENTIALITY AND SECURITY ISSUES

Loss of screening images was not a significant risk as images were laser printed for all examinations. Mutual backups of the digital data were provided by image caches on the plate reader and workstation, each cache storing up to 4000 images. This entailed some increased vulnerability to data theft. To enhance data security the system incorporates password protection for all image changes. In addition, the breast unit is secured with digital locks on individual doors and an intruder alarm which is set when the unit is vacated.

The digital screening images will be archived to the recently installed screening PACS over the next few months.

15. CONCLUSIONS AND RECOMMENDATIONS

This has been an excellent preparation for the move to digital screening mammography and has given film readers the opportunity to develop their soft copy reporting skills. The Breast Unit is now more aware of where problems are likely to arise and how they can be addressed, with minimal impact on screening activity, when a digital service is introduced.

The Konica Minolta CR was used with a GE Healthcare mammography unit already in place; the collaboration of technical staff from both organisations was vital in setting up the automatic exposure control (AEC) to optimise the imaging chain.

To evaluate the quality of clinical images, seven experienced readers scored the images on a scale of 1 (inadequate) to 5 (excellent). The majority of images scored 4 (good) in all categories (sharpness, contrast and exposure). The data were separated according to breast composition. Similar image quality was achieved for all breast types. The average sharpness score is slightly higher for fatty breasts than for dense breasts. However the differences are small when compared with the standard deviation in the results.

Commissioning tests showed that the equipment was performing to the standards anticipated in the NHSBSP technical evaluation.⁴ The GE Senographe DMR+ was tested to the NHSBSP standards before the clinical evaluation. Routine tests were completed on both the GE and Konica Minolta equipment after six months; no significant changes in performance were registered. Radiographer quality control tests were completed during the evaluation and satisfactory results were recorded.

A dose audit was completed using data from the first 100 women, excluding those with implants. The average MGD for breasts in the range 50–60mm was 1.98mGy. This is slightly higher than the

1.77 mGy measured in 2007 using Kodak Min R2000 film but compares favourably with the national reference level of 3.5 mGy. Optimisation has to balance image quality and dose, and a reduction in dose would have adversely affected the image quality.

The system under evaluation was very reliable overall. Downtime was caused mainly by connectivity problems between computer systems, although there were occasional difficulties with reading barcodes and with cassettes that became stuck on ejection. There were also issues arising from the organisation of clinics. In particular, staffing pressures made it impossible to schedule six minute appointments, as a result of which the system could not be evaluated in optimum conditions. While this prevents colleagues using it from commenting authoritatively on its capacity, our experience suggests that typical six minute appointments could be supported by this system in a one-roomed static department in which two mammographers were working together.

In conclusion, it is the authors' view that the Konica Minolta CR 190 performed to acceptable levels in all respects and could be used in the NHSBSP.

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