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Focused practical evaluation of Philips MicroDose SI digital mammography system

NHS Breast Screening Programme Equipment Report 1402

February 2016

Public Health England leads the NHS Screening Programmes

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Contents

Executive summary

A focused practical evaluation of the Philips MicroDose SI was undertaken at the Breast Care Unit in Addenbrooke's Hospital, Cambridge. As the SI is similar to the older MicroDose L30 model, which is already in use in many screening centres, a full practical evaluation was not deemed necessary.

The equipment performed as well as the L30. It was easy to use, and was reliable during the evaluation period, although the duration was not long enough to assess X-ray tube life. The high collimator used for larger women was easy to change by the more experienced operators.

Doses are comparable with those of L30, although with larger breasts there may be a design issue where a maximum level is reached when the dose then decreases with thickness.

Image quality was found in most cases to be satisfactory or good (with some excellent), and similar to or better than that of another system which had image quality within acceptable limits for screening.

1. Introduction

1.1 Evaluation centre and timeline

The Philips MicroDose SI was installed in April 2013 in an X-ray room in the Cambridge Breast Unit, primarily for research into the dual-energy detector. As the SI has a full CE marking and the operators were already experienced in screening mammography, it was also used for routine clinical symptomatic use.

The evaluation took place between April and November 2013. A "focused" evaluation provides information relevant to its potential use in the NHS Breast Screening Programme (NHSBSP). A full practical evaluation was thought to be unnecessary because the MicroDose SI is essentially similar to the MicroDose L30 already in use in many screening centres. The approach set out in the evaluation guidelines[1] was broadly followed for this focused evaluation.

1.2 Equipment evaluated

Previously known as the L50, the Philips MicroDose SI is an upgraded model similar to the MicroDose L30. The mammography stand and the acquisition workstation of the SI are virtually identical in design and operation to the L30 model, but with a L50 detector instead. The layout of the acquisition workstation and monitor display is the same as for the L30, comprising a computer, keyboard and keypad, with an emergency stop button and exposure control as standard. An exposure foot switch is available as an option.

The mammography stand comprises the manually or automatically operated C-arm with upper and lower hand button controls and foot controls, face shield, collimator and detector. The compression paddles included are the high edge compression paddle, a small compression paddle and a standard low edge paddle. The high edge paddle is recommended for use as the default paddle, to minimise the risk of trapping the nipple of the other breast between the paddle edge and the collimator. Additional spot compression paddles, matrix and window compression paddles are also available.

1.3 Comparison with MicroDose L30

One marked difference of the SI from the L30 is the availability of a "high" collimator, which has been provided for imaging breasts of up to 120mm compressed thickness. The "low" collimator can only be used for imaging breasts up to 100mm compressed thickness. Changing the collimator is easy and takes less than one minute, but it requires careful handling. There are clear illustrated instructions for this operation from the manufacturer. When the SI is used for thicker breasts, a warning sign, which can be overridden, appears on the acquisition monitor informing the operator that the high collimator should be used. Use of the high collimator in this evaluation was only limited

to testing, as there were no women for which it was needed during the evaluation period.

The manufacturer states that the scan time, for the same breast thickness, is the same for both the high collimator and the low collimator. However, the scan time was not measured during this evaluation. The manufacturer also states that the image quality is the same for both collimators (as measured with a CDMAM, 0.1mm detail), but the NHSBSP technical evaluation[2] found that image quality was better with the high collimator, for which the automatic exposure control (AEC) selected a 10% higher dose. The slits are slightly wider for the high collimator, resulting in a somewhat worsened spatial resolution. This is compensated for by the 10% dose increase.

The L50 detector in the SI is physically the same as the L30 detector, but the SI has a different electronics system which enables spectral (dual-energy) imaging. However, this type of imaging was not included in the evaluation.

The SI acquisition workstation was unchanged from the L30 workstation, apart from a new icon for the selection of the high collimator used for larger breasts. The workstation was running on software version 9.0.

Cooling requirements for the SI are exactly the same as for the L30. The manufacturer recommends maintaining a stable environment of about 23ºC both in the room and the cabinet.

1.4 Objectives

The primary focus of the evaluation was to determine the performance and usability of the Philips MicroDose SI and its suitability for use in mammographic screening.

The detailed objectives were as follows:

- to report on the readers' views of image quality
- to assess the practical aspects of use and report on the operators' views and experience
- to comment on similarities to, and differences from, the MicroDose L30
- to assess the performance and reliability of the equipment
- to report on radiation dose to the breast for the women imaged during the evaluation

2. Acceptance testing, commissioning and performance testing

The installation of the SI in April 2013 included integration with the local PACS. The acceptance testing and commissioning[3] were carried out by the local physics service, the East Anglian Regional Radiation Protection Service, based at Addenbrooke's Hospital. The tests included measurement of dose and image quality.

The physics report for the acceptance tests is included at Appendix 1. Page 8 of the physics report shows a decrease in dose at the greater thicknesses, similar to that in the clinical dose audit (Section 4.1).

Near the end of the seven-month evaluation period, further performance testing was carried out. The results were satisfactory, but are not included in this focused evaluation.

3. Routine quality control

Routine quality control (QC) tests, as described in the NHSBSP guidelines[4] were carried out, using blocks of polymethyl methacrylate (PMMA). The results for mAs and contrast-to-noise ratio (CNR), as measured daily for 4.5cm PMMA blocks, are shown in Figures 1 and 2 as examples for this focused evaluation. All the measurements are well within the remedial limits.

All the recommended daily, weekly and monthly tests were carried out, with satisfactory results. Occasionally, CNR decreased to below the tolerance limits, but when the tests were repeated, either on the same or the next day, the results were back in line with expected performance.

AEC testing included the use of 8cm PMMA, in addition to the 2, 4.5 and 7cm thicknesses normally used. This was recommended by the local physicist, to ensure that the high collimator was tested.

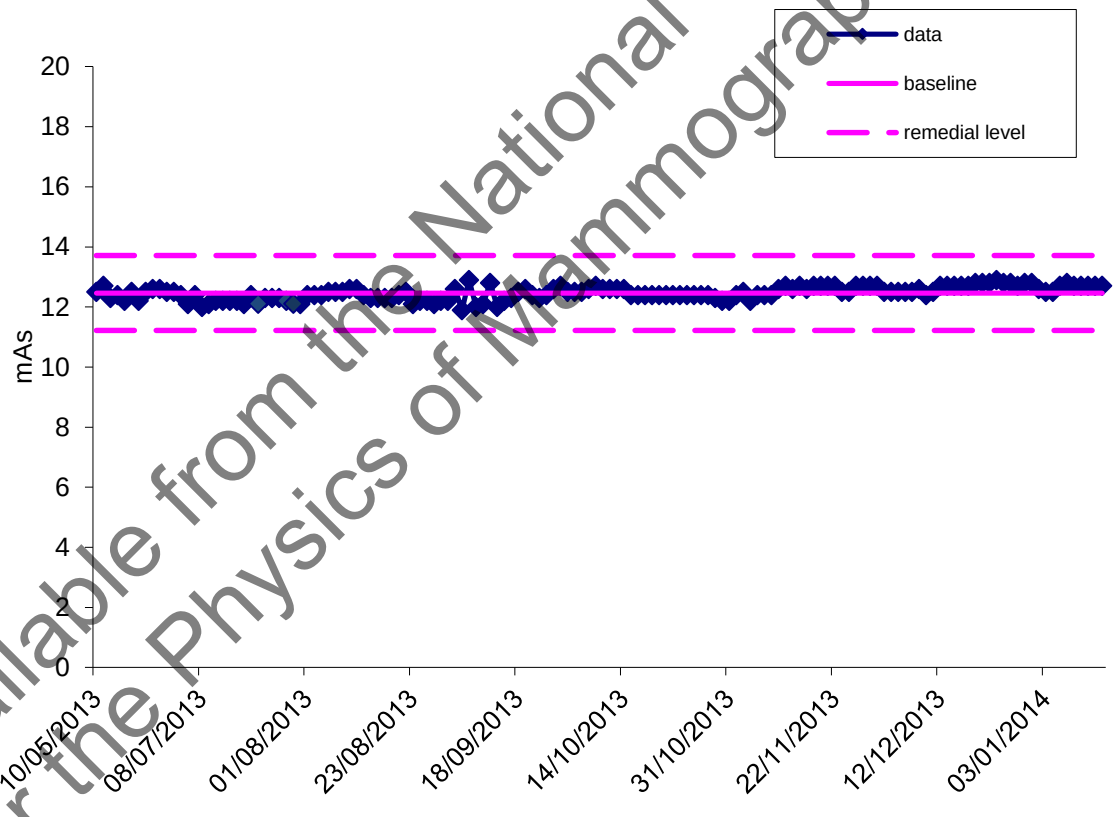

Figure 1. mAs recorded daily for 4.5cm of PMMA

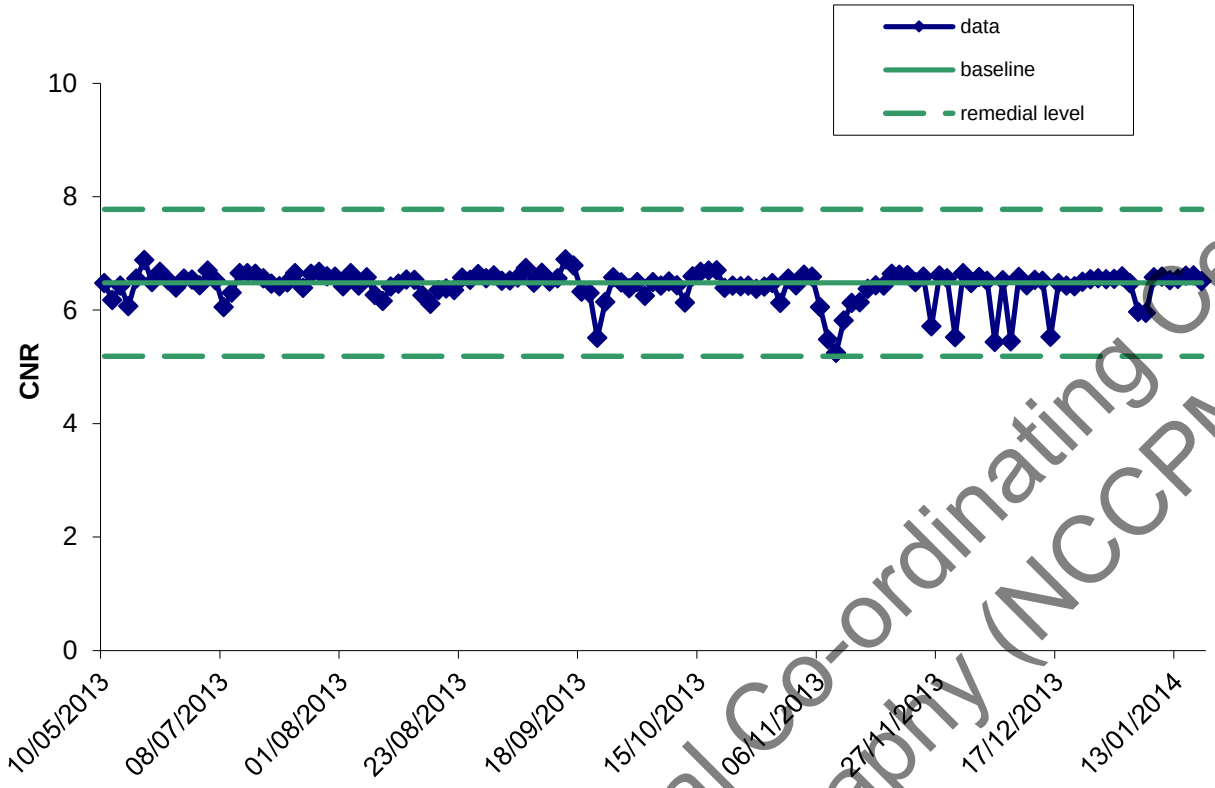

Figure 2. Daily CNR measurements for 4.5cm of PMMA

4. Data on imaging carried out

4.1 Clinical dose audit

Exposure details for images taken during the first 100 standard examinations using AEC were acquired for a clinical dose audit. These were entered, along with local equipment performance data, into the appropriate dose calculator version 2.3 from the National Co-ordinating Centre for the Physics of Mammography (NCCPM). This calculator uses data published by Dance et al.[5] For doses to thicker breasts, every examination with a compressed breast thickness of 80mm or more acquired between April and November 2013 was added to the data set. The final data set therefore included data from 143 women's examinations.

Figure 3 shows the results of the dose survey and includes the doses measured by the local physicist to equivalent thicknesses of PMMA. The cause of the higher and lower dose groupings of points, for large thicknesses, is unclear. More detailed results of the dose survey are presented in Appendix 2, together with results for the MicroDose L30 for comparison. The results are broadly similar. The average mean glandular dose (MGD) and compressed breast thickness (CBT) are summarised in Table 1.

Table 1. Average values of MGD and CBT for different components of exposure

View	Group of women	Average MGD (mGy)	Average CBT (mm)
CC	all	0.86	60
MLO	all	0.90	63
MLO	CBT 50-60mm	0.75	55

The average MGD for the MLO view, for 50–60mm thick breasts, compares favourably with both the national diagnostic reference level (DRL) of 3.5mGy[6] and the local DRL of 1.3mGy.

Since there were no clinical exposures made during the evaluation period with the high collimator, the effect on dose could not be audited. However, local tests with PMMA, and the technical evaluation,[2] suggest that there would be an approximate 10% increase in dose when using it.

On the whole, the MGDs measured for the MicroDose SI are similar to those recorded for MicroDose L30s in current use within the NHSBSP. The locally audited average MGD for the MLO view of 50–60mm thick breasts on the L30 at this centre was 0.74mGy as shown in Appendix 2.

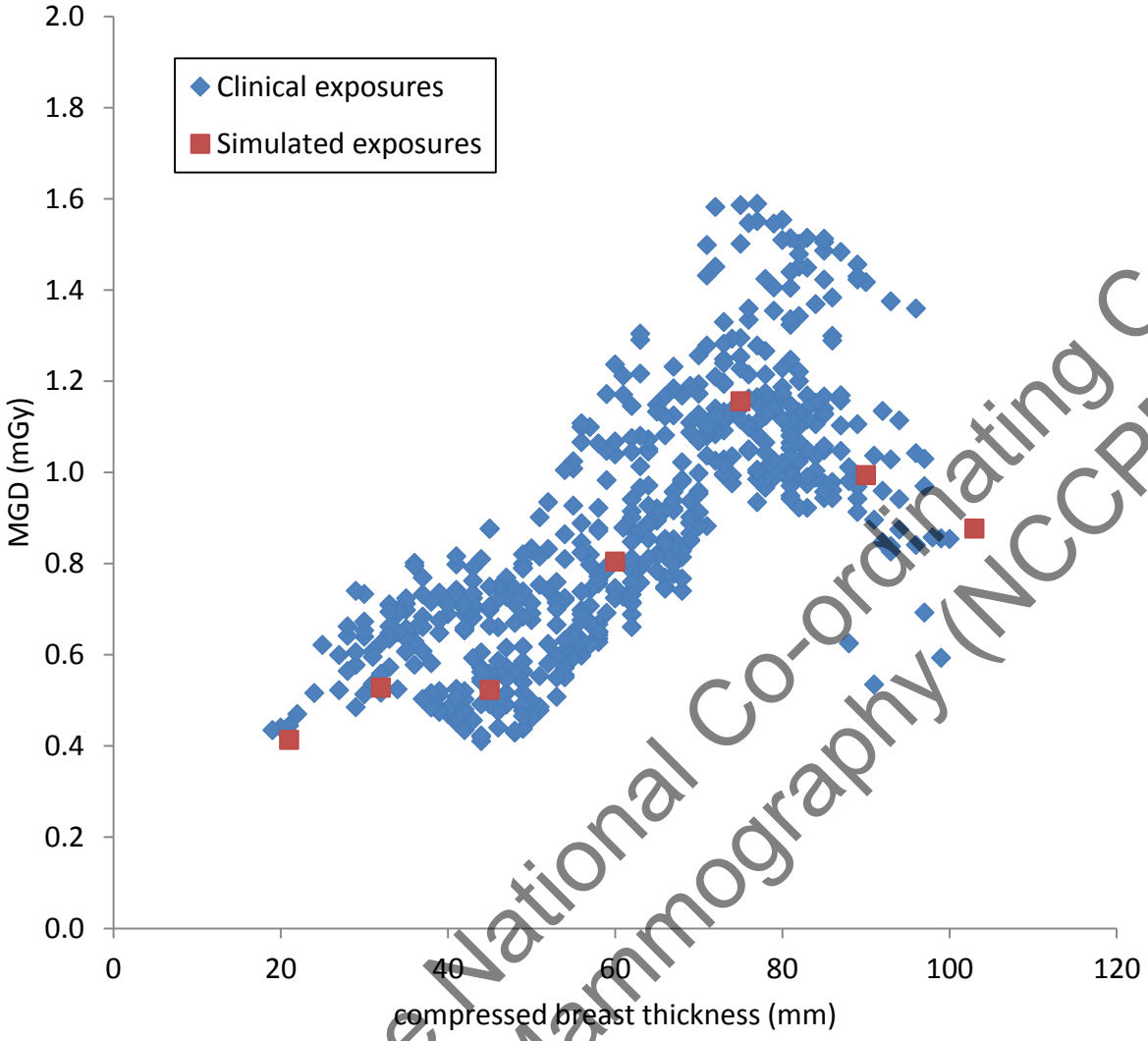

Figure 3. Results of dose survey and physics measurements of dose to breasts simulated by blocks of PMMA

4.2 Throughput

It was not possible to run a screening clinic, however, the centre regularly runs post-cancer follow-up and increased risk clinics on a Friday afternoon. These women have eight-minute appointments and no difficulties were reported with throughput. There were no technical repeats.

No timings were measured but a subjective comment on timing is included in Section 7.1.

4.3 Assessment of image quality

Ideally, both MicroDose L30 and SI images would be compared for this evaluation. However, because no women had been imaged on both systems, a comparison was

made with images acquired on another major manufacturer's system. Although taken for symptomatic patients, these images were of a quality standard acceptable for screening.

A total of 31 consecutive patients, imaged with the Philips MicroDose SI, were selected for an image review. These patients had attended post-cancer follow-up examinations. The prior images were their most recent ones and had been acquired over a period of up to thirteen months previously.

The current and prior images were reviewed side by side on the standard GE IDI workstation, with 5 megapixel monitors, within the normal reporting environment at the centre. Two consultant radiologists, a consultant radiographer and a research radiographer rated the images independently, on a five-point scale. Each image set was rated on a scale of -2, -1, 0, +1, +2, where -2 meant MicroDose SI images were worse than the priors, and +2 meant they were better. Radiographic positioning, sharpness, contrast (perception) and overall diagnostic quality were compared. No attempt was made to randomise case order. Since each of the 31 women's images was assessed by four readers, a total of 124 judgements were made. The results are presented as percentages in Figures 4 to 7.

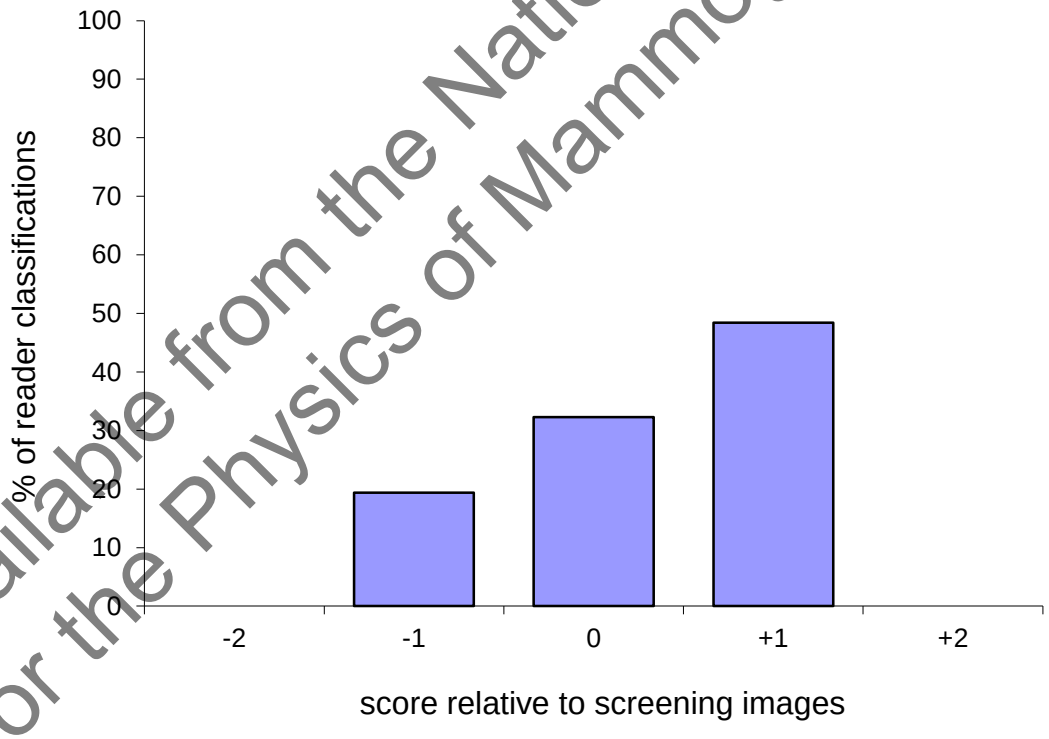

Figure 4. Readers' assessment of positioning for MicroDose SI images compared to priors. (+/- indicate better/worse than priors.)

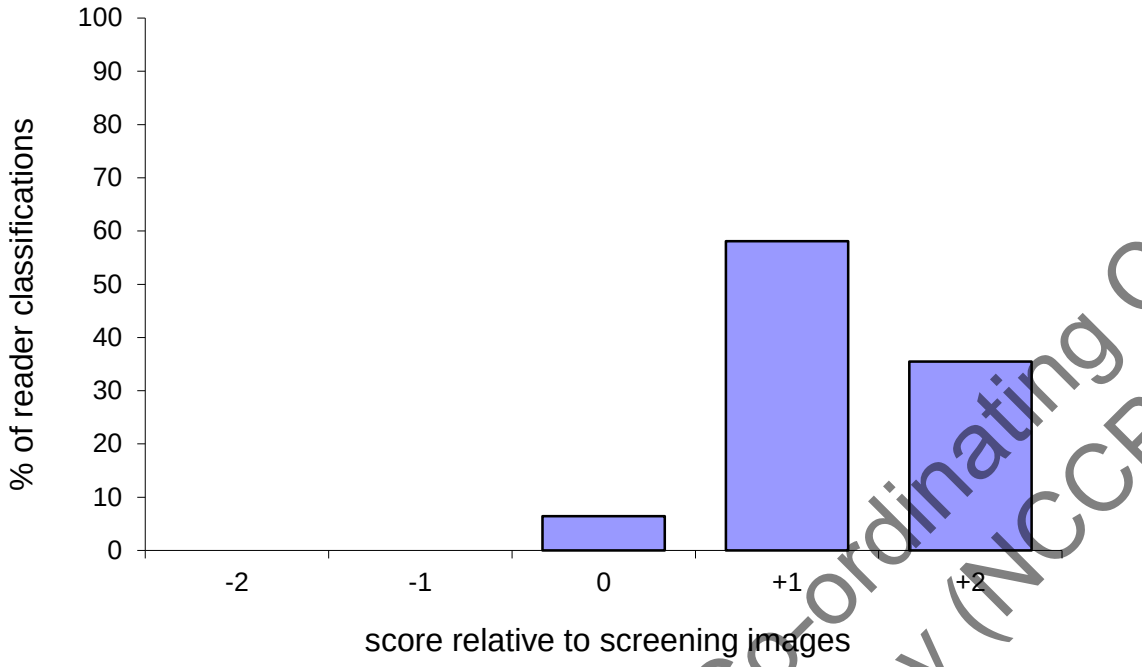

Figure 5. Readers' assessment of sharpness for MicroDose SI images compared to priors. (+/- indicate better/worse than priors.)

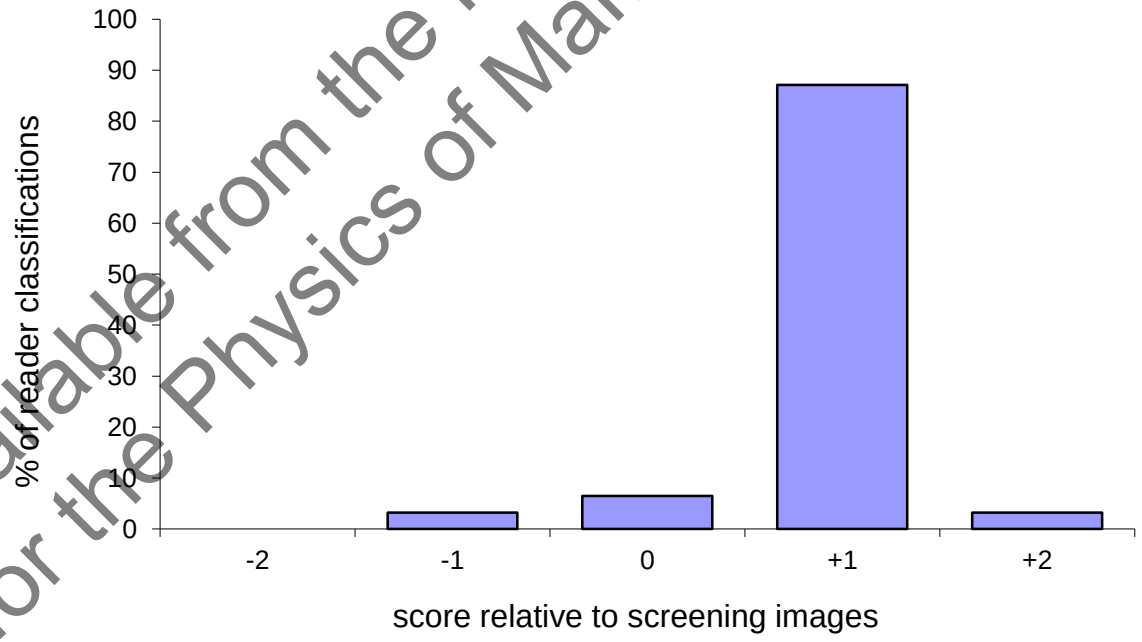

Figure 6. Readers' assessment of contrast for MicroDose SI images compared to priors. (+/- indicate better/worse than priors.)

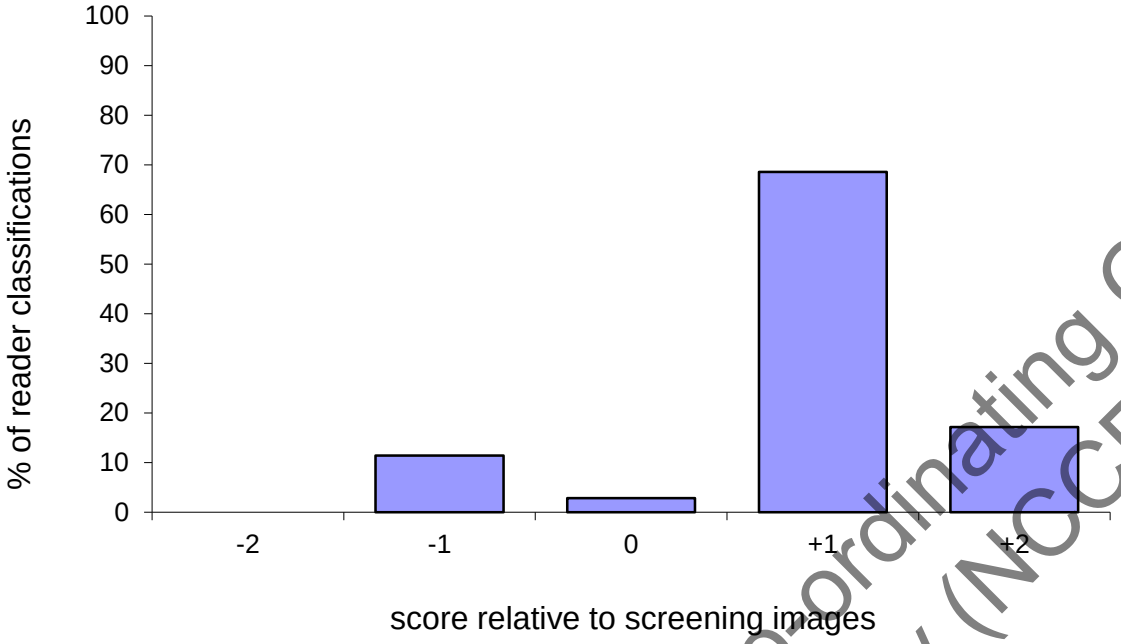

Figure 7. Readers' assessment of overall diagnostic quality for MicroDose SI images compared to priors. (+/- indicate better/worse than priors.)

In addition to the comparative assessments, the overall diagnostic value and sharpness of the MicroDose SI images were given an absolute rating by the same readers. The results are shown in Figures 8 and 9.

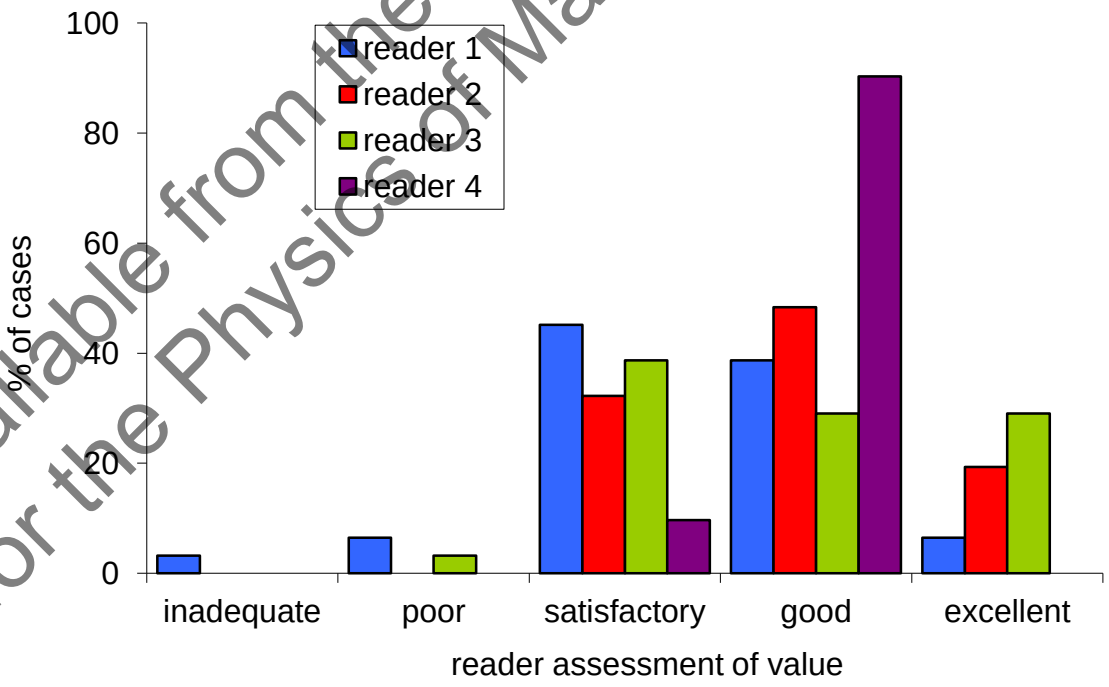

Figure 8. Readers' assessment of overall diagnostic value of the MicroDose SI images

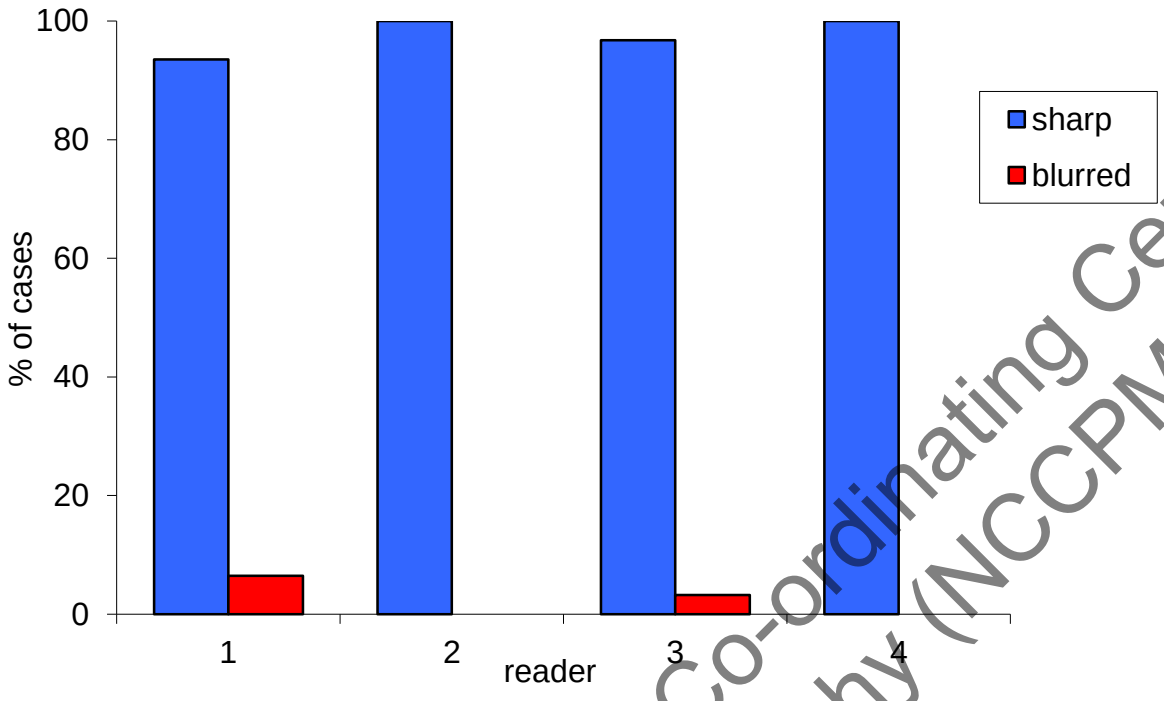

Figure 9. Readers' assessment of sharpness of the MicroDose SI images

The comparative assessments presented in Figures 4 to 9 should be viewed with caution, as images from different manufacturers' systems are not intended to look the same, and can appear quite different on any workstation. This caveat applies most strongly to the contrast of the images. However, the results give a general indication that the MicroDose SI images are, on the whole, as good as or slightly better than images from another widely used system.

Assessed on their own, the overall diagnostic value of the MicroDose SI images was judged to be mostly satisfactory or good, with some excellent as shown in Figure 8. Very few were poor or inadequate. Almost all images were sharp, as shown in Figure 9, with only 2% blurred.

5. Equipment reliability

The equipment was reliable during the assessment evaluation period. No faults were recorded on the NHSBSP Equipment Fault Report Forms during this period, and there was no downtime.

6. Electrical and mechanical robustness

There were no safety issues, and no electrical or mechanical problems were encountered during the evaluation period.

Evaluation over a longer period of time, with larger numbers of women imaged (as in the screening situation), would be needed to assess the reliability of the system and the lifetime of the X-ray tube.

7. Radiographers' and radiologists' comments and observations

A selection of opinions and comments were expressed by radiographers and radiologists, at the end of the evaluation period. For this focused evaluation, these are given in the following two sections.

7.1 Image quality and timing

- image acquisition, that is, the time from exposure to display, seems faster than other systems
- images from the SI appear very similar to images from the L30 in terms of contrast, definition and 'quality', with possibly slightly more contrast
- the general clinical view is that the appearance of images from the SI is better than images from the L30, both on the IDI workstations and the Philips Intellispace
- one individual's subjective view was "very similar to L30 images", and another's was "the appearance…..is better"

7.2 Practical comments from radiographers using the equipment:

- excellent
- familiarity with it from using the L30 on the van
- no noticeable difference from working with the L30
- the user guide is in plain English and self-explanatory
- upgrade training was straightforward, well delivered, with not many changes from the training for the L30 on the van

8. Information systems

The system was not connected to NBSS to retrieve a worklist directly for the high-risk women. The images were sent directly to both an existing legacy PACS and a Philips Intellispace Breast Solution 2.2 workstation.

It was very difficult to display any Philips images on the standard PACS monitors, using the legacy PACS. However, similar problems have been encountered with most other manufacturers' images.

Retrieving prior images from the legacy PACS onto the Intellispace workstation was also difficult. These issues had not been resolved by the end of the evaluation period.

9. Confidentiality and security issues

The evaluation complied fully with NHS Cancer Screening Programmes' Confidentiality and Disclosure Policy.[7]

Access to the Philips MicroDose SI acquisition workstation is controlled by typing a username and password. User names can be added to a drop-down user list, with an individual password entered for access to the acquisition workstation, just as for the MicroDose L30.

10. Training

Upgrade training (from the MicroDose L30 to the MicroDose SI) was provided for the radiographers. A representative of the group found this training straightforward and well delivered, as expressed in Section 7.2. The differences in operating the SI and the L30 were considered negligible, apart from the availability of a high collimator for the SI.

11. Conclusions and recommendations

In terms of practical aspects, the MicroDose SI was easy to use as it is very similar to the MicroDose L30 already in use in the centre. It was reliable during the period of the evaluation, but it was not used long enough to indicate whether the X-ray tube has a limited lifetime, which is the case with the L30. The high collimator was not used except for QC tests, but it was easy to change when necessary. The new spectral imaging functionality was not evaluated.

The image quality was judged by a small team of readers to be mostly satisfactory or good. There was no detailed comparison with L30 images, but when compared to another system, the images were mostly judged to be similar or somewhat better in quality. The MGDs calculated for the SI were very similar to those measured for L30. There is a decrease in dose for the larger breast thicknesses.

Overall, the MicroDose SI appears to be similar to the MicroDose L30 in terms of its practicality and usefulness in the NHSBSP.

References

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2. Strudley CJ, Young KC. *Technical Evaluation of Philips MicroDose SI digital mammography system* (NHSBSP Equipment Report 1310). London: Public Health England, NHS Cancer Screening Programmes, 2016

3. Kulana E, Burch A, Castellano I et al. *Commissioning and routine testing of full field digital mammography systems* (NHSBSP Equipment Report 0604, Version 3). Sheffield: NHS Cancer Screening Programmes, 2009

4. Baxter G, Jones V, Milnes V, Oduko J, Phillips V, Sellars S, Vegnuti Z. *Routine quality control tests for full field digital mammography systems, 4th Edition* (NHSBSP Equipment Report 1303). Sheffield: NHS Cancer Screening Programmes, 2013

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6. National Quality Assurance Coordinating Group for Radiography. *Quality Assurance guidelines for mammography: Including radiographic quality control* (NHSBSP Publication No 63). Sheffield: NHS Cancer Screening Programmes, 2006

7. McCorry P, Jones A. Confidentiality and disclosure policy, Version 4. Sheffield: NHS Cancer Screening Programmes, 2011

Appendix 1: Physics routine survey report

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Email: *firstname.lastname*@addenbrookes.nhs.uk

Addenbrooke's Hospital NHS
Cambridge University Hospitals NHS Foundation Trust

MAMMOGRAPHIC EQUIPMENT PERFORMANCE AND RADIATION PROTECTION SURVEY REPORT

This report assesses compliance with the following:

The Ionising Radiations Regulations 1999, SI 1999 3232 (1999)
Work with Ionising Radiation - Approved Code of Practice and Guidance, HSC (2000)
The Ionising Radiation (Medical Exposure) Regulations 2000, SI 2000 1059 (2000)
Medical and Dental Guidance Notes, IPEM (2002)
The Commissioning and Routine Testing of Mammographic X-ray Systems, IPEM (2005)
Commissioning and Routine Testing of Full Field Digital Mammography Systems, Equipment Report 0604 Version 3, NHSBSP (2009)
Further Revisions to Guidance Notes for Health Authorities and NHS Trusts on Mammographic X-ray Equipment for Breast Screening, MDA 61011 (2001)

Centre	Cambridge University Hospitals NHS Foundation Trust, Cambridge Breast Unit	**Date of Survey**	19/04/2013
Equipment	Philips MicroDose SI (L50) MDM (Room 2)	**Date of Previous Survey**	N.A.
Location	Cambridge Breast Unit	**Manufactured**	Aug-2012
Reference Number	132	**Assessor**	Oliver Morrish
Copied to	Breast Imaging Manager	Mrs B Knighton	
	Radiation Protection Supervisor	Mrs B Knighton	
	Radiation Protection Advisor	Mr S J Yates	
	ADO for Cancer	Mrs E Hunt	
	Consultant Radiologist	Dr M Wallis	
	ADO for Investigative Sciences	Ms J Smith	
	QA Radiographer	Mrs M Hunt	
	QA Radiographer	Mrs A Freeman	
	Head of Radiography	Mrs C Grundy	
	Operations Manager for Radiology	Mrs J Westbrook	

Summary Comments

Since this is a new system, Local Rules need to be written. It is recommended that they include within the system of work that the operator must check that the protective screen is positioned such that the operator is protected from scattered x-rays.

Authorised by Medical Physics Expert		Oliver Morrish	**Date**	07/06/2013

Centre	Cambridge University Hospitals NHS Foundation Trust, Cambridge Breast Unit	Date of Survey	19/04/2013
Equipment	Philips MicroDose SI (L50) MDM (Room 2)	Reference Number	132

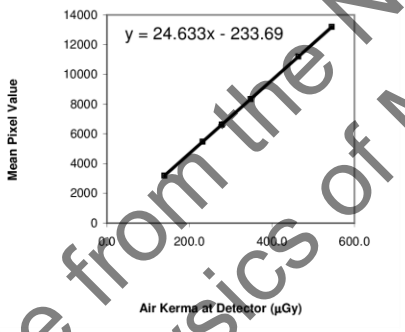
Integrated Digital Mammographic X-ray Equipment Performance

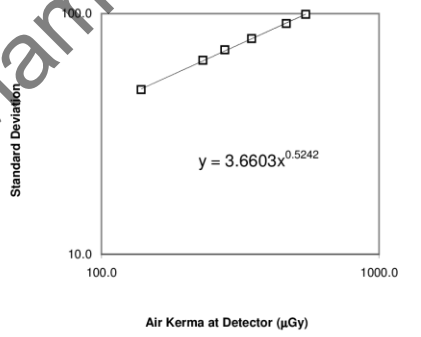
Test	Result	Tolerance	Satis.	Comment
Mechanical Safety and Function	System complies with recommended requirements	System complies with recommended requirements	Yes	It was noted that thin breast exposures can be taken with the high collimator in place. An on-screen message however highlights this to the operator.
Radiation Safety	Setup does not comply with recommended and regulatory requirements	Setup complies with recommended and regulatory requirements	No	See comment 1 and 2
Leakage Radiation	Leakage from the x-ray tube is 0.00 microGy in 1hr at 1m	Leakage from the x-ray tube must be <1000 microGy in 1hr at 1m	Yes	
Compression	Compression indicator error is 10N and maximum power driven force is 190N maintained over 30s	Compression indicator error should be <20N and maximum power driven force within 150 - 200N maintained for 30s	Yes	
Alignment	Radiation field and image are aligned correctly	Light field edge should be within 5mm of radiation field edge overlapping the image by 0 - 5 mm. There should be <5mm gap between the image and the front edge of the breast support platform.	Yes	The light field that is available is not intended to be aligned with the radiation field.
Focal Spot	Due to the design of the system, we are unable to measure the focal spot.	Measured dimensions should be within 50% - 150% of nominal values	N.A.	
X-ray Tube Voltage	Maximum difference between measured and set tube voltages is 0.2 kV	Difference between measured and set tube voltages <1 kV	Yes	kV measurements are made with a 2% uncertainty
X-ray Tube Output	Maximum deviation from the mean output of identical exposures is 1.3%	Maximum deviation from the mean output of identical exposures <5%	Yes	
	Specific output is 234.7 microGy/mAs	Specific output should be >120 microGy/mAs and >70% of baseline	N.A.	Tolerance not applicable for the beam quality available on this unit.
	Specific output rate is 0.9 mGy/s	Specific output rate should be >7.5mGy/s	N.A.	Tolerance not applicable for the beam quality available on this unit.
Half Value Layer	HVL for a 29kVp, W/Al beam is 0.31 mm Al	HVL for a 28kVp, Mo/Mo beam should be between 0.3 and 0.4 mm Al	N.A.	Tolerance not applicable for the beam quality available on this unit.
Anti-Scatter Grid	There is no grid with this system.	The grid should not be damaged and the grid factor should be <3	N.A.	
Electronic Calliper	Error in electonic callipers is 0.0%	Error should be < 2%	Yes	
Breast Thickness Indication	Difference between measured and indicated thickness is a maximum of 4 mm	Difference between measured thickness and indicated thickness should be less than 5 mm	Yes	

Centre	Cambridge University Hospitals NHS Foundation Trust, Cambridge Breast Unit	Date of Survey	19/04/2013
Equipment	Philips MicroDose SI (L50) MDM (Room 2)	Reference Number	132

Detector Performance

Test	Result	Tolerance	Satis.	Comment
Uniformity	Maximum deviation of pixel value from central region is 4.1%	Maximum deviation of pixel value from central region should be <10%	Yes	All target/filter combinations tested
Detector Response	Detector reference air kerma is 171.9 microGy	Detector reference air kerma should be within 20% of baseline	Yes	This is the dose required to achieve the representative pixel value of 4000
	SNR at detector reference air kerma is 78.1	SNR at detector reference air kerma should be within 10% of baseline	Yes	Detector reference air kerma, SNR and standard deviations at a range of doses are within 5% of those measured on the L30
	Baseline taken for future comparison	Standard deviation of pixel values at any entrance air kerma should be within 10% of baseline	Yes	
Artefacts	Artefacts that may affect clinical image quality are not present	Artefacts that may affect clinical image quality should not be present	Yes	
Resolution	Baseline taken for future comparison.	The square wave contrast transfer factor at measured frequencies should be within 10% of baseline	Yes	See comment 3
	This test is not applicable for this type of detector	The detector limiting spatial resolution should be >70% of the Nyquist frequency of the detector and >75% of baseline	N.A.	
Spatial Discontinuity and Resolution Homogeneity	There is no evidence of discontinuities or regions of blurring	There should be no evidence of discontinuities or regions of blurring	Yes	
Image Retention	This test is not applicable to this system.	The image retention factor should be <0.3	N.A.	



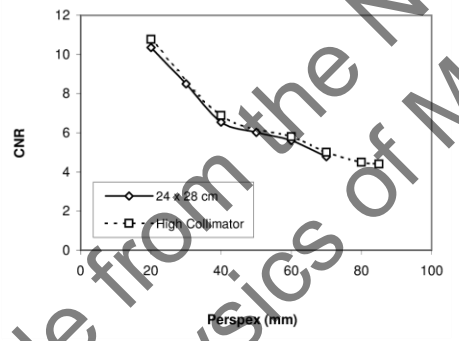


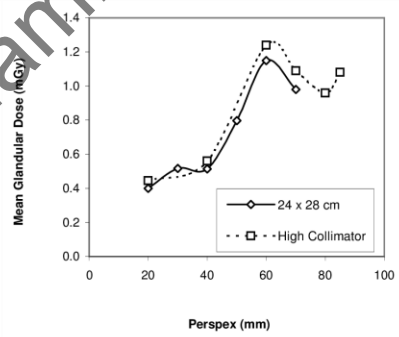
Centre	Cambridge University Hospitals NHS Foundation Trust, Cambridge Breast Unit	Date of Survey	19/04/2013
Equipment	Philips MicroDose SI (L50) MDM (Room 2)	Reference Number	132

Automatic Exposure Control System

Test	Result	Tolerance	Satis.	Comment
Repeatability	Maximum deviation of mAs of identical exposures is 0.0%	Maximum deviation of mAs of idential exposures should be less than 5%	Yes	
Exposure Time	This test is not applicable to this system	Exposure time for 40mm block should be less than 1s and for a 70mm block should be less than 4s	N.A.	
Variation with Density Control	Not available on this system	Density control step should be within manufacturers specification	N.A.	
Variation with Position of Detector	Not available on this system	The maximum devaition in mAs from the chest wall position should be <10%	N.A.	
AEC System Performance	Baselines taken for future comparison.	The Contrast Noise Ratio (CNR) for any thickness of Perspex should be within 10% of baseline	Yes	See comment 4 and 5

Table	Perspex (mm)	Exposure Factors	CNR	MGD (mGy)	Should be below	Satis.
24 x 28 cm (Low Collimator)	20	29kVp, W/Al, 8.2mAs	10.36	0.40	1.0	Yes
	30	32kVp, W/Al, 9.4mAs	8.50	0.52	1.5	Yes
	40	32kVp, W/Al, 11.0mAs	6.54	0.51	2.0	Yes
	50	35kVp, W/Al, 14.3mAs	6.02	0.80	3.0	Yes
	60	38kVp, W/Al, 17.9mAs	5.60	1.15	4.5	Yes
	70	38kVp, W/Al, 17.2mAs	4.78	0.98	6.5	Yes
High Collimator	20	29kVp, W/Al, 9.1mAs	10.77	0.44	1.0	Yes
	40	32kVp, W/Al, 12.0mAs	6.89	0.56	2.0	Yes
	60	38kVp, W/Al, 19.3mAs	5.80	1.24	4.5	Yes
	70	38kVp, W/Al, 18.6mAs	5.00	1.09	6.5	Yes
	80	38kVp, W/Al, 17.8mAs	4.49	0.96	7.5	Yes
	85	38kVp, W/Al, 21.7mAs	4.40	1.08	8.5	Yes





Centre	Cambridge University Hospitals NHS Foundation Trust, Cambridge Breast Unit	Date of Survey	19/04/2013
Equipment	Philips MicroDose SI (L50) MDM (Room 2)	Reference Number	132

Automatic Exposure Control System (continued)

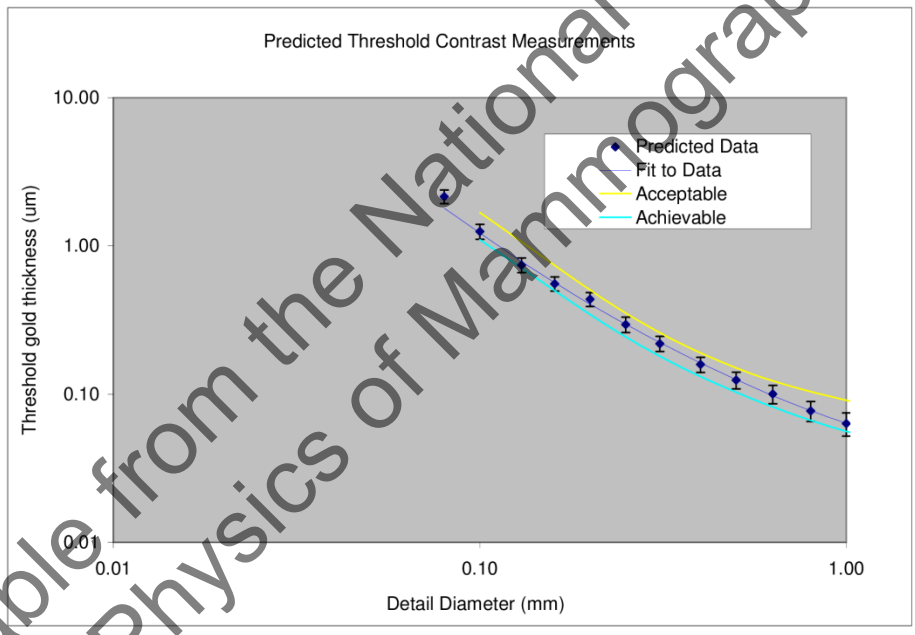
Test	Result	Tolerance	Satis.	Comment
Guard/Back-up timer	The system is functioning	The system should be functioning	Yes	See comment 6
Mean Glandular Dose to the Standard Breast	The MGD for the standard breast at clinical settings is 0.58 mGy	The MGD for the standard breast (45mm Perspex) at clinical settings should be less than 2.5mGy/film and within 25% of baseline	Yes	

Image Quality

	Bucky	TORMAM Score			
TORMAM	24 x 28 cm	98	These results are indicative only and can be used to determine long term performance. TORMAM is exposed under clinical conditions.	N.A.	

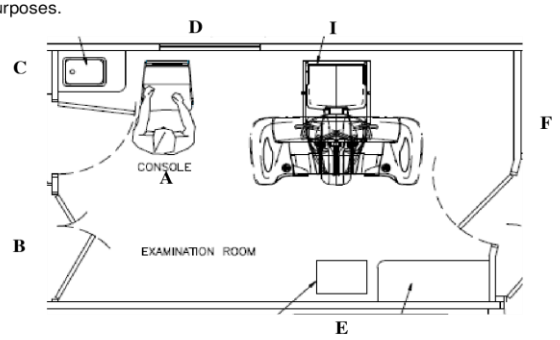
Detail Detectabililty - CDMAM

Diameter of detail (mm)	Threshold Gold Thickness (µm)			Satis.
	Acceptable value	Achievable value	Measured value	
2	0.069	0.038	N.A.	N.A.
1	0.091	0.056	0.064	Yes
0.5	0.150	0.103	0.125	Yes
0.25	0.352	0.244	0.296	Yes
0.1	1.68	1.10	1.222	Yes
Comment	See comment 5			



Comments and Recommendations

1 Environmental measurements were taken during a simulated mammogram exposing a 70mm block of PMMA with a 38kVp, W/Al, 16.9mAs x-ray beam. The results of these measurements are presented below and may be multiplied by workload and occupancy factors to determine the extent of the controlled area. Please note however that the plan below is not that of the room under discussion as there was not one available at the time of the survey – instead it is one that is similarly laid out for illustrative purposes.



Measurement Location	Dose
A (outside Pb screen)	1067 nGy
A (behind Pb screen)	<1 nGy
B (behind door)	42 nGy
C (in corridor)	<1 nGy
D (in corridor)	1 nGy
E (in darkroom)	1 nGy
F (in corridor)	<1 nGy

The largest dose measured outside the room is at the main door into the room. Assuming a workload for this room of 40 persons per day for four view mammography (160 exposures), the dose rate at this point when averaged over the working day is 0.8 µSv/h which is less than the 7.5 µSv/h required by the Health and Safety Executive's (HSE) Approved Code of Practice for compliance with the Ionising Radiations Regulations 1999.

The Health Protection Agency recommends that an annual dose constraint of 300µSv be applied for controlled sources of radiation. From these measurements and an application of the above workload the following annual doses can be determined at the following locations that exceed the 300µSv dose constraint:

C (main door) 1680 µSv

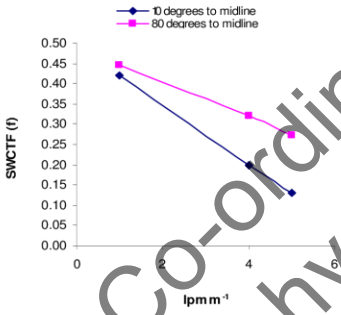
Occupancy factors may be applied which take into account the fraction of time spent by the single person who is there the longest (with a minimum of 5%). Minimal occupancy factors of 5% may be applied to the corridor outside the door bringing the annual doses to a satisfactorily low 84 µSv. It would be prudent however to provide for a period of monitoring on this door for a period of six months to record the actual doses encountered there (bearing in mind that our calculations predict doses based on a worst case exposure). Since we are in the process of carrying out an environmental dose survey across

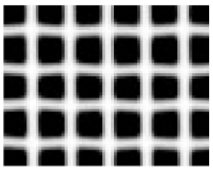
the Trust anyway we have included this door in our collection of sites and a dose monitoring badge will be mounted on the door in due course.

2 Since this is new equipment, Local Rules need to be written and made available within the Controlled Area.

At the time of the survey the protective screen was not fixed to the floor. The room is small and having the ability to move the protective screen may be of benefit when multiple operators are in the room (bearing in mind that the system's gantry also needs room to manoeuvre). Having it unfixed however does allow the possibility of it not being located in the correct place to protect operators. If it is the intention to leave it free to move around the room, it is essential that the Local Rules include the requirement for the operator to check that the screen is appropriately positioned.

3 Resolution was measured both parallel and perpendicular to the scan direction. The results of this measurement showed a difference between the two, with objects being better resolved in the chest wall – nipple direction. The difference can be seen in the graph to the right however it is perhaps better illustrated in the following image of a fine mesh placed in contact with the table. Careful examination of this image shows that the vertical lines (running parallel to the chest wall edge) are more distinct than those running horizontally.

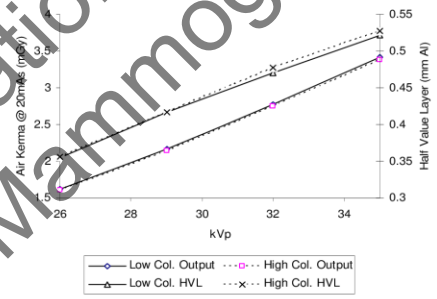




This is a particular feature of the unit and the result is consistent with the performance of the L30 MicroDose systems and with data published in the journal Medical Physics (Aslund et al, 2007 Vol 34 pages 1918-1925).

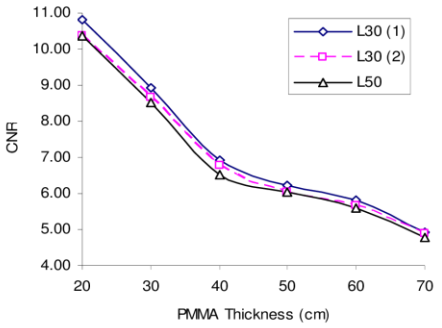
4 This system comes with two collimators, the low collimator which is similar to that found on the L30 and, the high collimator which allows for imaging of larger breasts. We have been informed that the intention is that the low collimator is to be used by default and the high collimators is to be used only when the compression paddle is too high to allow the low one to be used. To aid this, the system is prevented from taking a 'high' exposure when the low paddle is in place. It is however possible to take 'low' exposures when the high paddle is in place. Since this survey an error message has been enabled to warn operators when this latter scenario occurs.

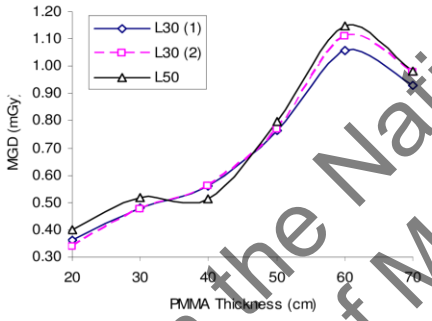
The graph to the right demonstrates the output and half value layer of the x-ray tube with each collimator in place in identical exposure geometries. As can be seen, the x-ray beam coming through each collimator is very similar.



It had been assumed that the higher collimator enabled imaging of thicker breasts by collimating the x-ray beam more closely to the detector elements and overcoming the beam divergence that presumably occurs at greater heights. Given these results however and the fact that there seems to be little difference in the performance of the automatic exposure control (AEC) at the lower thicknesses, this assumption would appear to be incorrect. The need therefore for the second collimator, while accepted, is unclear. Any comment from Philips on the design of the collimator would be appreciated.

5 The performance of the SmartAEC mode has been assessed by exposing a number of slabs of PMMA of various thicknesses containing a 0.2mm thick aluminium detail. The mean glandular breast dose and contrast-to-noise ratio (CNR) was then calculated from the resultant exposures, the results of which are given in the table on page 4 of this report. Comparison can be made between this system and the two existing L30 systems installed by the breast unit.

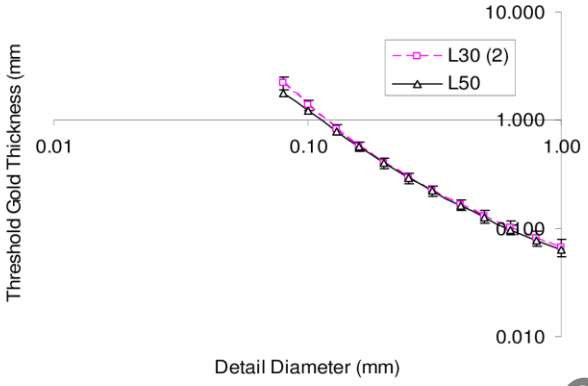




The graph to the left shows how CNR varies between the three systems. As can be seen they all perform similarly and the L50 delivers CNRs that are within 5% of the mean L30 result. This is despite the L50 generally preferring to select 38kVp for the thicker breasts compared to 35kVp on the L30.

Similarly the graph below shows how MGD varies between the systems. For this measure the L50 is within 10% of the mean L30 result with the exception of the dose for the 20mm block which is 15% greater on the L50 than the L30.

As mentioned in previous reports for the L30, this system is performing satisfactorily and delivers a very low radiation dose to the breast. There may however be some benefit in exploring the possibility of increasing the dose to improve the image quality which is currently better than the minimum acceptable NHSBSP standard but less than the achievable level that many digital systems meet. When compared with the L30, the image quality in terms of threshold gold thickness for a range of details of varying diameter (as measured by the CDMAM test object) is very similar with results lying within two standard errors of the mean L50 result as demonstrated on the next page.



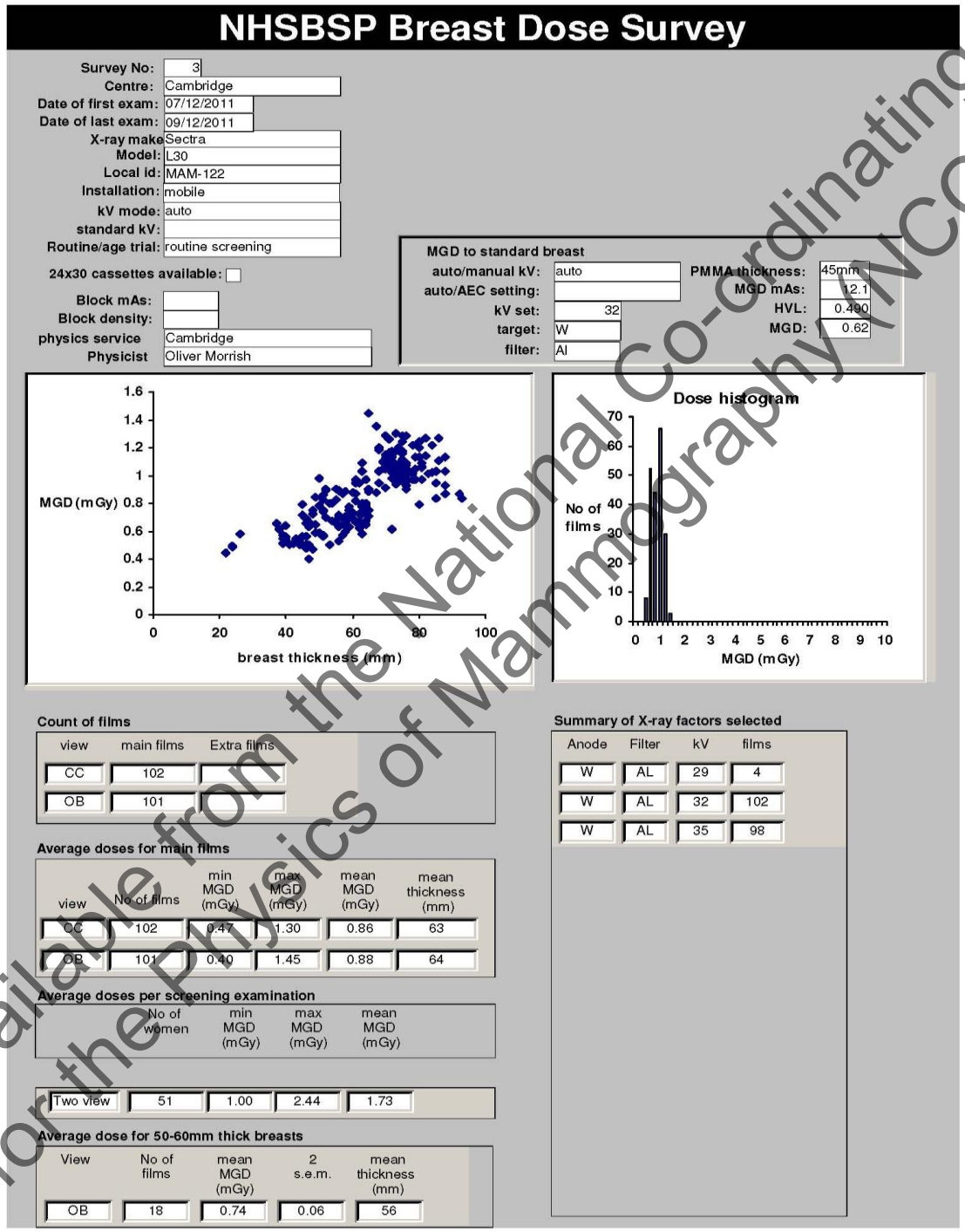
6 Conventional designs of automatic exposure control (AEC) systems would be expected to terminate the exposure if the detecting device determined that the dose being delivered to the detector was insufficient to complete the exposure within a reasonable time. This would be the case if an object of high density covered the AEC sensitive area or if the system failed. This is to prevent excessively high exposures occurring from such a fault and is often referred to as the guard timer.

This system has no such function due to the way in which the exposure is determined by the AEC and the fact that the detector cannot see objects of high density until the scan has reached that part of the breast. However placing lead objects in various parts of the scan has shown that if the detector sees a significant drop in signal in any part of the scan it will deliver the lowest possible dose to that area until it sees an increase again, following which is will resume the scan as expected. A warning message appears after the exposure to indicate that this has happened. Smaller pieces of lead appear to be ignored by the system, presumably so that the presence of implants doesn't cause excessive increases in dose.

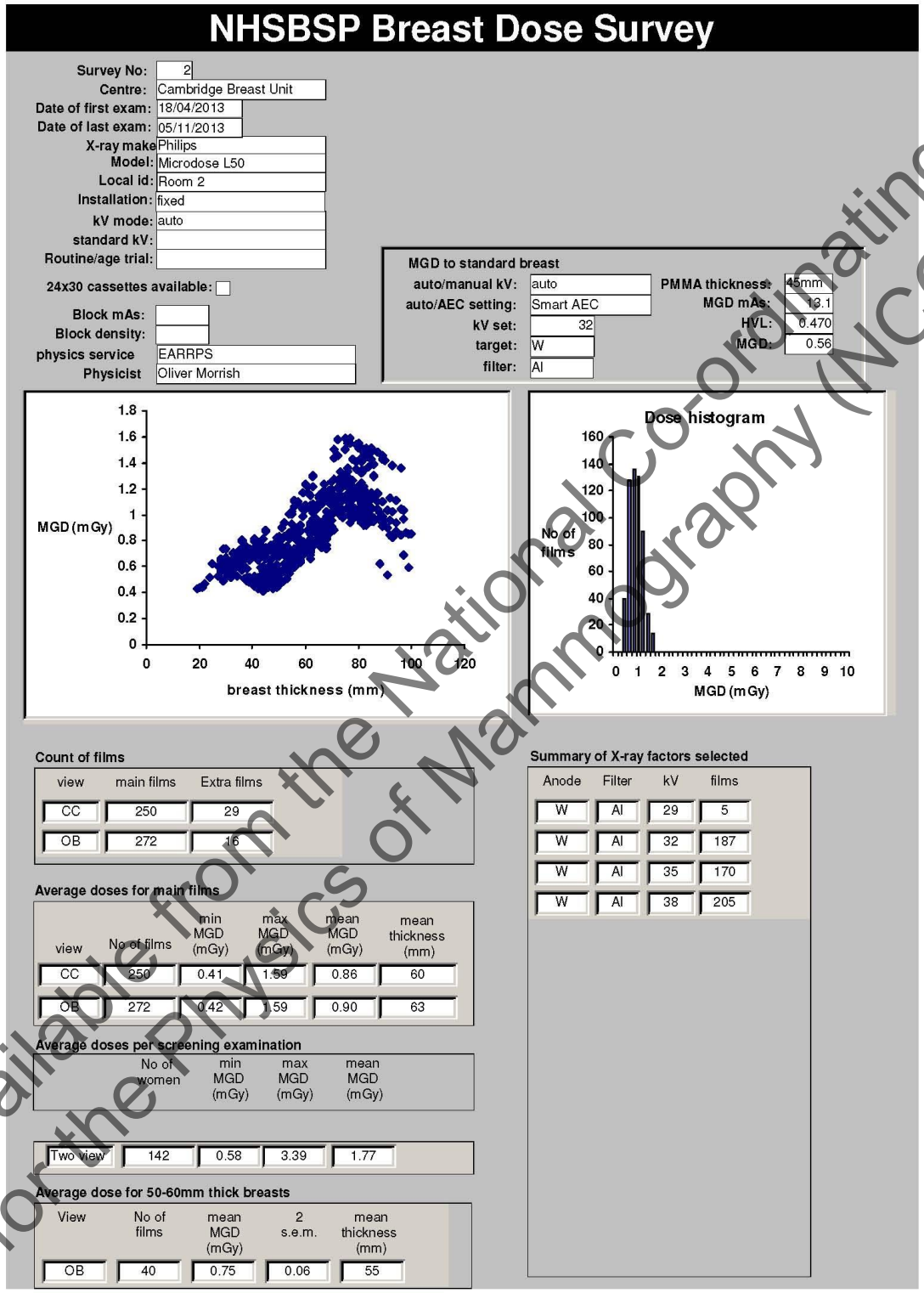
This design would seem sensible given the operation of the system and is satisfactory.

Appendix 2: Clinical breast dose surveys

A2.1 MicroDose L30



A2.2 MicroDose SI



NHSBSP Breast Dose Survey

Survey No: 2
Centre: Cambridge Breast Unit
Date of first exam: 18/04/2013
Date of last exam: 05/11/2013
X-ray make: Philips
Model: Microdose L50
Local id: Room 2
Installation: fixed
kV mode: auto
standard kV:
Routine/age trial:

24x30 cassettes available:

Block mAs:
Block density:
physics service: EARRPS
Physicist: Oliver Morrish

MGD to standard breast
auto/manual kV: auto
auto/AEC setting: Smart AEC
kV set: 32
target: W
filter: Al
PMMA thickness: 45mm
MGD mAs: 13.1
HVL: 0.470
MGD: 0.56

MGD (mGy) vs breast thickness (mm)

Dose histogram
No of films vs MGD (mGy)

Count of films

view	main films	Extra films
CC	250	29
OB	272	16

Summary of X-ray factors selected

Anode	Filter	kV	films
W	Al	29	5
W	Al	32	187
W	Al	35	170
W	Al	38	205

Average doses for main films

view	No of films	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	250	0.41	1.59	0.86	60
OB	272	0.42	1.59	0.90	63

Average doses per screening examination

	No of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
Two view	142	0.58	3.39	1.77

Average dose for 50-60mm thick breasts

View	No of films	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
OB	40	0.75	0.06	55