

**GUIDANCE NOTES FOR THE EVALUATION OF
MAMMOGRAPHIC X-RAY EQUIPMENT**

**Prepared by the Equipment Evaluation Sub-group of the
National Coordinating Group for Equipment**

**NHSBSP Publication No 51
October 2002**

First published by:

NHS Cancer Screening Programmes
The Manor House
260 Ecclesall Road South
Sheffield S11 9PS

Tel: 0114 271 1060

Fax: 0114 271 1089

Email: nhs.screening@sheffield-ha.nhs.uk

Web site: www.cancerscreening.nhs.uk

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ISBN 1 871997 64 X

Further copies of this publication are available from:

NHS Responseline

Tel: 08701 555 455

Fax: 01623 724 524

Email: doh@prolog.uk.com

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

Printed by Streamline Offset, Hoddesdon, Herts

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1. INTRODUCTION

This is the first revision of these guidance notes and supersedes the previous version (published in November 1997).

The evaluation of mammographic x-ray equipment used in the UK NHS Breast Screening Programme (NHSBSP) is carried out in centres where the staff routinely perform screening and assessment examinations of women.

Currently, a number of centres located throughout the UK perform the evaluations using clinical protocols provided by the NHSBSP National Coordinating Group for Equipment. Measurements for the technical evaluation are made by the medical physics group at the King's Centre for the Assessment of Radiological Equipment (KCARE) and by the local mammography physics service.

The resulting reports, which are published by the Medical Devices Agency (MDA), are intended to determine the suitability of equipment for use within the NHSBSP, to assist potential purchasers in making their choice and to provide existing users with performance data about their equipment. Because consistent performance standards are used for any particular type of equipment, comparisons can be made by studying several reports. Comparative reports of several systems are also published periodically.

2. SELECTION OF EQUIPMENT

Suitable equipment for inclusion in the evaluation programme should be brought to the notice of a member of the Equipment Evaluation Sub-group of the National Coordinating Group for Equipment (Appendix 1). This sub-group decides whether a particular model of equipment requires evaluation and the priority that should be given to the evaluation. In reaching its decision, a range of factors are considered, including whether the equipment is, or is likely to be, offered for sale in the UK, whether it is significantly different from a previous model that has been evaluated and whether it incorporates new technology. If in doubt, the decision may be referred to the National Coordinating Group for Equipment.

As the National Coordinating Group for Equipment normally meets only twice per year, evaluations can commence as soon as convenient by agreement with the sub-group.

The sub-group will liaise with the NHSBSP, the supplier/manufacturer/installer of the equipment and the staff at the evaluation centre to arrange and schedule the evaluation.

3. SELECTION OF EVALUATION CENTRES

Breast screening centres taking part in the evaluation programme must fulfil the following criteria to ensure that they are able to provide the right level of expertise and sufficient throughput of women for examination. Centres may be suitable for the evaluation of mammography screening machines, of assessment machines or both. To prevent difficulties that may result from time lost for installation, training, familiarisation and technical problems, the machine under evaluation should not be the only x-ray machine available to the centre.

The breast screening centre selected for the evaluation should be screening a minimum of 50 000 women over a three-year period and must have an established quality assurance system that meets all relevant NHSBSP objectives and technical guidelines. An established and stable film processing system with dedicated processing facilities is an essential requirement and should be used throughout the evaluation. In addition, a set of good quality matched cassettes/intensifying screens should be available for the evaluation. The local mammography physics service, radiographers and radiologists involved in the evaluation should all comply with the relevant NHSBSP professional guidelines.

Mammography screening machines may also require evaluation when mounted in trailers or vans. This should be carried out after the machine has been fully evaluated at a static site. Specific protocols for such additional evaluations will be provided by the Equipment Evaluation Sub-group.

A formal service agreement between the NHSBSP and the evaluation centre is required because costs incurred by the evaluation projects are funded by the NHSBSP. Copies of a service level agreement and forms are given in Appendix 2. The centre undertaking the evaluation will be responsible for distributing the funding to the various internal groups and external agencies involved in the installation, safety and performance checks, in the clinical use and evaluation, in the collation of data and in report writing.

A project leader should be appointed by the centre to coordinate the evaluation, to ensure that all required areas are covered and to liaise between the centre, the Equipment Evaluation Sub-group and the supplier/manufacturer/installer of the equipment. KCARE will provide project management services for the evaluation. Time scales should be established and agreed as soon as availability of the equipment is confirmed. Once the equipment is installed, the supplier/installer should arrange for a critical examination to be performed in accordance with the *Ionising Radiations Regulations 1999* (regulation 31).¹ The project leader should ensure that the correct equipment and all of the necessary options and accessories have been supplied, and the supplier should demonstrate satisfactory operation of the equipment (acceptance).

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Arrangements should be made for appropriate electrical and mechanical safety checks and for commissioning and performance testing by the local mammography physics service. The medical physics group at KCARE can provide advice and assistance if required.

4. EQUIPMENT TYPES AND WORKLOADS

4.1 General

The workloads at the evaluation site should mirror standard work practice at a screening centre or assessment centre as appropriate. Minimum levels of throughput are suggested, but higher levels are desirable.

To provide an indication of long-term reliability and consistency of performance, the evaluation period (not including installation and technical acceptance testing) should be for a minimum of 3 months but usually not more than 6 months. A longer time period may be necessary for systems that have frequent breakdowns or inconsistency in performance.

4.2 X-ray machines for mammography screening

Evaluators of mammography screening machines should aim to examine at least 500 women on that machine during the period of the evaluation in order to highlight any operational defects or shortcomings in performance. A full range of breast sizes should be covered, including larger and denser breasts. Once the machine has reached full and acceptable operational status, a number of full screening sessions (a minimum of eight is suggested) should be arranged, with at least 50 women examined over a working day. Such workloads should not prove a problem at screening centres, but special arrangements may have to be made if the evaluation is performed at a centre that is primarily used for assessment.

4.3 X-ray machines for mammography assessment

The evaluators should aim to examine at least 200 referred women on an assessment machine, although at larger/busier centres the number may be considerably higher.

All modes of operation of the machine should be evaluated, including magnification and stereotactic operation. For the latter, both adaptation of the equipment to stereotactic use and operation of the equipment in the stereotactic mode should be examined. In the event that a full evaluation of the stereotactic device is required, this will be the subject of separate protocols and addressed within the service agreement.

The minimum workload should be at least 25 magnification examinations and 10 stereotactic examinations. The evaluation period should be similar to those for screening machines. As with screening machines, the evaluation should cover a full range of breast sizes and densities.

Centres may be asked to evaluate the suitability of assessment machines for screening purposes. This will be addressed in the service agreement.

4.4 Other types of mammography x-ray machines and equipment for mammography

Occasionally, there may be a requirement to evaluate other types of mammography x-ray machine, such as prone biopsy systems. Digital imaging devices will also require assessment. In such cases, the workload will be decided by discussion between the centre and the representatives of the Equipment Evaluation Sub-group.

4.5 Particular features of mammography machines

All evaluations should pay particular attention to any novel design features or modes of operation of the machine. Some examples are automatic exposure control systems with target material, filter material and/or tube voltage selection, the use of different additional filter materials, the design and operation of compression devices and the dose and image quality performance of digital imaging devices.

5. AVAILABILITY OF X-RAY ROOM

Ideally, the centre should have an empty x-ray room available for the evaluation. Otherwise, the centre must be prepared to have an existing x-ray machine disconnected, removed and stored for the period of the evaluation within the funding agreed in the service agreement. After the evaluation, the original machine will be reinstalled. If the x-ray room is sufficiently large, it may be possible to disconnect and move the existing machine to provide space for the evaluation machine.

Suggested time scales will be specified in the service agreement, but a degree of flexibility will be allowed to account for difficulties in delivery or installation, major breakdowns, unacceptability of equipment, etc.

6. TECHNICAL EVALUATION AND STAFFING REQUIREMENTS

- 6.1 Critical examination** Once the equipment is installed, the supplier/installer should arrange for a critical examination in line with the requirements of the *Ionising Radiations Regulations 1999* (regulation 31).¹ This ensures that the safety features and warning devices operate correctly and that everyone will be sufficiently protected from exposure to ionising radiation. The critical examination will (by arrangement) frequently be performed by the local mammography physics service.
- 6.2 Acceptance** The project leader should ensure that the correct equipment, documentation and all the required options and accessories to allow full clinical use have been supplied. The supplier should be asked to demonstrate satisfactory operation of the equipment. Any omissions, problems or discrepancies should be rectified as soon as possible.
- 6.3 Electrical and mechanical safety checks** These form an important part of the evaluation and should be organised by the evaluation centre through the usual local channels or by arrangement with the local mammography physics service or the medical physics group at KCARE.
- 6.4 Commissioning and performance testing** The evaluation centre must arrange for the local mammography physics service to perform a series of installation, performance and radiation safety checks before clinical use of the machine. The physicists carrying out these checks must have appropriate experience and be trained in the testing of mammography x-ray equipment in line with NHSBSP Publication No 33 (*Quality Assurance Guidelines for Medical Physics Services*)² and should be routinely involved in the breast screening programme.
- The physics test methods and protocols should broadly follow the procedures described in the latest edition of *IPSM Report No 59*.³ A physics report should be presented as part of the evaluation process. In addition to a description of the tests performed and the results, reference should be made to specific problems encountered during installation and commissioning, equipment shortcomings, modifications performed by the supplier/manufacturer, etc. This information should also be made available to the medical physics group at KCARE before its visit.
- 6.5 Technical evaluation by the medical physics group at KCARE** To provide continuity from evaluation to evaluation, all systems will be tested by the medical physics group at KCARE at a convenient point during the evaluation period. This will be by arrangement with the project leader. A full technical evaluation of the machine will be performed with particular reference to MDA Document No 01011 (*Further Revisions to Guidance Notes for Health Authorities and NHS Trusts on Mammographic X-ray Equipment for Breast Screening*).⁴ The KCARE evaluation will also highlight areas such as novel design features and modes of operation, new methods of image acquisition, etc.

These measurements should normally be completed in two to three days. For certain installations, members of the medical physics group at KCARE may (by arrangement) attend or perform the electrical and mechanical safety checks and attend or assist with the commissioning and performance testing.

7. CLINICAL EVALUATION AND STAFFING REQUIREMENTS

The clinical evaluation should be coordinated by an experienced mammography radiographer, who may also be the project leader appointed by the centre. The radiographic staff must be prepared for the extra work involved in using a new x-ray machine and the associated record keeping and data collation. They should also have experience of a range of mammography machines. Before the clinical evaluation begins, arrangements should be made with the supplier for user training on the equipment.

Radiographers working on the machine under evaluation will be required to keep details of all clinical films taken. The associated data should be summarised in clear tabular form. Standard forms are provided; examples are appended to this document and should be printed as required from the web site addresses in section 10.3. The forms may, by agreement, be modified for specific equipment or situations. Note should be made of all service visits to allow evaluation of the reliability of the machine and the level of service provided by the supplier and/or manufacturer. An NHSBSP equipment fault report form (Form 4) may need to be completed. The original should be forwarded to the National Coordinating Centre for the Physics of Mammography (NCCPM); a copy should be kept with the evaluation data.

Familiarity with MDA Evaluation Report No 01011⁴ and with MDA (blue cover) evaluation reports on similar mammography equipment is expected.

The input and commitment of radiologists is also required. For both screening and assessment machines, the films from at least 100 women (covering a range of breast sizes and densities) should be scored and the results kept on the appropriate forms in order to provide the basis of a quantitative summary of clinical image quality. Only films obtained once the machine has reached full and acceptable operational status should be considered. This function should be performed by a radiologist experienced in mammographic imaging (satisfying the requirements set out by the Royal College of Radiologists for specialisation in mammography) or a designated and approved film reader (for example, a radiographer or breast physician with appropriate training) who is routinely involved in the NHSBSP. It should not be undertaken by a trainee.

In addition to collection and collation of the basic data, a clinical report summarising the findings of both the radiographers and the radiologists must be prepared for publication. The report should comment on the operation and specific features of the machine and refer to the level of service provided by the supplier, the competence of service staff and the availability of clinical applications training and support. If necessary, the report may include photographs and illustrations.

8. ROUTINE QUALITY ASSURANCE MEASUREMENTS

The routine quality assurance measurements will depend to some extent on the protocols in force at the centre and the facilities available, but should comply with the requirements of NHSBSP Publication No 21 (*Radiographic Quality Control Manual for Mammography*).⁵ Tests should include daily measurement of automatic exposure control (AEC) film density (with standard Perspex blocks) and monitoring of film processing (using sensitometric strips). It is essential that film processing is maintained within acceptable limits. The collection of exposure data (Form 1) is necessary to allow a dose survey to be completed using standard software developed for the NHSBSP (NHSBSP Report No 01/10, *Breast Dose Surveys in the NHSBSP: Software and Instruction Manual*⁶).

Extra measurements to supplement the results from the local mammography physics service and from the medical physics group at KCARE are desirable but not essential. These could include routine monitoring of tube output and tube voltage and the evaluation of image quality using standard imaging phantoms.

A record of all quality assurance and constancy measurements over the test period should be kept. The local mammography physics service may be asked to assist in the analysis of these data.

9. DATA COLLECTION AND REPORT PREPARATION

The technical report from the medical physics group at KCARE and from the local medical physics service should be completed and submitted to KCARE within three months of the completion of the clinical evaluation.

The radiographers and radiologists of the breast screening centre performing the evaluation will prepare the clinical report. The radiographic staff at KCARE and at the NHSBSP office can provide assistance in collating the data and guidance in the production of the report. The clinical report should be completed and submitted to KCARE within three months of the completion of the clinical evaluation. If appropriate, exposure data (Form 1) should be forwarded to the National Coordinating Centre for the Physics of Mammography (NCCPM) to allow a dose survey to be completed.

The final report will be produced by KCARE and published and distributed by the MDA.

10. SERVICE AGREEMENT AND CLINICAL EVALUATION FORMS

10.1 Service agreement and information form

The service agreement (Appendix 2) must be completed before the evaluation starts to outline what is required from the centre in terms of the evaluation.

The equipment assessed and evaluation centre information form requires a summary of information about the equipment evaluated and the evaluation centre. Sections 1–3 can be completed at the start of the evaluation and section 4, giving details of the number of examinations, can be completed at the end.

Copies of the service agreement and equipment assessed and evaluation centre information form can be downloaded from the website addresses in section 10.3.

10.2 Clinical evaluation forms

Appendix 3 shows the forms designed for the collection of data during the clinical evaluation. These will need to be completed by the breast screening centre staff. Copies of these forms may be printed from the website addresses shown in section 10.3.

Forms 1–9 are used at different stages during the evaluation as appropriate.

Forms 1, 2 and 3 are used routinely during the evaluation to record exposure and image quality data, depending on the mode of operation of the equipment.

Form 4 (the NHSBSP equipment fault report form) is used each time an equipment fault occurs. The original is forwarded to the National Coordinating Centre for the Physics of Mammography (NCCPM); a copy should be kept with the evaluation data.

Form 5 records details of the mammography sessions during the evaluation. It is particularly important to record this information for screening sessions in order to allow the average examination time per woman to be calculated.

Form 6 records radiographers' observations and findings and should be completed soon after the start of the assessment and again towards the end of the evaluation period. All aspects of the equipment and its operation should be covered, including magnification and stereotactic operation if provided.

Form 7 is the mammography quality assurance record and is used to collect data from routine AEC tests.

Form 8 is the radiologist's or film reader's report. A copy of this form should be completed by at least two radiologists or film readers, preferably

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by each radiologist or film reader reporting on images from the unit, both soon after the start of the assessment and again towards the end of the evaluation period.

Form 9 documents the assessment of image quality and is used by the radiologist or film reader to record data on clinical image quality for a sample of the films from the system under evaluation.

10.3 Website addresses

Service agreement	www.cancerscreening.nhs.uk/ breastscreen/equip/evalserv.pdf
Equipment assessed and evaluation centre information form	www.cancerscreening.nhs.uk/ breastscreen/equip/evalinfo.pdf
Equipment evaluation form 1	www.cancerscreening.nhs.uk/ breastscreen/equip/evalform1.pdf
Equipment evaluation form 2	www.cancerscreening.nhs.uk/ breastscreen/equip/evalform2.pdf
Equipment evaluation form 3	www.cancerscreening.nhs.uk/ breastscreen/equip/evalform3.pdf
Equipment evaluation form 4	www.cancerscreening.nhs.uk/ breastscreen/equip/evalform4.pdf
Equipment evaluation form 5	www.cancerscreening.nhs.uk/ breastscreen/equip/evalform5.pdf
Equipment evaluation form 6	www.cancerscreening.nhs.uk/ breastscreen/equip/evalform6.pdf
Equipment evaluation form 7	www.cancerscreening.nhs.uk/ breastscreen/equip/evalform7.pdf
Equipment evaluation form 8	www.cancerscreening.nhs.uk/ breastscreen/equip/evalform8.pdf
Equipment evaluation form 9	www.cancerscreening.nhs.uk/ breastscreen/equip/evalform9.pdf

APPENDIX 1: EQUIPMENT EVALUATION SUB-GROUP

Membership	Jenny Caseldine Donald Emerton Chris Lawinski Alan Robinson Ken Young	NHSBSP – national office of the NHS Cancer Screening Programmes KCARE – Project manager KCARE – Consultant physicist National Coordinating Group for Equipment – chair NCCPM – Consultant physicist
Remit of the sub-group	This sub-group is responsible to the National Coordinating Group for Equipment. It advises on and determines which equipment is to be evaluated for the NHSBSP and then coordinates and manages the evaluation process.	
Process of evaluation	<p>All equipment suppliers have been advised by letter from the national office that any equipment to be put forward for evaluation should be notified to the NHSBSP, via a member of the Equipment Evaluation Sub-group (contact details below). The sub-group will decide whether it is appropriate to perform an evaluation and will report accordingly to the National Coordinating Group for Equipment. Once the decision to proceed is made, a suitable equipment evaluation centre will be determined in liaison with the individual centres and the suppliers.</p> <p>The Equipment Evaluation Sub-group also acts as the editorial board in producing the final evaluation report.</p>	
Contact details	<p>Mrs J Caseldine NHS Breast Screening Programme The Manor House 260 Ecclesall Road South Sheffield S11 9PS Tel: 0114 271 1060 Fax: 0114 271 1089 E-mail: jenny.caseldine@sheffield-ha.nhs.uk</p> <p>Mr D P Emerton KCARE King's College Hospital Faraday Building Denmark Hill London SE5 9RS Tel: 020 7346 1623 Fax: 020 7346 1631 E-mail: donald.emerton@kingsch.nhs.uk</p>	

Mr C P Lawinski
KCARE
King's College Hospital
Faraday Building
Denmark Hill
London SE5 9RS
Tel: 020 7346 1624
Fax: 020 7346 1631
E-mail: chris.lawinski@kingsch.nhs.uk

Mr A Robinson
Department of Medical Physics and Clinical Technology
Weston Park Hospital
Whitham Road
Sheffield
South Yorkshire S10 2SJ
Tel: 0114 226 5182
Fax: 0114 226 5521
E-mail: alan.robinson@csuh.nhs.uk

Dr K C Young
Radiation Protection Service
St Luke's Wing
Royal Surrey County Hospital
Egerton Road
Guildford
Surrey GU2 7XX
Tel: 01483 406736
Fax: 01483 406742
E-mail: ken_young_98@yahoo.com

APPENDIX 2: SERVICE AGREEMENT AND EQUIPMENT ASSESSED AND EVALUATION CENTRE INFORMATION FORM

The service agreement for the evaluation of equipment for the National Breast Screening Programme and the equipment assessed and evaluation centre information form are overleaf. Copies can be downloaded from the website addresses shown below:

Service agreement	www.cancerscreening.nhs.uk/ breastscreen/equip/evalserv.pdf
Equipment assessed and evaluation centre information form	www.cancerscreening.nhs.uk/ breastscreen/equip/evalinfo.pdf

SERVICE AGREEMENT FOR THE EVALUATION OF EQUIPMENT FOR THE NATIONAL BREAST SCREENING PROGRAMME

Between NHSBSP and breast screening centre _____ Date _____

Equipment to be evaluated _____

1. DESCRIPTION

This agreement covers the evaluation of equipment for use in the National Breast Screening Programme in accordance with the equipment evaluation guidance notes issued by the NHSBSP Equipment Coordinating Committee, a copy of which has been provided to the centre undertaking the work.

2. FEES

The NHSBSP will reimburse the expenses incurred for the additional work undertaken by staff in the evaluation of a unit of mammography x-ray equipment, up to the maximum amounts stated below.

2.1 For the preparation of a report based on an evaluation protocol and data sheets provided by the NHSBSP on equipment installed in a centre by arrangement with the NHSBSP for use by a centre that meets the eligibility criteria set out in the equipment evaluation guidance notes for the specific purpose of providing physical and clinical information that will enable prospective purchasers within the NHS to determine the suitability of the equipment for their intended application.

Negotiable up to £5000

2.2 For the preparation of a report based on an evaluation protocol and data sheets provided by the NHSBSP on equipment installed and used by a centre that meets the eligibility criteria set out in the equipment evaluation guidelines for the benefit of the centre or the equipment supplier.

Negotiable up to £2000

2.3 For other equipment, such as accessories and other ancillary equipment, lesser amounts will be as agreed with the centre before commencement of the contract.

Note. The centre undertaking the evaluation will be responsible for distributing the fees to the various internal groups and external agencies involved in the commissioning, safety and physics checks, clinical use, collation of data and writing of reports.

Evaluation category (please circle): 2.1 2.2 2.3 Fee £ _____

3. PERSONNEL

Contact telephone number

Superintendent radiographer _____

Lead radiologist _____

Breast screening centre project leader _____

Breast screening centre physicist _____

NHSBSP project supervisor _____

KCARE project manager _____

4. TIME SCALE

Projected date of installation _____

Projected duration of evaluation _____

Projected date of completed report _____

Signed: NHSBSP _____

Breast screening centre _____

EQUIPMENT ASSESSED AND EVALUATION CENTRE INFORMATION

1. DETAILS OF EQUIPMENT ASSESSED AND CENTRE

1.1	Equipment model	
1.2	Manufacturer	
1.3	Supplier	
1.4	Serial number(s)	
1.5	Evaluation centre	
1.6	Breast screening centre project leader (including telephone number)	

2. INSTALLATION

2.1	Date of start of installation	
2.2	All adjustments made to suit local radiographic requirements by the installation engineer should be recorded. The engineer should confirm that all adjustments made conform with the manufacturer's installation protocol	
2.2.1	Adjustments to suit local radiographic requirements	
2.2.2	Comment by engineer on adjustments made	
2.3	Date of acceptance for clinical use	
2.4	Date of start of clinical evaluation	
2.5	Date of completion of clinical evaluation	

3. FILM AND FILM HANDLING EQUIPMENT (Note: It is important that these are not changed during the evaluation period)

3.1	Manufacturer and type of film used during the evaluation	
3.2	Manufacturer and model of film processor	
3.3	Processing time dry to dry	
3.4	Developer temperature	
3.5	Manufacturer and type of processing chemicals	
3.6	Make and type of cassettes and screens used during the evaluation	
3.7	Total number of clinical films taken during the evaluation period	
3.8	Total number of sensitometry films taken during the evaluation period	

4. NUMBER OF EXAMINATIONS UNDERTAKEN

4.1	Number of women screened	
4.2	Number of women assessed	
4.3	Number of women examined with magnification	
4.4	Number of stereotactic examinations	

APPENDIX 3: CLINICAL EVALUATION FORMS

There are nine forms in this appendix, starting on the next page. Copies can be downloaded from the website addresses shown below:

Equipment evaluation form 1	www.cancerscreening.nhs.uk/ breastscreen/equip/evalform1.pdf
Equipment evaluation form 2	www.cancerscreening.nhs.uk/ breastscreen/equip/evalform2.pdf
Equipment evaluation form 3	www.cancerscreening.nhs.uk/ breastscreen/equip/evalform3.pdf
Equipment evaluation form 4	www.cancerscreening.nhs.uk/ breastscreen/equip/evalform4.pdf
Equipment evaluation form 5	www.cancerscreening.nhs.uk/ breastscreen/equip/evalform5.pdf
Equipment evaluation form 6	www.cancerscreening.nhs.uk/ breastscreen/equip/evalform6.pdf
Equipment evaluation form 7	www.cancerscreening.nhs.uk/ breastscreen/equip/evalform7.pdf
Equipment evaluation form 8	www.cancerscreening.nhs.uk/ breastscreen/equip/evalform8.pdf
Equipment evaluation form 9	www.cancerscreening.nhs.uk/ breastscreen/equip/evalform9.pdf

NHSBSP EQUIPMENT EVALUATION (FORM 6)

Radiographers' Observations and Findings

A copy of this form should be completed near the start and again towards the end of the evaluation

Unit: _____

Evaluating centre: _____

General	Poor	Satis- factory	Good	Excellent	Comments
1. How good was the operator's manual?					
2. How good was the user training provided by the supplier?					
3. 3.1 How do you rate the unit's ease of use? 3.2 How do you rate the unit's help in minimising fatigue?					
4. Were the x-ray exposure times acceptable? (If not, explain, eg hit backup timer frequently.)					
5. Setting for radiographic views: 5.1 How do you rate the rotation of the support arm? 5.2 How do you rate the visibility of the set angle?					
6. Setting position of breast support table: 6.1 How do you rate the facility for positioning the height of the breast support table?					
7. Range of movements: 7.1 How do you rate the adequacy of the range of movements offered by the unit?					
8. Compression 8.1 How effective was the compression system? 8.2 How good was the visibility of compression force from breast support table?					

General	Poor	Satisfactory	Good	Excellent	Comments
9. AEC detector positioning: 9.1 Ease of setting? 9.2 Adequacy of detector position options?					
10. Visibility of AEC detector marking					
11. Ease of insertion and removal of cassettes					
12. Performance of supplied radiographic view markers					
13. Effectiveness of brakes: 13.1 How well did the brakes work? (eg was there any backlash or movement?)					
14. Comfort of women: 14.1 Did the women experience excessive discomfort or pain? 14.2 Were there any sharp corners, etc?					
15. Range of controls and indicators: 15.1 Were all the expected controls present? 15.2 Were they easy to find and use?					
16. How do you rate the choice of collimators supplied for spot compression?					
17. Confidence of good results: 17.1 What was your level of confidence in the machine?					
18. Hazards: 18.1 Were there any potentially hazardous areas (eg hot spots) accessible to either you or the woman?					

General	Poor	Satisfactory	Good	Excellent	Comments
19. Equipment cleaning: 19.1 Ease of cleaning the machine? 19.2 Were there instructions in the manual?					Yes/no
20. Patient and exposure data and postexposure printout facility (if available)					
21. Did the performance of the x-ray set limit patient throughput? (If so, say why, eg to allow for cooling.)					Yes/no
22. Overall film quality: 22.1 How would you rate the image quality of films taken on this unit?					
23. Relative image quality: 23.1 Was the image quality attained by this unit better, worse or the same as that by other units?	Worse	Same	Better		
Any additional comments on general performance:					

Magnification	Poor	Satisfactory	Good	Excellent	Comments
1. Rate the ease with which the magnification equipment may be assembled and dismantled					
2. Rate the ease of use of the magnification breast support table					
3. Grade how the magnification support table performs					
4. Visibility of indication of focal spot size selected?					
5. Removal and insertion of collimator plates: 5.1 Range of collimators 5.2 Operation of automatic diaphragms					

Stereo	Poor	Satisfactory	Good	Excellent	Comments
1. Rate the ease with which stereotactic equipment may be assembled and dismantled					
2. How easy is the stereo to clean?					
3. Ease of rotation of support arm with stereo assembly fitted?					
4. Overall, how easy to use was the stereo assembly?					
5. Comment on the accuracy of the stereo in needle positioning					

NHSBSP EQUIPMENT EVALUATION (FORM 8)

Radiologist's or Film Reader's Report

Unit: _____ Evaluating centre: _____

At least two and preferably all the radiologists, or other film readers reporting films produced on this unit, are asked to provide subjective opinions on image quality and to rate the unit's performance against other mammographic units of their experience. In order to judge whether their opinions on performance have changed over the assessment period, a copy of this form should be completed near the start and again towards the end of the evaluation.

Date: _____

Radiologist's name or code: _____

Type and make of viewer used: _____

Summary data on subjective opinions of the diagnostic quality of films viewed (enter approximate number of films in boxes):

	Excellent	Good	Satisfactory	Poor	Inadequate
Full size	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Magnified (if applicable)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Reasons for films of inadequate image quality (enter approximate number of films in boxes):

Exposure factors

Positioning

Movement blur

Other

State reason: _____

Form 9 may be used to grade different aspects of film quality for a sample of films for the system under evaluation.

REFERENCES

1. *The Ionising Radiations Regulations 1999*. Statutory Instrument 1999 No 3232: HMSO, 1999.
2. *Quality Assurance Guidelines for Medical Physics Services*. NHS Breast Screening Programme, 1995 (NHSBSP Publication No 33).
3. *The Commissioning and Routine Testing of Mammographic X-ray Systems*. Institute of Physical Sciences in Medicine, 1994 (IPSM Report No 59, 2nd edition) (under revision).
4. *Further Revisions to Guidance Notes for Health Authorities and NHS Trusts on Mammographic X-ray Systems for Breast Screening*. Medical Devices Agency, 2001 (MDA Evaluation Report MDA 01011).
5. *Radiographic Quality Control Manual for Radiography*. NHS Breast Screening Programme, 1999 (NHSBSP Publication No 21).
6. *Breast Dose Surveys in the NHSBSP: Software and Instruction Manual*. NHS Cancer Screening Programmes, 2001 (NHSBSP Report No 01/10).

