

**Evaluation and clinical assessment of the
Philips MammoDiagnost DR
full field digital mammography system**



Cancer Screening Programmes

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Philips MammoDiagnost DR
full field digital mammography system

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EXECUTIVE SUMMARY

The Philips MammoDiagnost DR Full Field Digital Mammography System was evaluated by the South West London Breast Screening Unit from mid-2009 to early 2011 to establish its suitability for use in the NHS Breast Screening Programme (NHSBSP).^{*} The primary focus of the evaluation was screening performance: there was limited evaluation of assessment and no evaluation of stereotaxis. The evaluation included the Philips MammoDiagnost VU digital reporting workstation.

The evaluation was delayed briefly by connectivity problems affecting the acquisition workstation and the reporting workstation and printer. Connection to a printer was essential for archiving purposes, as there was then no connection to the Trust's Picture Archiving and Communication System (PACS). Unfortunately, there also was an unavoidable and considerably longer delay in connecting the MammoDiagnost to the National Breast Screening System (NBSS). This resulted in longer examination times, as all patient information had to be input manually. Once NBSS connectivity was established examination times reduced significantly.

The MammoDiagnost system was judged to be reliable as no downtime was caused by equipment breakdown during the course of the evaluation. The most frequent problem was the need to reboot the system two or three times a week because the computer had frozen during an examination. This caused a delay each time of 10–15 minutes.

In general the mammographers found the MammoDiagnost easy to use, above all the acquisition workstation, but felt that a few physical changes would enhance the image quality and comfort of use for the operator and the client. Suggested improvements included providing a tilting compression paddle that could be off-set and slowing the movement of the support arm and breast support table.

A review of screening examination times revealed that just under half (46%) of examinations were completed within the six minutes specified by the NHSBSP. Experience with the Philips MammoDiagnost DR system nevertheless indicates that, with the suggested improvements, it would be capable of completing examinations within the required six minutes.

The MammoDiagnost VU reporting workstation was well received by the screening unit's film-readers, who rated most of its features either excellent or good. It was considered relatively easy to master and straightforward to use.

^{*} The reasons for this extended evaluation period are detailed below.

The screening unit also trialled a prototype of desktop integration with NBSS. This, too, was simple to use although some improvements have been recommended for inclusion in the final version.

Film-readers found the workflow of image presentation user friendly and preferred the image quality to that of film–screen images.

The MammoDiagnost met the NHSBSP’s minimum standards for image quality and dose. (A full technical evaluation is in progress and its findings will be published early in 2012.)

The overall conclusion of this evaluation and clinical assessment is that, with the recommended modifications, the Philips MammoDiagnost DR and MammoDiagnost VU reporting workstation are suitable for use in the NHSBSP.

1. INTRODUCTION AND BACKGROUND

The Philips MammoDiagnost DR System (hereafter 'MammoDiagnost') was evaluated within the South West London Breast Screening Programme at St George's Healthcare NHS Trust. The evaluation was commissioned by the NHSBSP and undertaken in accordance with the relevant NHSBSP equipment evaluation protocol.¹

The evaluation centre (hereafter 'the Unit') is an NHSBSP unit currently screening approximately 36,000 women per year. It meets the relevant national quality standards required for breast screening and the eligibility criteria outlined in the NHSBSP's *Guidance Notes for Equipment Evaluation*.¹

The MammoDiagnost system comprises the mammography unit (Figure 1), magnification table and MammoDiagnost VU workstation. A stereotactic device is also available but was not installed and was excluded from the evaluation.

The system was installed by Philips on loan for the duration of the evaluation. They agreed to accept liability for the equipment throughout the period and to provide technical support.

The project lead was the screening unit's director, who also took responsibility for key clinical decisions. Other members of the evaluation team included experienced and accredited breast screening radiographers.

2. OBJECTIVES OF THE EVALUATION

The aim of the evaluation was to assess the suitability of the MammoDiagnost system for use in NHSBSP mammographic screening, using soft copy reporting.

The objectives of the evaluation were to

- assess the system against the clinical image quality and dose standards set out in the NHSBSP protocol[†]
- appraise clinical image quality by comparing the digital images with the standard local film–screen combination used three years previously (ie the ‘priors’).
- assess the impact of user interfaces on workflow, focusing on
 - the MammoDiagnost unit and acquisition workstation
 - the MammoDiagnost VU reporting workstation
- evaluate the ability of the system to integrate with the National Breast Screening System in the unit
- assess whether the Philips MammoDiagnost DR could accommodate typical screening slots of five or six minutes
- evaluate the reliability of the system when used in the context of the NHSBSP.

[†] Physics image quality and dose will be documented in the forthcoming technical evaluation.

3. SYSTEM DESCRIPTION

3.1 Philips MammoDiagnost DR Full Field Direct Digital Mammography System



Figure 1 Philips MammoDiagnost DR FFDM Mammography System

The MammoDiagnost DR includes a gantry with integrated generator. The movements are motorised with a pre-set facility for single touch adjustment of the C-arm to the next position. Also incorporated is a mechanism that stops the rotation of the C-arm on contact with an object.

The x-ray tube has Molybdenum and Tungsten targets and Molybdenum and Rhodium filters with two standard focal spots: large (0.3 mm) and small (0.1 mm).

The amorphous Selenium flat panel detector has a pixel size of 85 μm . The detector size is 24 x 30 cm but the field automatically changes to 18 x 24 cm when the smaller compression plate is fitted.

The automatic exposure control works by optimised dose calculation. The target/filter combinations and kV values are predefined according to the compression thickness, but can be manually overridden.

Two foot pedals provide controls for compression and height adjustment. On either side of the tube head are controls for height adjustment and rotation and a rotary wheel for fine adjustments to the compression.

The operator's console (with radiation shield) contains a PC, a flat-screen monitor, a keyboard, a mouse and a control panel. The acquisition workstation includes the Eleva Workspot with a touch-screen facility in addition to its keyboard. The Eleva Workspot was designed for creating, processing, saving and transferring digital x-ray exposures. It supports a fully automatic workflow, comprising the entering of patient data, image processing and presentation for reading and archiving.



Figure 2 Philips MammoDiagnost DR and acquisition workstation

Accessories were provided as follows

- magnification table (magnification factor 1.5)
- 18 x 24 cm compression plate with 4 cm front edge
- 18 x 24 cm compression plate with 7 cm front edge
- 24 x 30 cm compression plate with 4 cm front edge
- 24 x 30 cm compression plate with 7 cm front edge
- 9 x 9 cm spot compression plate
- 8 x 20 axilla compression plate (for use also on small breasts)
- spot compression plates for magnification.

3.2 Philips MammoDiagnost VU reporting workstation



Figure 3 Philips MammoDiagnost VU reporting workstation

The Philips MammoDiagnost VU reporting workstation consists of a computer, two 5 megapixel greyscale monitors, a keyboard and a specialised mammography keypad. A colour monitor was connected to the MammoDiagnost VU reporting workstation and used to display the National Breast Screening System (NBSS) and the workstation's navigation console.

3.3 Workflow configuration

There was no PACS in the department and no configuration to NBSS for the first year of the evaluation. Consequently, worklists could not be downloaded to the acquisition workstation. Until these connectivity problems were resolved and a worklist could be downloaded each morning the mammographers were obliged to enter each woman's identification details manually.

In the absence of PACS a laser printer was used for archiving purposes. It was recognised that this was not an ideal solution as digital images should not normally be stored as printed film. As each examination was completed the images were sent automatically to the MammoDiagnost VU reporting workstation and to the printer.

4. ACCEPTANCE TESTING, COMMISSIONING AND PERFORMANCE TESTING

Acceptance and commissioning tests were conducted by the local physics service (Radiological Protection Centre, St George's Healthcare NHS Trust, hereafter 'the local physics service') in accordance with NHSBSP guidance.² In addition, technical evaluation was carried out by staff from the National Coordinating Centre for the Physics of Mammography (NCCPM), Royal Surrey County Hospital Guildford.[‡]

The clinical evaluation began once the technical evaluation was complete and had confirmed that the system's performance met the required standards.

[‡] For details of the National Coordinating Centre for the Physics of Mammography see www.nccpm.org.

5. ROUTINE QUALITY CONTROL

The following tests were conducted under the guidance of the local physics service and applications specialists from Philips Healthcare.

The 4.5cm signal-to-noise ratio (SNR) tests were undertaken daily; contrast-to-noise (CNR) tests were undertaken weekly; 2cm and 7cm SNR and CNR tests were undertaken monthly. The remedial levels are set 20% above and below a baseline that is derived by performing a group of ten successive tests and calculating the mean results.

There is no software on the system's acquisition workstation to calculate the SNR and CNR values. These had to be calculated using software developed by the local physics service. This made routine quality control a lengthy process. The evaluation team understand that software to calculate the SNR and CNR is being developed by the manufacturer.

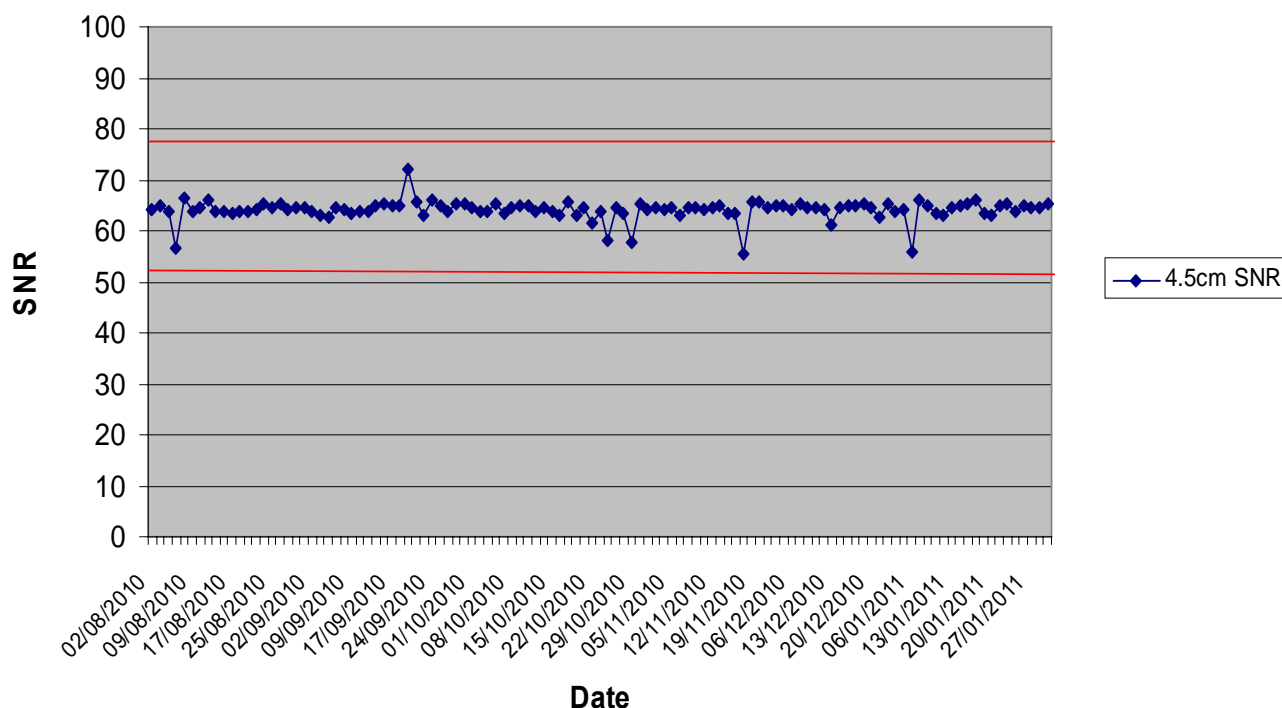


Figure 4 Daily 4.5cm signal-to-noise ratio

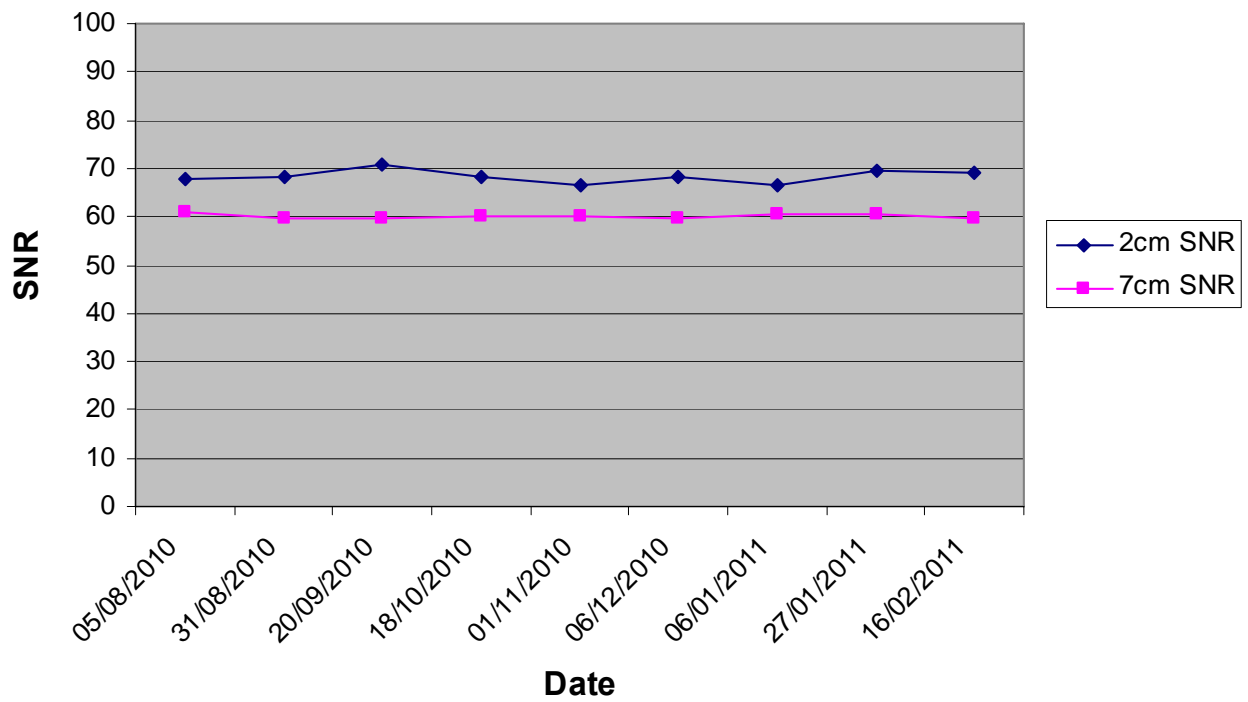


Figure 5 Monthly 2cm and 7cm signal-to-noise ratio

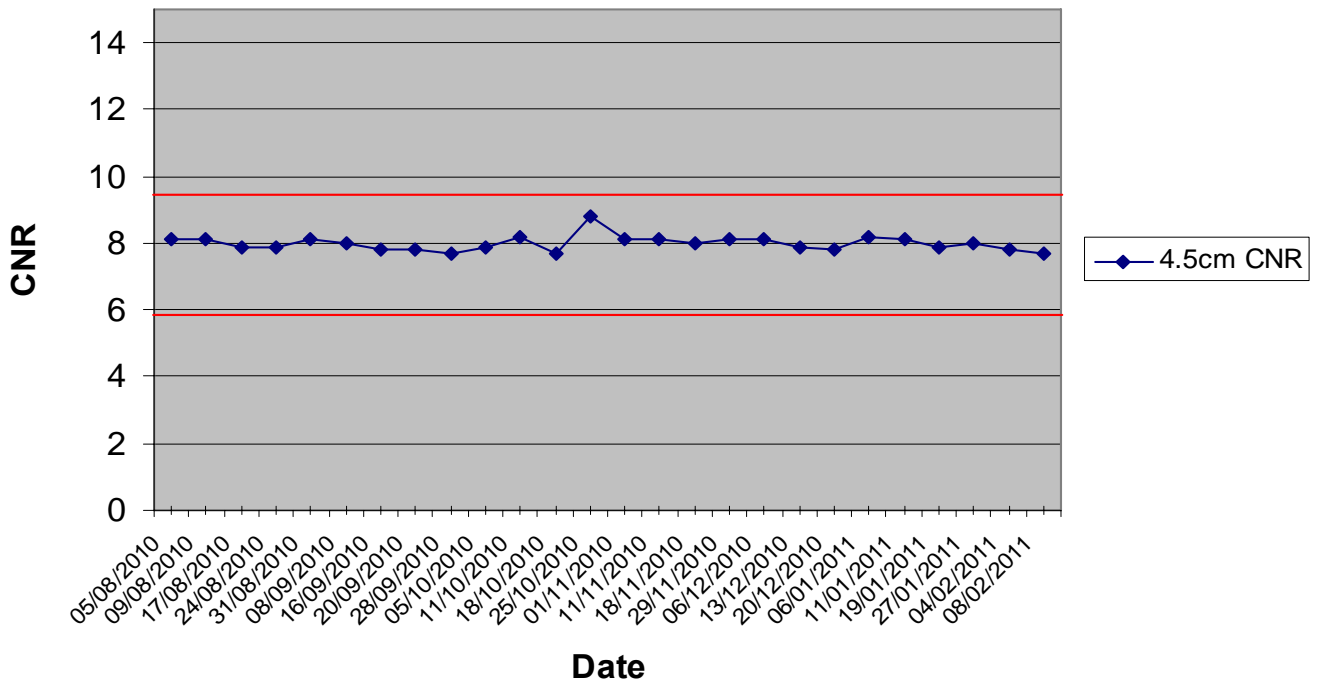


Figure 6 Weekly 4.5cm contrast-to-noise ratio

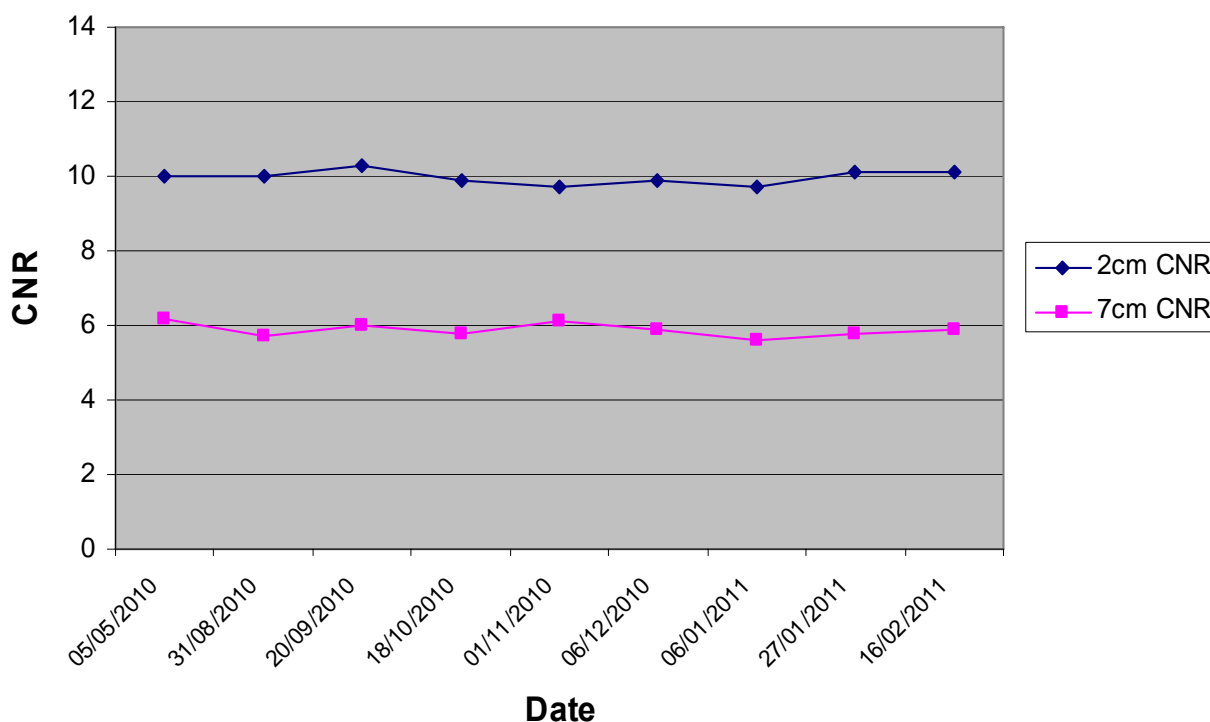


Figure 7 Monthly 2cm and 7cm contrast-to-noise ratio

Figures 4-7 demonstrate the excellent stability of routine quality control results, with the SNR and CNR consistently within the set limits. Inconsistencies were rare and were a result of operator error.

A detector test was carried out weekly (see Figure 8 below) using a 4cm block of Plexiglas (polymethylmethacrylate) supplied with the unit and designed to slot on to the tube head. This test checks that the mean pixel value deviations and SNR calculated in specific regions of interest (ROI) are within acceptable limits. The system's software calculates the results automatically. The overall mean pixel value and SNR values should not differ by more than $\pm 15\%$ from the previous measured values.

Other routine quality control tests carried out included

- detector calibration tests (monthly, alternating small and large focus) using the 4cm Plexiglas block
- automatic exposure control security tests (monthly), using a small lead plate supplied with the unit.

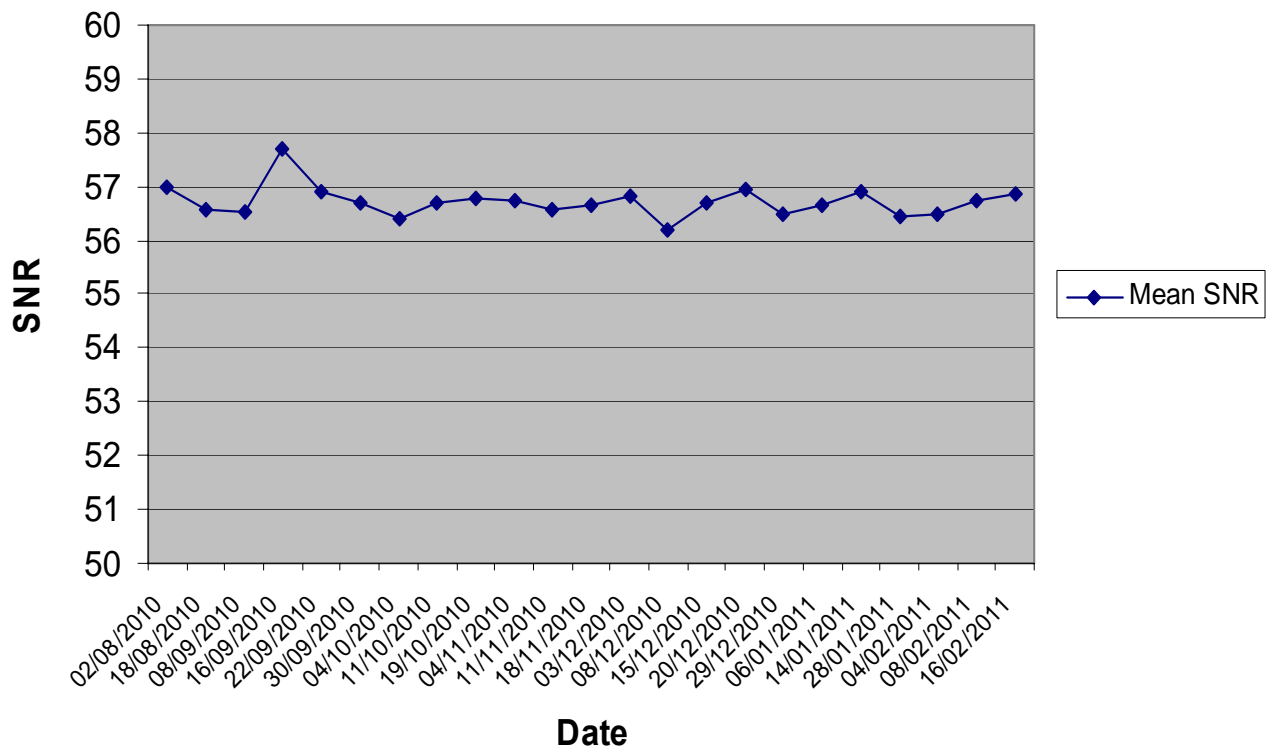


Figure 8 Weekly detector test

6. IMAGE QUALITY ASSESSMENT

The quality of film and digital clinical images was assessed by six radiologists and film-readers, using Form 8 from the NHSBSP's *Guidance Notes for Equipment Evaluation*.¹ The current screening digital images of 20 women were compared with their screening film–screen images from three years earlier, giving 120 opinions (6 readers x 20 examinations). The cases were selected to include all breast types and a variety of mammographic features including calcification, masses and asymmetry.

As Figure 9 indicates, when the overall exposure of the digital films was assessed one reader rated one client's images 'slightly low'. All other readers rated the overall exposure of every image as acceptable or better. One reader commented that there was more variation in the quality of film–screen images (for example, in the exposure and degree of blurring), whereas the digital images were more consistently uniform.

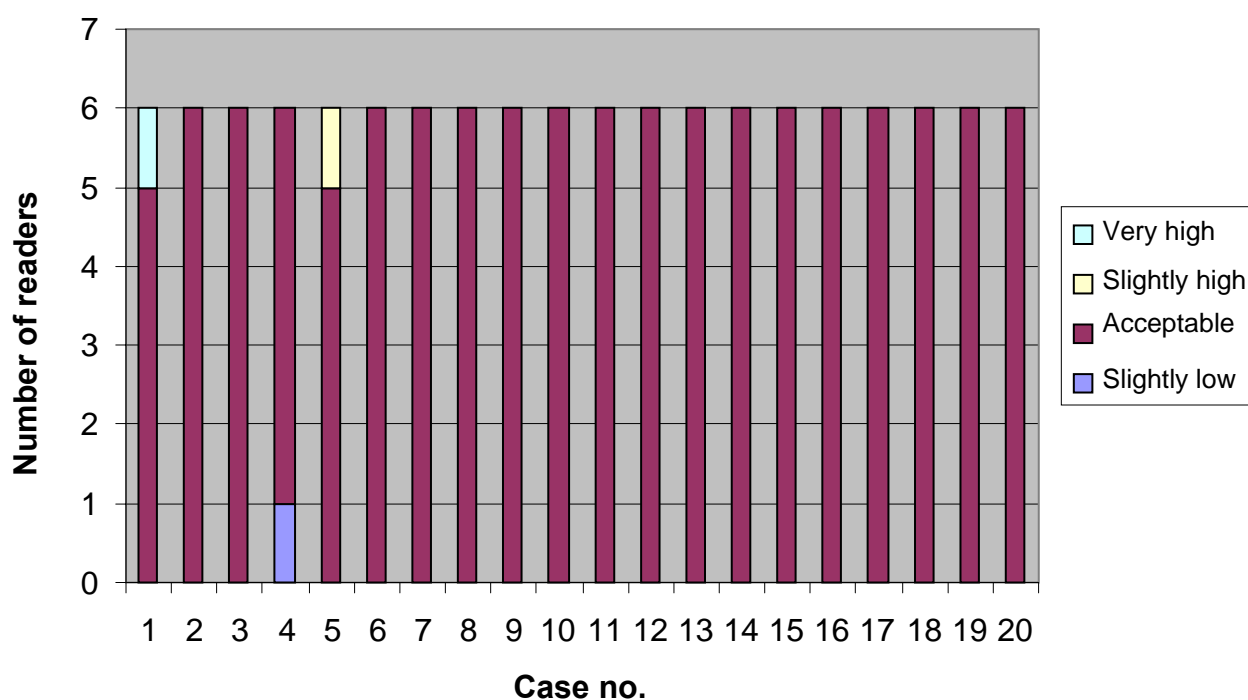


Figure 9 Overall exposure of the digital images

Figure 10 shows that when digital contrast was evaluated only 11 of the 120 subjective assessments rated it low or slightly low, with the remaining 91% judging it acceptable.

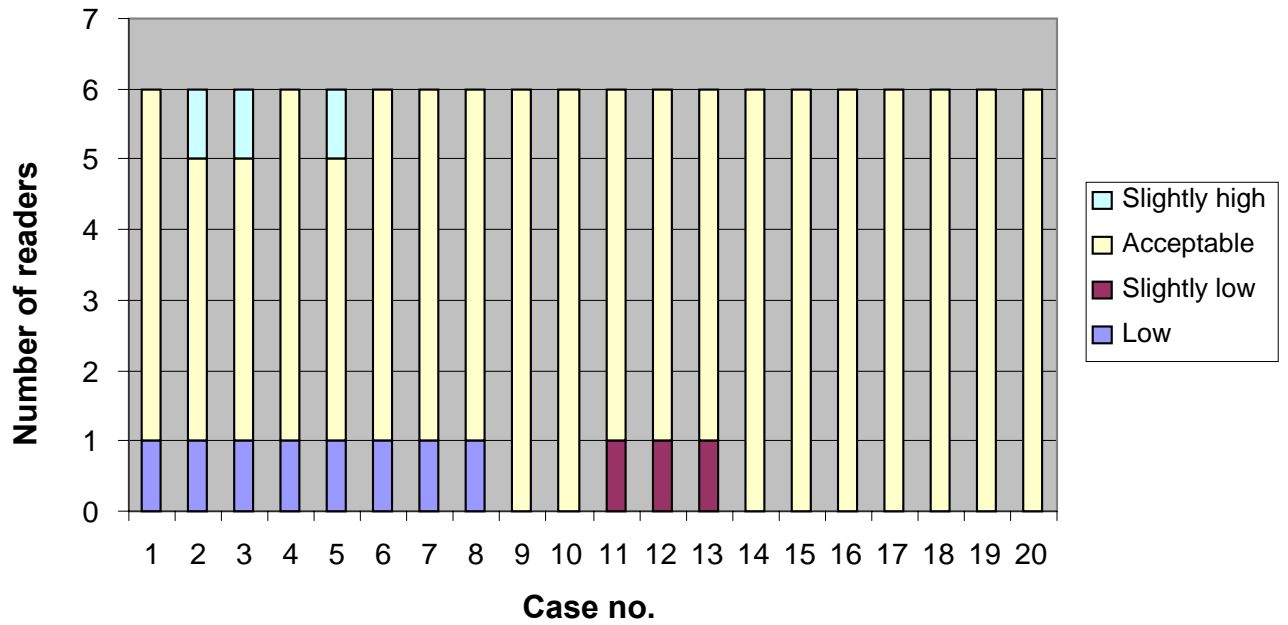


Figure 10 Overall contrast of the digital images

Figure 11 shows that when the digital images were assessed for sharpness 97% of the reader assessments rated the image as satisfactory or sharp. Three cases underlined the subjectivity of film reading, each being judged blurred, satisfactory or sharp by different readers.

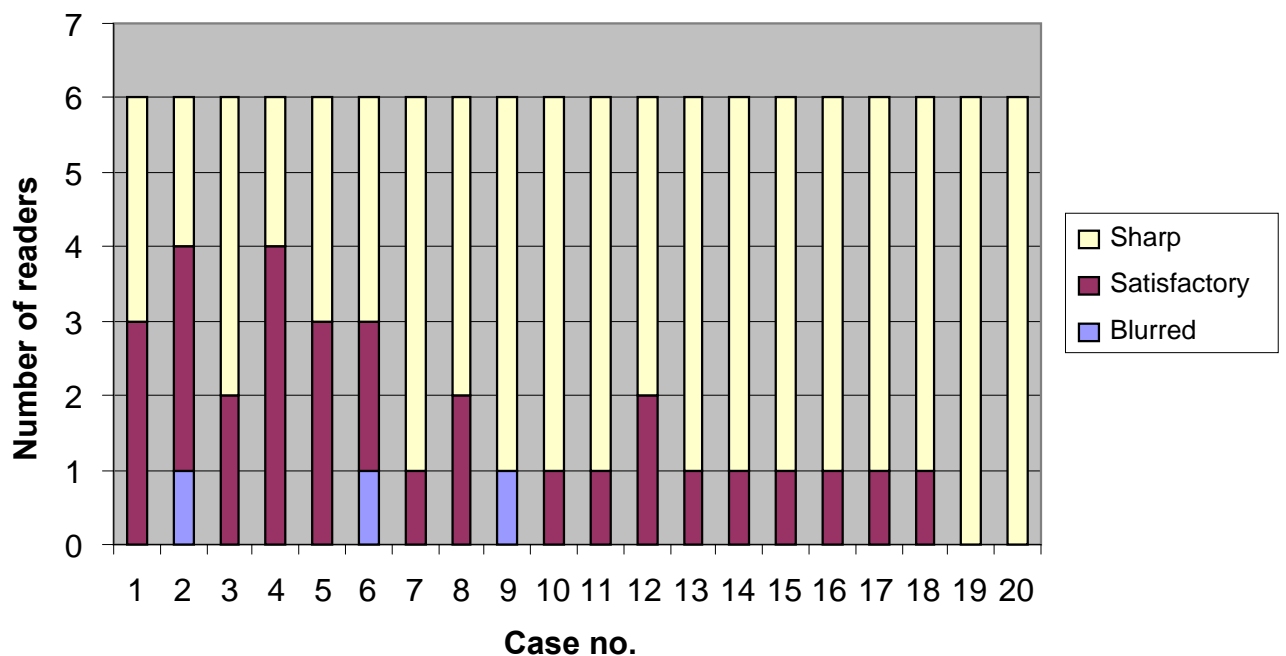


Figure 11 Sharpness of the digital images

When the digital images were assessed for noise, 100% of the images were judged not noisy.

Figure 12 indicates the subjective assessment of the absolute diagnostic value of film–screen images taken three years previously. It reveals significant variation.

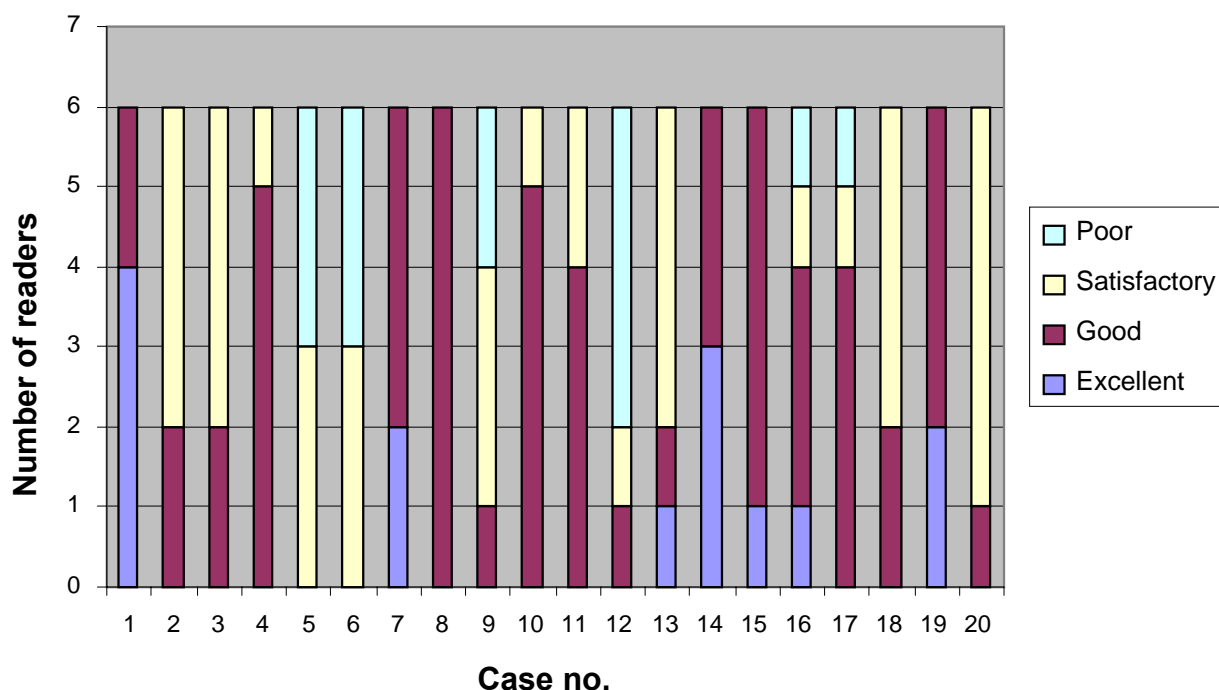


Figure 12 Absolute diagnostic value of the film–screen images

As can be seen in Figure 13 below, when the absolute diagnostic value of the digital images was assessed all were considered to be of acceptable diagnostic value and 97.5% were rated good or excellent. A comparison of Figures 12 and 13 reveals that the absolute diagnostic value of the digital images was judged in every case to be equal to or better than that of the film–screen images.

Figure 14 shows that when the digital images were compared with the film–screen images taken three years previously, the relative diagnostic value of the digital images at normal magnification was considered the same, slightly better or better than the film–screen images of each examination.

Figure 15 shows that opinion was divided on the relative diagnostic value of digital images on zoom magnification and film–screen images. One film–reader felt that digital images created with the zoom feature on the reading work station were less sharp than the film–screen magnification images. The remaining film–readers rated the relative diagnostic value of digital images using zoom magnification as the same, slightly better or better than their film–screen counterparts.

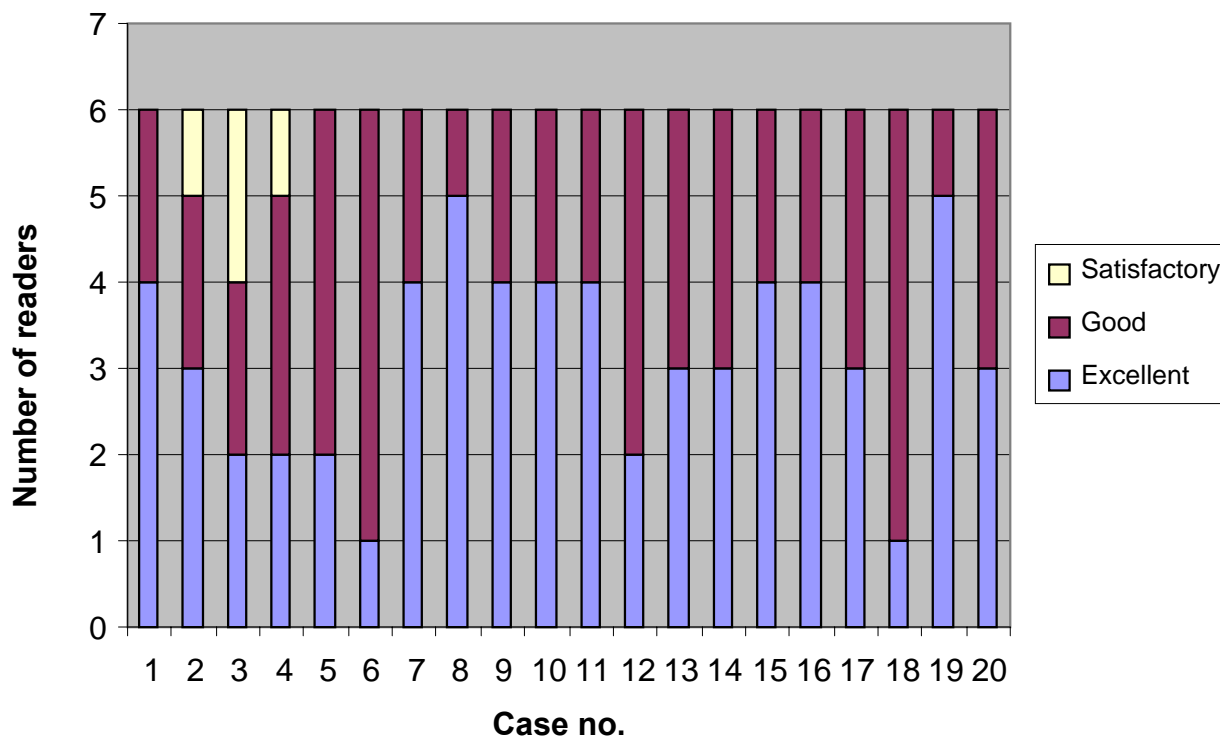


Figure 13 Absolute diagnostic value of the digital images

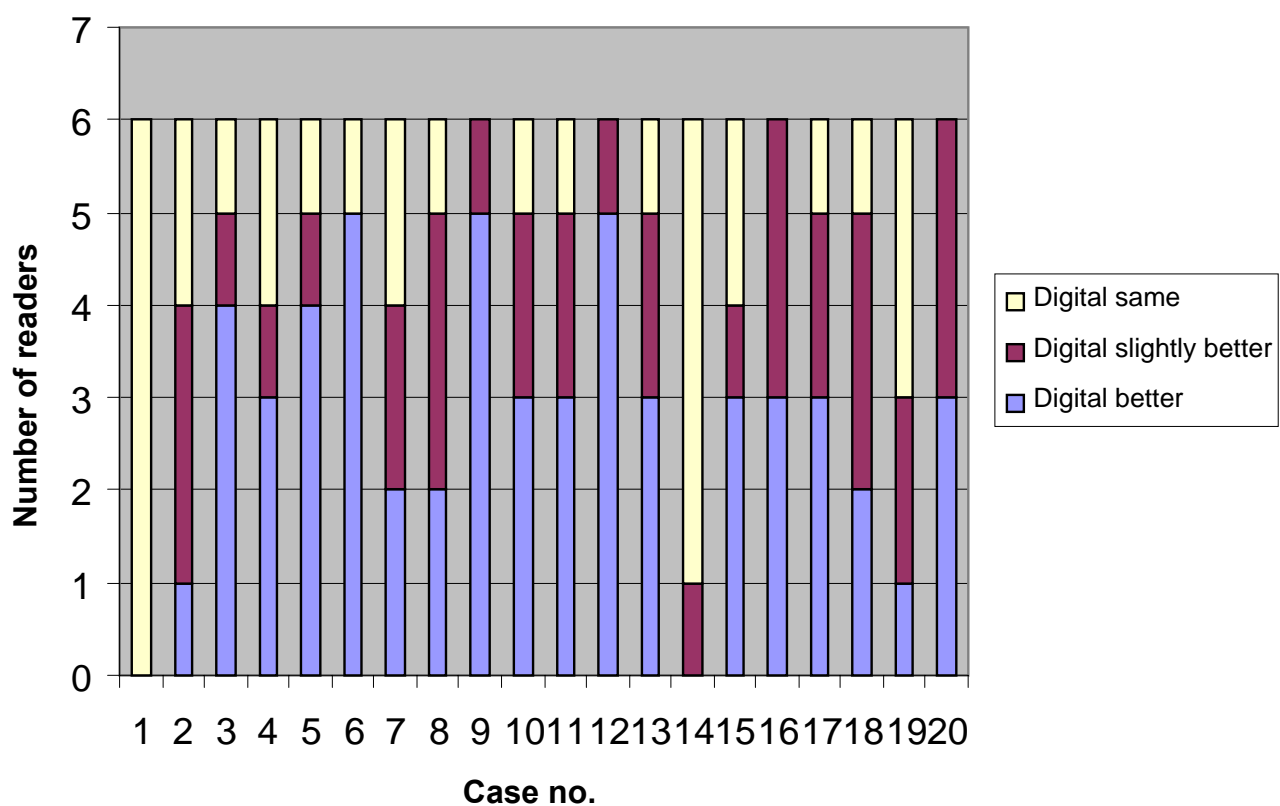


Figure 14 Relative diagnostic value of digital images compared with film-screen images: normal magnification

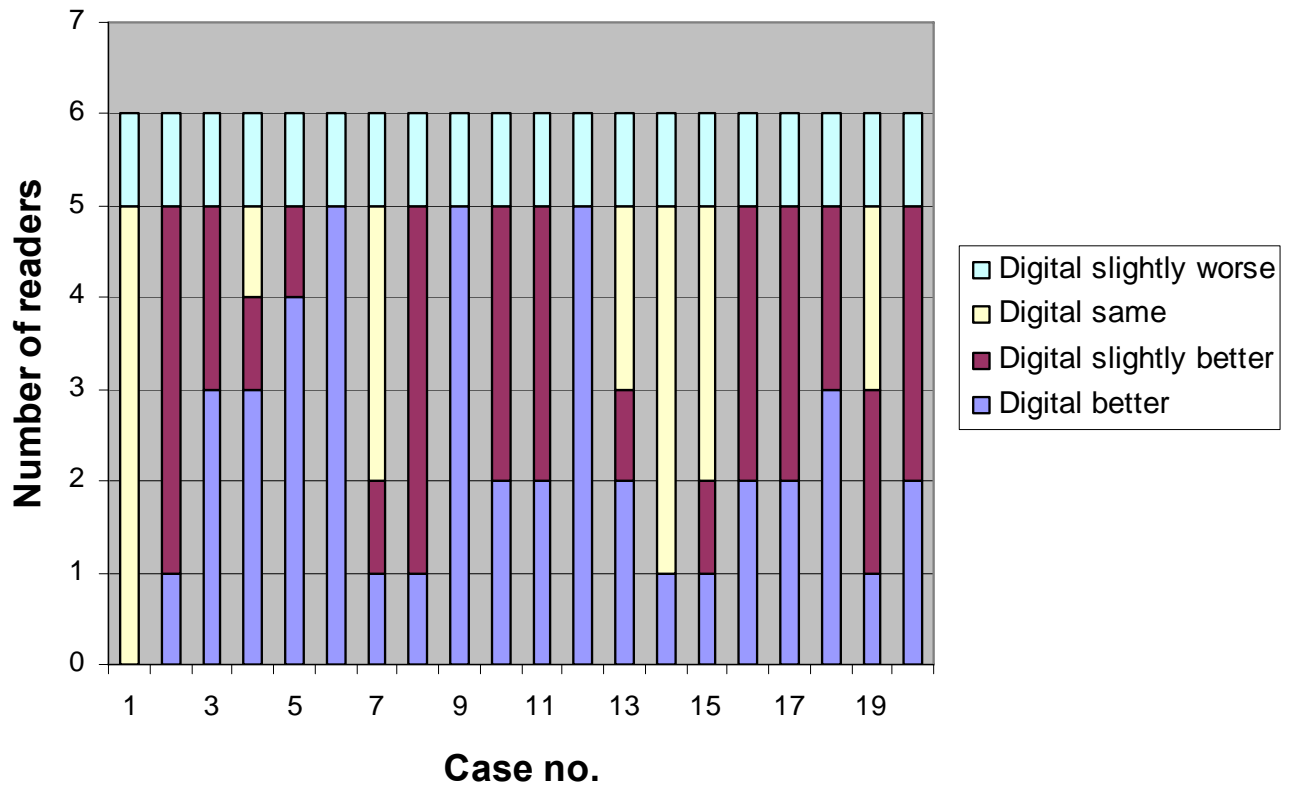


Figure 15 Relative diagnostic value of digital images compared with film–screen images: zoom magnification

7. DATA ON SCREENING CONDUCTED

7.1 Clinical dose audit

The exposure data from 50 screened women were entered into the NCCPM dose survey software.³ The results are summarised in Appendix 1.

The mean glandular dose (MGD) was as follows

- 1.11 mGy for the craniocaudal (CC) view, for a mean thickness of 58 mm
- 1.26 mGy for the mediolateral oblique (MLO) view, for a mean thickness of 62 mm
- 1.13 mGy for the MLO in the 50-60 mm breast, for a mean thickness of 56 mm.

NHSBSP protocol states that the average value of MGD to the 50-60 mm thick breast should not exceed 3.5 mGy per film.⁴ The dose survey results for the MammoDiagnost DR system show it to be well below this level, with an average MGD per examination for a two-view mammogram of 2.48 mGy.

7.2 Clinical organisation

The NHSBSP's *Guidance Notes for Equipment Evaluation* states that a minimum of 500 clients are required for comprehensive screening evaluation,¹ and it was agreed in advance of the evaluation that they would be the first 500 clients. At that time there was no connection to NBSS and, as all patient data had to be entered manually, appointments were extended to 15 minutes.

Of the 500 clients screened, none was recalled for technical reasons. A total of 54 clients had a view repeated and for 45 of them it was an MLO view. In the case of 40 women, this was caused by a short pectoral muscle, and one woman had both MLO views repeated. Four others had MLOs repeated because part of the breast was not imaged. The remaining woman had hers repeated because of blurring. The CC view of nine women was repeated as it was considered short.

Once configuration to NBSS was achieved a review of examination times was undertaken over two days, involving eight mammographers. Each woman attending for screening undressed and dressed again in a cubicle; the stopwatch was started when she entered the room and stopped when she had left.

A summary of the resulting examination times is shown in Table 1. It shows that just under half (46%) of the examinations were performed within the 6 minute interval expected by the NHSBSP. The minimum examination time was 4 mins 3 secs; the maximum time was 14 mins 55 secs, and was a result of technical difficulties; the mean time was 6 mins 44 secs.

The mammographers commented afterwards that some of the design features of the gantry and bucky hampered the process of positioning women for optimum diagnostic imaging. This is discussed in more detail in section 11.

Table 1 Examination times

First screen	Compression plate size changed	Time taken mins/secs	Mammographer's comment/s
No	No	14 55	Technically difficult - limited movement - arthritis. Repeat left MLO
No	No	10 5	No comment
No	No	10 2	No comment
No	No	9 57	No comment
No	No	9 56	Disability - unable to lift left arm
No	No	9 56	No comment
No	No	9 51	No comment
No	No	8 3	No comment
No	No	7 47	Unsteady on feet - repeated both MLOs
No	No	7 2	No comment
Yes	No	7 0	Discussion of clinical signs
No	No	6 58	No comment
Yes	No	6 47	No comment
No	No	6 17	Repeated left MLO - short
No	No	6 10	Difficult to position - very small breasts
No	No	6 9	No comment
No	No	6 6	No comment
Yes	No	6 2	No comment
No	No	6 2	Discussion of clinical signs
No	No	5 50	No comment
No	No	5 28	No comment
No	No	5 12	No comment
Yes	No	5 6	No comment
No	No	5 2	No comment
Yes	Yes	5 1	No comment
No	No	4 54	No comment
No	No	4 42	No comment
No	No	4 41	No comment
No	No	4 21	No comment
No	No	4 20	No comment
No	No	4 17	No comment
No	No	4 12	No comment
No	No	4 7	No comment
Yes	No	4 6	No comment
No	No	4 3	No comment

8. ASSESSMENTS CONDUCTED

As this evaluation was primarily to assess the suitability of the MammoDiagnost DR for screening mammography, there was limited evaluation of assessments.

Four mammographers carried out assessment images on 25 women over three weeks. They noted that the magnification table was surprisingly light and easy to attach or remove, as was the compression paddle. They therefore rated the magnification equipment very highly, as can be seen in section 11.

There were magnification views on

- calcification (8)
- irregular masses (6)
- round masses (4)
- spiculate masses (1)
- asymmetry (5)
- distortion (1).

9. EQUIPMENT RELIABILITY

As the system was on loan from the manufacturers for the duration of the evaluation it was not covered by a formal maintenance agreement. However, Philips Healthcare provided technical and engineering support when needed.

The equipment was judged to be reliable during the evaluation period and no faults were recorded on NHSBSP Equipment Fault Report Forms. Nor was there any downtime arising from equipment faults during the 19-month evaluation period. While there were errors recorded in the X-ray room's communication book, these were not significant enough to warrant a fault report and were corrected by rebooting the system.

The most common fault recorded in the communication book was the freezing of the computer during an examination. This caused a delay of around 10–15 minutes while the system was rebooted and seemed to occur two or three times each week.

There was one recorded gantry error. It was accompanied by a request to reset the gantry, which resolved the problem and enabled the examination to continue.

On two occasions, a 'flat detector error' occurred, accompanied by a request to recover the image. Although the recovery process took 5–10 minutes, it was still necessary to repeat the image afterwards.

The engineer was informed of the gantry and flat detector errors. As both were resolved with no further problems, however, the decision was made to monitor the situation and inform the engineer if they occurred more regularly.

10. MAMMOGRAPHERS' COMMENTS AND OBSERVATIONS

Mammographers' opinions were collected using Form No. 6 from the NHSBSP's *Guidance Notes for Equipment Evaluation*.¹ A total of 19 mammographers returned forms, although not all questions were answered. A summary of their responses appears in Appendix 2.

10.1 Operator's manual

A large manual was provided. Although its instructions were easy to read and follow, the required information was not always easy to locate and 9 respondents did not use it. A departmental *Quick User Guide* was created which was rated excellent (2), good (2) and satisfactory (4)

There is currently no online user guide. However, Philips Healthcare report that a printed quick user guide is in development.

10.2 Training

The applications specialist spent two days training the two mammographers who were evaluating the system. She later returned for two days to train other members of staff in small groups for half a day each. The six mammographers who were not present in the department at that time and did not receive training from the applications specialist were trained by the mammographers evaluating the system.

Those who did receive specialist training rated it good (6), satisfactory (5) and poor (2). Some respondents felt they would have benefited from more time for training. One of those who considered the training poor felt that it was delivered too early in the evaluation process. This was because the start of screening was delayed by local IT connectivity problems. This prevented the system from being linked to a laser printer and meant that films could not be printed to archive for future reference.

10.3 Using the equipment

10.3.1 Ease of use

Ease of use was rated excellent (5), good (10) and satisfactory (4). While most mammographers found the MammoDiagnost DR easy to use, they disliked some aspects of it (see below). This was chiefly because it lacked certain features found in other equipment in the unit.

10.3.2 Minimising fatigue

This was rated excellent (4), good (9) and satisfactory (4). The majority of the mammographers commented on how much they liked the one touch 'move to next position' button. Two respondents reported that fatigue levels were similar to those seen with the film–screen mammography systems used elsewhere in the unit. Another noted that the system's overall effect on fatigue would be known only when it was being used by two mammographers for continuous screening in a remote unit.

10.4 Acceptability of exposure times

The majority of the mammographers found exposure times acceptable: they were rated excellent (2), good (11), satisfactory (4) and poor (1). One felt that the exposure times were too long, while two others agreed that they were longer than with other digital systems they knew.

10.5 Setting for radiographic views

10.5.1 Rotation of support arm

There was a range of opinion on the rotation of the support arm, which was rated excellent (4), good (5), satisfactory (7) and poor (2).

The one touch 'move to next position' button was popular with all respondents. However, most would have preferred it to maintain the same angle automatically for the second MLO view as for the first – a facility available on most of the other mammography equipment in the unit. Most respondents also felt that the rotation of the support arm, when adjusted for different angles, was too fast to allow fine adjustments. As the operator's manual makes clear, however, there is a safety feature built into the system that interrupts the rotation of the support arm if a person or an object is in its path.

10.5.2 Visibility of set angle

Opinion was also divided on the visibility of the set angle, which was rated excellent (4), good (6), satisfactory (6) and poor (2).

The display for the set angle is at the base of the gantry. Some mammographers would have liked to see a second display, higher up the gantry and above the breast support table.

10.6 Setting the position of the breast support table

This was rated excellent (1), good (8) and satisfactory (10). Although all mammographers considered this aspect acceptable, most found that the foot pedal adjusted the height of the table so rapidly that it was difficult to make fine changes. Some reportedly preferred to use the button on the tube head, which adjusted the table height more slowly and was easier to control.

10.7 Range of movements

Most mammographers found the range of movements acceptable, rating them excellent (1), good (11), satisfactory (6) and poor (1). However, they underlined the difficulty of making fine adjustments to the rotation of the support arm and the height of the breast support table.

10.8 Effectiveness of brakes and locks

The brakes and locks worked well with no reports of backlash or movement. They were rated excellent (1), good (10) and satisfactory (6).

10.9 Compression

10.9.1 Effectiveness of the compression system

This was rated excellent (1), good (8), satisfactory (9) and poor (1). Some respondents felt that the application of the compression was too fast, despite the fact that it had been slowed down a little at installation at the request of the two mammographers who were evaluating the system. Many reportedly found the rotary wheel for fine adjustments to compression ineffective and would have preferred a handle to turn.

Compression is applied with a fixed compression plate. This is available in two sizes (18 cm x 24 cm and 24 cm x 30 cm) with either a 4cm or 7cm front edge. The plate does not tilt and could not be offset for the MLO views. The majority of respondents felt that a tilting compression plate would have been beneficial. Many reported that the front of the breasts, especially in the MLO views, were often inadequately compressed and as a result extra views were required.

As noted earlier, the mammographers' opinions were in some cases influenced by features available on equipment elsewhere in the unit. On one of the foot pedals, for example, the position of the controls for compression and for adjusting the height of the breast support table is reversed when compared with other equipment in the unit. This caused considerable confusion and meant that, instead of applying compression, a mammographer might suddenly lower the height of the breast support table. To make it easier

to distinguish from the height adjustment pedal, one mammographer highlighted the compression pedal with a coloured pen.

10.9.2 Visibility of compression force

This was rated excellent (3), good (9), satisfactory (5) and poor (2). The display for compression force is at the base of the gantry. The mammographers would have preferred a second display higher up the gantry and above the breast support table (see section 10.5.2).

10.10 Comfort of women

This was rated excellent (2), good (3), satisfactory (13) and poor (1).

Although almost all respondents described levels of comfort as acceptable, most reported that about a third of women found aspects of this system uncomfortable and sometimes painful. Two reasons were given for this. First, the non-tilting compression plate meant that mammographers could achieve optimum compression to the front of the breast only by applying more compression than is needed with other equipment in the unit. Second, 74% of mammographers reported that women also found the positioning for MLO views very uncomfortable. The breast support table is large enough to accommodate image sizes of both 18 cm x 24 cm and 24cm x 30cm, so to achieve effective positioning for a high standard MLO mammogram women had to stretch further across the breast support table and it was often a little too high for comfort.

All respondents felt that the women's discomfort would be greatly reduced by a tilting compression plate, and by a feature enabling the compression plate and the imaging field to be offset towards the women's shoulder.

10.11 Range of controls and indicators

10.11.1 Presence of expected controls

All the expected controls were present.

10.11.2 Ease of finding and using controls

This was rated good (13), satisfactory (4) and poor (1). (For details see separate headings in section 10.)

10.12 Choice of collimators for spot compression

One collimator was provided for spot compression. This was rated good (5) and satisfactory (2); 12 mammographers responded 'not used' as the unit rarely uses spot compression without magnification.

10.13 Time for images to appear at workstation

This was rated excellent (2), good (13), satisfactory (3). The images appeared at the workstation in six seconds and six respondents noted that this was quicker than other digital systems they had worked with. One mammographer commented that there was a time lag if the previous image was being sent to the printer.

Ten of the 19 respondents commended the system's ability to cut examination times by proceeding to the next view without having to wait for an image to be acquired and accepted.

10.14 Image handling and processing facilities at workstation

This was rated excellent (3), good (13) and satisfactory (3). The majority of the mammographers commended the workstation's efficiency and ease of use. The touch screen facility was popular with everyone.

10.15 Acquisition workstation image quality

The image quality at the acquisition workstation was rated excellent (4), good (12), satisfactory (2) and poor (1). However, two mammographers who are also film-readers noted that it was not always easy to see blurred images and as a result several women had to be recalled. One reason for this may be that the acquisition workstation has a 1.3 megapixel display. While this is also the case with certain other systems, the NHSBSP recommends a minimum of 3 megapixels.

10.16 Transferring images to reporting workstation and printer

Once the examination was complete, images were transferred automatically to the reporting workstation and the printer. The process was rated excellent (5), good (8) and satisfactory (1)

10.17 Confidence level of good results

This was rated excellent (2), good (11) and satisfactory (5). The lowest ratings were from mammographers who had experienced difficulty positioning women for MLO views (see section 11.10) and had had to adjust their technique to achieve MLOs of a good diagnostic standard. However, some adaptation of

technique is arguably inevitable in the change from analogue to digital systems.

10.18 Potential hazards to women and mammographers

Mammographers reported no potential hazards, although three found the emergency compression release button difficult to access and press. Two others found the tube head too bulky and easy to bang one's head on.

10.19 Equipment cleaning

The mammographers who completed this section encountered no problems cleaning the equipment and rated this aspect excellent (3), good (11) and satisfactory (1). Seven mammographers had read the cleaning instructions in the operator's manual, five had not looked and seven did not complete this section.

10.20 Patient and exposure data and post exposure print out facility

Only 10 of the 19 respondents answered this question; they rated it excellent (3), good (5) and satisfactory (2). It was noted that when reprinting films at a later date from the MammoDiagnost VU reading workstation the patient and examination data on film is too small to be read easily. However, the size can be increased.

10.21 Did the digital x-ray system performance limit patient throughput?

All mammographers who answered this section replied 'no' (11).

10.22 Additional comments

One mammographer commented that she would like to set the order in which the views are taken; that is not currently possible on this system.

Two mammographers would like to see paired images of CCs and MLOs side by side; it is not currently possible on this system.

Two mammographers commented on how easy it is to move images if they have the wrong marker.

Three mammographers found the computer system and its language excellent, easy to use and to negotiate.

One mammographer commented that the extra view addition was the simplest she had encountered.

Another commended the simplicity of the log on/off.

(These additional comments on the returned evaluation forms were supported by verbal feed back, but this was not recorded.)

10.23 Magnification

Only four mammographers completed this part of the questionnaire. (The remainder had had no clinical experience with the magnification, although all had been given the opportunity to acquire it.) Respondents who had used the magnification rated it highly.

The ease with which the magnification equipment was attached and removed was rated excellent (3) and good (1)

The ease of use of the magnification breast table was also rated excellent (4) and all were surprised by its lightness.

Only one compression paddle is provided and the collimation is matched to it automatically. One mammographer would have liked a second paddle of a different size while another would have liked to be able to alter the collimation manually.

10.24 Stereo

Stereotaxis did not form part of the evaluation.

11. RADIOLOGISTS'/FILM-READERS' COMMENTS AND OBSERVATIONS

The opinions of six radiologists and film-readers were sought using Form No. 9 from the NHSBSP's *Guidance Notes for Equipment Evaluation*.¹ Although six forms were completed, not all questions were answered. A summary of responses appears below.

	Excellent	Good	Satisfactory	Poor	Comments
How good was the operator's manual? (State N/A if not applicable)		2			4 – N/A
How good was the training by the supplier?		2	1		3 – not trained by supplier
How easy is it to adjust the height and angle of the reporting monitors to suit the user?		2	1		3 – N/A, no adjustment needed
How easy is it to adjust the height and angle of the database monitor to suit the user?		2	1		3 – N/A, no adjustment needed
How do you rate the ease of use of the workstation controls a) mouse b) keyboard c) keypad?	3 3 3	3 3 3			All simple to use Unable to use keypad for data entry on this prototype [§]
How do you rate the image handling tools (zoom etc)?		4	2		
Rate visibility and usability of on-screen icons	1	3	1		1 – Not needed
How do you rate the post processing image manipulation (window and level)?	1	4	1		Not needed but easy to do. Images 'easy' to look at.
How do you rate the reading/ reporting flow pattern?	2	2	2		Simple workflow – no changes needed.

[§] The MammoDiagnost VU reading workstation was connected to NBSS. The workstation served as a 'mini PACS archive'. This was a prototype solution for desktop integration in beta-testing for the purpose of this evaluation.

	Excellent	Good	Satisfactory	Poor	Comments
					Would help workflow if intelligent roaming were part of normal 'scroll through' function, not a separate button
If there was a choice of hanging protocols, how easy was it to set these?		1	1		4 – N/A
Within a hanging protocol, how easy was it to display a different choice of imaging: eg images performed beyond the standard four?		4	2		Required mouse action to highlight image to be displayed. Would rather have it as part of workflow. Easy – intuitive to use
How do you rate the time taken between an image being selected and its appearing on the screen					
a) new patient selected	4	2			
b) in-examination change?	4	1	1		
Did the database or PACS software allow for recording findings under NHSBSP reading protocols?	Yes – 6				
How easy was it to record findings?					N/A
How much of a problem was light from the database screen raising ambient lighting around the reporting monitors?	A slight problem (1) Not a problem (4) Not a problem – dark background and small NBSS window (1)				
Did you identify any hazards associated with the workstation or its use?	No – 6				
Describe any additional or unusual features or quirks of the system	N/A				
What is your overall level of satisfaction with the reporting workstation	1	5			

12. INFORMATION SYSTEMS

At the time of the evaluation there was no connection to the Trust's PACS in the unit. Consequently, screening results were entered on the NBSS system manually.**

** A mouse was used to populate the relevant fields.

13. CONFIDENTIALITY AND SECURITY ISSUES

Both the acquisition workstation and the reporting workstation are password protected.

As there was no connection to the Trust's PACS, images from all examinations were laser printed. The MammoDiagnost Vu reporting workstation was connected to NBSS and served as a 'mini PACS' on which all images were available for reading.

All staff who come into contact with patient identifiable information sign the Unit's National Information Governance Board compliance form.^{††}

^{††} On the NIGB's role in information governance and patient data disclosure, see <http://www.nigb.nhs.uk/>.

14. CONCLUSIONS AND RECOMMENDATIONS

The evaluation team consider that, with the adaptations indicated below and full integration with Trust IT infrastructure, the Philips MammoDiagnost DR Full Field Digital Mammography System and the MammoDiagnost VU workstation would be suitable for screening use in the NHSBSP.

The mammographers found the MammoDiagnost DR easy to use, particularly the acquisition workstation. The film-readers found the reporting workstation similarly easy to use, and intuitive in its design. Over the course of the evaluation the system was shown to meet the key requirements for clinical image quality and radiation dose, and system stability.

Two factors limited the system's ability to meet the NHSBSP's key requirements for workflow and throughput during the course of the evaluation. The first was a temporary connectivity issue unrelated to the system's design: the manufacturers were initially not asked to connect the system to the Trust PACS and the manual procedures adopted to compensate for this had a significant impact on examination times.

The second was a design issue, however, relating to the gantry and breast support table. The evaluation team recommends the following alterations and adaptations to ensure that mammograms can be performed within the six minutes expected by the NHSBSP

- reduce the speed at which the support arm moves, to allow fine adjustments in angulation
- reduce the speed at which the breast support table is raised and lowered, to allow fine height adjustments.
- supply a tilting compression plate that ensures adequate compression to the front of the breast, thus eliminating the need for extra views.
- supply a compression plate that can also be offset towards the woman's shoulder, to ensure easier positioning and greater comfort.

Philips Healthcare advise that calibration of the speed and fine adjustment of the support arm and breast support table is being addressed at manufacturing level. A tilting compression plate is now available, and one that can also be offset is in development. As requested by the mammographers, the possibility of a second display, higher up the gantry, for the set angle of the support arm and compression force is also being investigated.

It is our view that, once these adaptations are introduced, the system will be well placed to meet the NHSBSP's key requirements for workflow and throughput.

The acquisition workstation has a 1.3 megapixel display. While this is also true of certain other systems, the NHSBSP recommends a minimum of 3 megapixels to ensure that the mammographer can see blurring and, if necessary, repeat the image.

The unit evaluated a trial version of desktop integration with NBSS and, unsurprisingly, issues arose that would normally have been resolved in a finished product. In particular, the NBSS screen had to be used to enter results because the means of using the keypad for this had not been finalised.

We are unable to comment on the stereotactic device provided, as it did not form part of the evaluation.

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*, 3rd edition. NHS Cancer Screening Programmes, 2009 (NHSBSP Equipment Report 0604).
3. National Coordinating Centre for the Physics of Mammography. *Patient Dose Software v2.1*. Available at <http://www.nccpm.org/tools/dose.php>. Accessed 25.07.2011.
4. *Quality Assurance Guidelines for Mammography, Including Radiographic Quality Control*. NHS Cancer Screening Programmes, 2006 (NHSBSP Publication No 63).

APPENDIX 1: CLINICAL BREAST DOSE SURVEY

Philips MammoDiagnost DR

NHSBSP Breast Dose Survey

Survey No: <input type="text" value="102"/> Centre: <input type="text" value="South West London"/> Date of first exam: <input type="text" value="09/11/2009"/> Date of last exam: <input type="text" value="09/12/2009"/> X-ray make: <input type="text" value="Philips"/> Model: <input type="text" value="Mammodiagnost DR"/> Local id: <input type="text" value="Room 5"/> Installation: <input type="text" value="fixed"/> kV mode: <input type="text" value="auto"/> standard kV: <input type="text"/> Routine/age trial: <input type="text"/> 24x30 cassettes available: <input type="checkbox"/> Block mAs: <input type="text"/> Block density: <input type="text"/> physics service: <input type="text" value="St. George's"/> Physicist: <input type="text"/>	Processor make: <input type="text"/> Processor ID: <input type="text"/> Developer: <input type="text"/> Fixer: <input type="text"/> Dev Temp (deg C): <input type="text"/> Proc time (s): <input type="text" value="0"/> Cassette make: <input type="text"/> Film make: <input type="text"/> Screen make: <input type="text"/>
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MGD to standard breast	
auto/manual kV: <input type="text" value="auto"/>	PMMA thickness: <input type="text" value="45mm"/>
auto/AEC setting: <input type="text" value="Standard"/>	MGD mAs: <input type="text" value="104.0"/>
kV set: <input type="text" value="28"/>	HVL: <input type="text" value="0.567"/>
target: <input type="text" value="W"/>	MGD: <input type="text" value="1.18"/>
filter: <input type="text" value="Rh"/>	film density: <input type="text"/>

MGD (mGy) vs breast thickness (mm)

Dose histogram

Count of films		
view	main films	Extra films
CC	94	3
OB	97	8

Average doses for main films					
view	No of films	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	94	0.63	2.09	1.11	58
OB	97	0.29	2.48	1.26	62

Average doses per screening examination				
	No of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
One view	2	0.44	0.70	0.57
Two view	48	1.31	3.90	2.48

Average dose for 50-60mm thick breasts				
View	No of films	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
OB	25	1.13	0.08	56

Summary of X-ray factors selected			
Anode	Filter	kV	films
W	Rh	26	12
W	Rh	27	29
W	Rh	28	108
W	Rh	29	4
W	Rh	31	51

APPENDIX 2: DIGITAL EQUIPMENT EVALUATION (FORM 6) – MAMMOGRAPHERS' COMMENTS AND OBSERVATIONS

Question	Excellent	Good	Satisfactory	Poor	Other (NA = not answered)
1. Operator's manual	2	2	4		'Not used' (2) N/A (2)
2. Training by supplier		6	5	2	'No training by supplier' (6)
3.1 Unit's ease of use	5	10	4		
3.2 Minimising fatigue	4	9	4		N/A (2)
4. Acceptability of exposure times	2	11	4	1	N/A (1)
5.1 Rotation of support arm	4	5	7	2	N/A (1)
5.2 Visibility of set angle	4	6	6	2	N/A (1)
6. Positioning height of breast support table	1	8	10		
7. Adequacy of range of movements	1	11	6	1	
8. Effectiveness of brakes and locks	1	10	6		N/A (2)
9.1 Effectiveness of compression system	1	8	9	1	
9.2 Visibility of compression force	2	9	5	3	
10. Comfort of women	2	3	13	1	
11.1 Presence of expected controls	All expected controls present				
11.2 Ease of finding and using controls		13	4	1	N/A (1)
12. Choice of collimators for spot compression		5	2		'Not used' (12)
13. Time for image to appear at acquisition workstation	2	13	3		N/A (1)
14. Image handling and processing facilities at acquisition workstation	3	13	3		
15. Acquisition workstation image quality	4	12	2	1	

16.	Transferring images to reporting workstation and printer	5	8	1		N/A (5)
17.	Confidence level of good results	2	11	5		N/A (1)
18.	Potential hazards to women and radiographers	None (12) Yes (5)				N/A (2)
19.1	Ease of equipment cleaning	3	11	1		N/A (4)
19.2	Were there instructions in the manual?	Yes (7) Don't know (5)				N/A (7)
20.	Patient and exposure data and post exposure print facility	3	5	2		N/A (9)
23.1	Ease with which magnification table may be attached and removed	3	1			'Not used' (15)
23.2	Ease of use of magnification table	4				'Not used' (15)

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