Screening mammography technology

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Any comments or information relevant to the subject matter of this report would be welcome. Correspondence should be directed to:

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Foreword

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Work on this report was undertaken in response to a request from the Breast Cancer Screening Evaluation Coordination Committee of the Australian Health Ministers' Advisory Council. The Committee requested advice on technological aspects of breast cancer screening.

As well as serving as a source of information for the current Australian breast cancer evaluation program, the report is intended to be used as a guide to assist in future decisions on equipment for screening mammography.

The report was prepared by a Working Party comprising:

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Executive summary

- At present, mammography is the only proven technique suitable for breast cancer screening. Film-screen mammography is the modality of choice.
- In 1989 there were at least 267 mammography units in Australia. Data are not available on the proportion of these which would be available for use in screening.
- Specifications for screening (and assessment) mammography units are given in Table 1 of this report. They should be taken as guidelines only and not mandatory requirements.
- The Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) has prepared guidelines for quality control of equipment performance in mammography screening, entitled 'A quality assurance programme for mass screening in mammography'. A summary is given in Tables 4 and 5 of this report.
- The Working Party **recommends** that:
 - the specifications for screening mammography units given in this report should be used as guidelines in the selection of units for screening programs in Australia;
 - these specifications should be kept under review;
 - subject to the formal approval of the Royal Australasian College of Radiologists, the ACPSEM document 'A quality assurance programme for mass screening in mammography' should be adopted as the official guidelines for quality control of equipment performance in screening mammography programs in Australia.

3.4

Introduction

The Breast Cancer Screening Evaluation Coordination Committee of the Australian Health Ministers' Advisory Council (AHMAC) is currently coordinating a national program for the evaluation of breast cancer screening pilot projects. In the context of this program, the Committee asked the Health Technology Unit of the Australian Institute of Health (AIH) to provide advice on technological aspects of breast cancer screening, as an update to the report Screening mammography services published by the National Health Technology Advisory Panel (NHTAP) in March 1988(1).

In particular, the Committee sought advice on the advantages of film-screen mammography in comparison with other possible techniques for breast cancer screening, specifications for screening mammography units, existing equipment in Australia and quality assurance requirements.

This report has been prepared in response to the Committee's request by a Working Party comprising AIH officers and experts drawn from the fields of radiology, radiography and medical physics. While the report is focused primarily on technology for screening tests, it should be noted that a screening program encompasses follow-up assessment, including further mammography for the assessment of abnormalities detected in screening tests.

Mammography techniques

The film-screen process is currently the most widely used form of mammography. In this technique, a fluorescent screen converts X-rays transmitted through the breast into visible light, which exposes the X-ray film. Processing of the film gives the image. Because the film is more sensitive to visible light than to X-rays, the use of the screen enables good film exposure with a lower radiation dose. Earlier methods which used film without fluorescent screens resulted in excessive patient doses.

Xeromammography is an alternative technique once used extensively in mammography. It involves the use of a charged photoconductive plate in place of X-ray film. Ionising radiation striking the plate selectively discharges the photoconductor, yielding a latent image that is visualised with toner and transferred to paper.

Film-screen mammography has become the more popular technique largely because xeromammography gives a higher radiation dose to small and average size breasts. An Australian study has indicated that the dose with xeromammography can be three times as high as that with the film-screen technique. Xeromammographic systems developed more recently have been reported to give a reduced radiation dose (9). However, the manufacturers, Xerox, have ceased production of xeromammography units, and this imaging process is little used in Australia at present.

Digital imaging could be applied to mammography either by digitising the film image or by direct digital recording. As yet, these techniques have not been applied in routine clinical operation, but they are being developed for mammography and could have a major impact. There is a need for the AIH to maintain a watching brief on developments in this field.

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Mammography in comparison with other possible breast cancer screening techniques

Comparison with physical examination

In the past, the initial detection of breast cancer has generally been through breast self-examination or clinical examination. The major advantage of mammography in comparison with physical examination is that it is able to detect breast cancer at a much earlier, non-palpable stage. A large proportion of mammographically detected breast cancers are not palpable. Mammography has higher sensitivity and specificity than physical examination.

Early detection of breast cancer allows earlier, less radical treatment. Results from overseas trials indicate that mammography screening programs reduce mortality from breast cancer_(4,5).

Comparison with other imaging techniques

A number of other imaging technologies have been considered for use in the diagnosis of breast cancer. These include ultrasound, transillumination light scanning, thermography, computed tomography, and magnetic resonance imaging.

Ultrasound has an important function in the evaluation of established breast abnormalities, primarily in the differentiation of cystic from solid breast lesions. However, it has severe limitations. It is significantly less sensitive than mammography for the detection of cancers smaller than one cm, and it cannot reliably distinguish between benign and malignant solid masses. The available data fail to support the use of ultrasound as a primary screening tool₍₆₎.

Transillumination light scanning uses far-red and near-infrared light transmissions to scan breast tissues. The basic premise for its use is that cancer tissue absorbs more light at these wavelengths than normal tissue because of its increased blood supply, and can be distinguished on the light scan.

Although early results with this technique were favourable, later studies indicated that its sensitivity was well below that of mammography. It performed particularly poorly in the detection of cancers smaller than one cm in diameter₍₆₎.

The US Office of Health Technology Assessment undertook an assessment of transillumination light scanning in 1988. The Office reported that the National Cancer Institute, the American Cancer Society and the American College of Radiology considered that it should not be regarded as a substitute for mammography, and was still in the investigational phase(7).

Thermography is a technique for imaging temperature differences on the surface of the body. It has been investigated as a means of diagnosing breast cancer but results have been poor (50 per cent sensitivity and 70 per cent specificity). In addition, there are practical problems associated with the need for stabilising surface body temperature before measurement_(8,9).

Computed tomography is currently attracting little interest as a screening tool for breast cancer. Its low sensitivity, high cost and relatively high radiation dose in comparison with mammography make it unsuitable for this application.

Magnetic resonance imaging has been shown to be less accurate than mammography in the detection of breast cancer (10). In particular, it is unable to detect early disease(6). Its high cost and long examination times would make it unsuitable for use as a screening tool.

Comparison with immunological techniques

Immunological techniques based on monoclonal antibodies (MCAs) are being investigated for use in the detection of breast and other cancers. Studies have been undertaken on the use of MCAs in serum testing, immunohistologic testing and radioimmuno detection techniques. Of these, only serum testing techniques would be suitable for screening asymptomatic women for breast cancer.

In serum testing, the MCA is used to determine the level in the serum of a particular antigen associated with breast cancer, with a certain level chosen as the criterion for a positive result. Many MCA- antigen combinations have been investigated, but in most cases they have given poor results in the detection of early cancer. More promising results have been obtained for a test involving the use of an MCA termed 3E1-2 to detect the serum level of mammary serum antigen (MSA). Using a level of 300 units or greater as the criterion for a positive result, the test detected the presence of breast cancer in 69-72 per cent of Stage I and 78-82 per cent of Stage II cases(11,12). There was a false positive rate of 2 per cent in tests on serum samples from apparently normal individuals, 18 per cent for patients with benign breast disease(12).

In a study by Hare et al $_{\rm (13)}$, the MSA test was compared with two-view xeromammography in a study of 97 symptomatic patients (37 with Stage I or II breast cancer and 60 with benign breast disease). The MSA test gave superior results in the detection of breast cancer in this study. The MSA test had a sensitivity of 76 per cent for the detection of Stage I and II breast cancers, while the mammographic technique had a sensitivity of 54 per cent. The mammography results in this study were particularly poor, indicating that the technique used had a sensitivity well below that of modern film-screen techniques. The study had the limitation that only symptomatic women were studied, and gives no information on the usefulness of the MCA test as a screening technique.

It is possible that future tests based on new MCAs will have greater sensitivity and specificity, with improved prospects for application in breast cancer screening. At the present time, the value of MCA-based serum tests in screening programs involving large numbers of asymptomatic women has not been determined.

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Specifications for mammography units

Mammography systems are required to give images with high contrast between normal and abnormal soft tissue, and high resolution, while at the same time delivering a low radiation dose. To fulfil these requirements, a number of design specifications need to be met.

The 1988 NHTAP report 'Screening mammography services' (1) listed suggested specifications for screening and diagnostic units. The Working Party considers that some amendments are now necessary to the list. The updated specifications are given in Table 1. They are intended to provide a guide for the purchase of new equipment and should not be regarded as mandatory requirements for mammography in future screening programs. It is recognised that excellent results may be obtained with older equipment which do not fully meet the specifications.

The specifications and related technical matters are discussed below. Appendix 1 gives specifications for some of the mammography units marketed in Australia.

X-ray generators

The X-ray generator of a mammographic unit transforms mains alternating voltage to rectified high voltage required for the X-ray tube. Generators may require power from either single or three phase sources. With a single phase generator operating at low frequency the tube voltage fluctuates, affecting the X-ray energies produced and the exposure time. Fluctuations in tube voltage are greatly reduced by use of three phase generators.

Recently, medium to high frequency microprocessor-controlled generators have come into use for mammography. They are reported to give nearly constant tube voltage from single or three phase sources.

Target material and beam filtration

Image contrast in film–screen mammography is strongly influenced by the energy distribution of the photons produced by the X–ray tube. It is optimal with photons of effective energy in the range of 16–23 keV(14). These conditions are usually achieved by the use of a molybdenum target X–ray tube operated at low voltage (typically less than 30 kVp), with a beryllium window to allow the exit of low energy radiation from the tube, and a molybdenum filter placed in the beam. The resulting X–ray spectrum is dominated by k–characteristic radiation from the molybdenum target at energies of 17.4 and 19.6 keV.

A tungsten target produces a broader spectrum which has more high energy photons than molybdenum. Either aluminium or 'rare earth' filters (such as rhodium) are used to modify the spectrum. Rhodium filtration will give a spectrum very similar to that of molybdenum with the peak at the slightly higher energy of approximately 23 keV. If an aluminium filter is used, the film–screen images may have reduced contrast. There is evidence that tungsten targets with specific 'rare earth' filters such as rhodium will give reduced mammographic dose without loss of contrast for larger breast sections(14,15,16). The performance of these systems has not been fully demonstrated in clinical use and few units of this type are in operation. However, it is considered that a tungsten target would be acceptable if it could be demonstrated that there is no loss of image quality compared with a suitable molybdenum target.

Focal spot size

The area of the X-ray tube anode that emits X-rays is called the focal spot. Its size is a major factor influencing image sharpness; the smaller the spot the sharper the image. For screening purposes a nominal focal spot no larger than 0.4 mm is suitable. For magnification mammography, an ultrafine focal spot, in the region of 0.1-0.15 mm, is essential.

Heat load capacity

It is desirable to maintain a high patient throughput through a screening unit to optimise cost benefit. When considering throughput, it is important to take into account the heat load capacity of the X-ray tube and the housing. It should be high enough to permit the required level of usage without damage to the anode.

Tube current

Film image density is determined by the selected X-ray energy and the product of tube current and exposure time. Exposure time should be as short as possible in order to minimise motion blurring. Consequently it is important that tube current should be maximised to allow appropriate exposure times (typically less than two seconds).

The generator output, X-ray tube loading, and focal spot size determine the maximum current which can be used. As focal spot size is reduced, the maximum current available falls owing to problems of heat generation. For example, in a system with dual or triple focus tubes, and a generator capable of producing 100 mA, the maximum current available for an exposure may be well below 100mA when the finer focal spots are used.

Focus film distance

In principle, it is advantageous to maximise the focus film distance (FFD), as image definition is improved by increased FFD through the reduction of geometric blurring. If FFD is increased, the tube current must be increased to achieve the same film image density in the same X-ray exposure time, or exposure time must be increased if tube current is held constant. It is essential that when a long FFD is used, the tube current should be high enough to keep exposure times low (preferably less than two seconds).

Radiation field size

The radiation field size which is possible is determined by the FFD and the tube target angle. All screening mammography units should provide coverage for a film size of 18x24 cm and preferably up to 24x30 cm.

Automatic exposure control

Automatic exposure control (AEC) devices automatically adjust the length of an exposure so that a pre-selected amount of radiation strikes the film. There have been problems with the accuracy of AEC devices used in older mammography units, and in 1986 a Mammography Users Guide published by the US National Council on Radiation Protection did not recommend their use(17).

The accuracy and reproducibility of these devices have been greatly improved in the most recent generation of mammographic units, and many models now include microprocessors in their AEC systems (18). Microprocessor-controlled AEC devices can automatically correct for thickness and density of the breast so that manual corrections based on estimates of breast density are no longer necessary. Effective automatic exposure control, preferably microprocessor controlled, is essential in a screening program.

In some cases it may be possible to update the exposure control of older mammography units by fitting automatic devices with limited capability, but in general older mammography units cannot be updated to incorporate the latest microprocessor–controlled AEC devices.

Magnification

For assessment mammography, including work up of cases giving a positive result in a screening test, a capacity for magnification is essential. However, the Working Party supports the view expressed by the NHTAP (1) that it is not necessary for a screening unit.

In magnification mammography a small focal spot is used and the object-film distance is increased. The resulting enlarged X-ray pattern gives an improvement in effective resolution with reduced noise and radiation scatter. The high resolution image may contain more diagnostic information, with the result that the number of unnecessary biopsies may be reduced. However, the exposure time and radiation dose are increased(19,20). The optimum magnification may vary according to the equipment and accessories used and ranges between 1.5 and 2.2.

Breast compression

Vigorous breast compression is required in mammography to reduce geometric blurring, improve contrast by reducing radiation scatter, lessen the chances of motion blurring, achieve more uniform film density, give better visualisation of lesions, provide a more accurate assessment of the density of masses, and reduce the radiation dose(3,17,19,20).

The compression device for film-screen mammography should have a flat base. The edge towards the chest wall should be straight rather than curved and should form a 90 degree angle with the base (19). There should be a stiff support table (1). It is considered essential for the device to be motorised and foot controlled, leaving the radiographer's hands free for patient positioning. Manual fine tuning should be possible for final compression, to avoid excessive discomfort or injury for the patient (19).

A device for compression of a specific region (spot compression) of the breast is essential for assessment units. Such devices are often used in conjunction with magnification. The Working Party supports the NHTAP view that they are not required for screening(1).

Film sizes

Although most patients' breasts can be accommodated on 18x24 cm film, a small percentage require 24x30 cm film for all tissue to be imaged on one exposure (19). The alternative to using larger film is to provide full coverage by making several exposures, at the cost of increased radiation dose. Screening units should have the capacity to use film of both sizes.

Use of grids

The use of specifically designed grids for mammography can reduce scattered radiation and improve subject contrast, which is especially significant when imaging thick dense breasts(20). When grids are used, the radiographic exposure will need to be increased by a factor of about two, resulting in a corresponding increase in the radiation dose.

It is possible to offset the increased radiation dose by using a higher voltage setting, higher speed film–screen systems, or a combination of these(19). Nevertheless, it is fundamental to good mammography that a voltage setting as low as possible should be used.

General purpose moving grids should not be used in mammography because of the high absorption of X-rays by their interspace material and the inherently large object-film distance. Grids specially designed for mammography are available. They are thinner and contain interspace material of low absorption such as carbon fibre.

A moving grid is activated by initiation of a radiographic exposure. As a result of the movement, the lines of the grid are blurred on the film and are usually undetectable, although they may occasionally be observed with long or very short exposures.

Mammography units without grids may be retrofitted with either stationary or moving grids. Where grids are used, it is desirable that they should be available for both 18x24 cm and 24x30 cm film sizes.

Stationary grids with very fine ultra-high density lines (80 lines/cm) are now available. The lines are not visible on the mammogram to the naked eye. These grids have been demonstrated to have a 64 per cent contrast improvement factor and to increase patient exposure 2.7 times (17,21).

Although the use of grids in assessment mammography is considered essential, opinions have differed on their desirability in screening mammography. The Working Party believes that it is increasingly becoming accepted practice to use grids in screening and supports the view that their use is preferred.

Film type and processing

The relationship between the X-ray intensity pattern and the optical density pattern finally observed in the mammogram will depend on many factors. These include film type (high or low contrast), processing conditions such as types of solution, temperature, and time, and fog level, which is affected by storage conditions, safelight, and light leaks(20).

Mammography normally uses single emulsion film with one intensifying back screen, whereas double emulsion film with two screens is used in conventional radiography. For mammography, it is essential to have a film processor specially set up to process single emulsion film $_{(1,18)}$. Development time and fluid replenishment rate must be optimised for mammography films. The radiation dose to patients can be substantially reduced if optimal conditions are used $_{(18)}$.

For the processing of single emulsion mammographic film, Tabar has recommended specific extended development times, temperatures, and replenishment rates(1,22). These recommendations were developed on the basis of a particular film type and brand, processed with specific chemicals. Research has since shown that the various new dedicated mammographic films require different development times, temperatures, and replenishment rates if optimal results are to be achieved. These processing steps usually include extended development times, though often of shorter duration than those recommended by Tabar. There is a need to take care to establish the optimal conditions for each type and brand of film used.

Recently, a new high–speed, two–screen double emulsion screen–film combination for mammography has been introduced. It has been designed for use when grid or magnification techniques result in excessively long exposure times. However, it may have limited usefulness in other situations, as it has slightly lower resolution and higher noise than single emulsion film(20).

Film loading, unloading and identification

Loading, unloading and identification of film are basic radiographic procedures. There is no set protocol for loading and unloading, details of which will vary according to the type of cassette and processing method used. Film identification equipment should be of a type that allows for identification to be carried out by the radiographer who radiographed the patient.

Automated loading/unloading systems for mammography would have advantages as their use would eliminate finger/pressure marks on film, reduce the incidence of dust and other particles, and reduce work load and operator fatigue. Use of these systems should be kept under review.

Film viewing

The NHTAP report (1) noted the advantages of motorised viewing devices with multiple screens for reading films. The Working Party considers that the use of these devices would be highly desirable in a screening program, though not essential, to facilitate rapid interpretation of mammograms.

Table 1: Suggested specifications for mammography units

Note: This table is intended only as a guide for the purchase of new equipment. The suggested specifications should not be seen as mandatory requirements for equipment in any future screening program.

Specifications	Screening	Assessment
Target material	molybdenum	molybdenum
Nominal focal spot size	0.3 to 0.4	0.3 to 0.4 (regular) 0.1 to 0.15 (magnification)
Maximum output	100mA	100mA (regular focal spot)
Filtration	beryllium window molybdenum filter aluminium filter with reversible interlock over 35kVp	beryllium window molybdenum filter aluminium filter with reversible interlock over 35kVp
Automatic exposure control	essential	essential
Microprocessor control of automatic exposure	highly desirable	highly desirable
Magnification	not necessary	essential (1.5 to 2.2 times)
Motorised compression device with foot pedal (both directions) with quick release	essential	essential
Stiff support table (distorting less than 1mm under full compression)	essential	essential
Spot compression device	not necessary	essential
Stationary or moving grid	desirable	essential
Heat load capacity	important consider- ation (see text)	not critical
Film size	18x24cm essential, 24x30 desirable	18x24cm essential, 24x30 not critical
Dedicated single emulsion processor (cycle tailored to mammography film in use)	essential	essential

Existing mammography units in Australia

The Australian Radiation Laboratory (ARL) has undertaken a survey of radiology practices to collect information on mammography units operating in Australia. The survey identified 267 mammography units. Response to the survey was incomplete, and the ARL estimates that this figure represents about 90 per cent of the total number of units. Thus it seems likely that close to 300 mammography units are operating in Australia. Table 2 gives the distribution by State and Territory of the units identified in the ARL survey. Table 3 gives information on the brands of units being used.

The ARL survey did not provide information on the availability of the mammography units for screening. It cannot be assumed that they would be available for a screening program. Machine time may already be fully taken up with diagnostic or assessment work, or the operators may not wish to undertake screening tests.

Table 2: Distribution of mammography units by State/Territory

State	Number of units
New South Wales	89
Victoria	80
Queensland	48
South Australia	19
Western Australia	13
Tasmania	8
Australian Capital Territory	6
Northern Territory	4
Total	267

Source:

Australian Radiation Laboratory, unpublished data.

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Table 3: Brands of mammography units in Australia

Brand of unit	Number of units
CGR (Senographe now marketed by General Electric)	107
Soredex	36
Toshiba	24
Philips	22
Siemens	18
Acoma	15
Bennett	10
Lo-rad	8
Fischer	7
Elscint	6
General Electric	5
Metaltronics	3
Instrumentarium	2
GM-Merate	2
GEC	1
Xerox	1

Source:

Australian Radiation Laboratory, unpublished data.

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Quality assurance

If mammography screening is to meet the goal of contributing effectively to women's health, it is essential that quality control mechanisms are established to ensure reliable equipment performance, high quality images, and accurate interpretation.

The Australian College of Physical Scientists and Engineers in Medicine (ACPSEM) has prepared an official statement, *A quality assurance programme for mass screening in mammography* which provides guidelines for quality control of equipment performance in mammography screening(18). The paper identifies the components of a quality assurance program, the parameters to be tested, and the equipment required. The document covers acceptance testing, involving tests of all aspects of equipment performance after initial installation, routine quality control tests and checks to be undertaken regularly by a radiographer, and full quality control testing to be undertaken by a physicist at appropriate intervals (at least annually) or after any event that might alter the performance of the unit.

Table 4 gives the ACPSEM list of items to be tested. It is closely similar to the list included in the 1988 NHTAP report(1). Table 5 lists the equipment required in a comprehensive quality assurance program, as identified by the ACPSEM, with some additional specifications for the equipment suggested by this Working Party.

In relation to absorbed dose measurement, the College notes that mean absorbed dose to glandular tissue is the accepted dose measurement for mammography(17,18). For comparative assessment, however, the use of skin absorbed dose may be useful, provided a standard phantom is used by all centres involved. Consequently, the College has stressed the need for screening centres to use the same phantom and voltage setting to ensure that there can be meaningful comparisons of image quality and absorbed dose index between centres. The College recommends the CIRS Model X phantom(18).

The Working Party notes that an Australian phantom is being developed which may meet requirements at a lower cost. It is suggested that this development should be kept under review.

The ACPSEM document does not cover quality control of interpretation of mammograms. The Working Party notes the importance of assessing performance in the interpretation of mammograms, to ensure that false positives and recalls are minimised. This matter is being addressed by other bodies.

It is recommended that, subject to the formal approval of the Royal Australian College of Radiologists (RACR), the ACPSEM document should be adopted as the official guidelines for quality assurance of equipment performance in screening mammography programs in Australia.

Table 4: Technical items to be evaluated in a quality assurance program

Item	Specification	Frequency of evaluation
Mammographic unit		
Focal spot	dual, 0.1 to 0.15mm and 0.3 to 0.4 mm typically	acceptance, tube change, annually
Leakage radiation	≤ 1 mGy/h at 1m from housing when maximum continuous rated technique factors used.	acceptance, tube change
	≤ 20 µGy/h at 5cm from the cone on the chest wall margin	
Half value layer	> 0.3 mm A1 at 30 kVp	acceptance, tube change annually
Filter choice	0.03 mm Mo	acceptance, tube change
kVp interlock	ensures Mo filter used at kVp ≤ 35	acceptance, tube change, annually
Light/X-ray field alignment	± 5mm of each other on all margins and not overlapping cassette holder on chest wall	acceptance, tube change, annually
Compression device	should not be curved or mildly contoured	acceptance, annually
Output reproducibility	coefficient of variation $\leq 5\%$	acceptance, tube change, annually
Output linearity	coefficient of linearity ≤ 0.1	acceptance, tube change, annually
Timer accuracy	≤ 5%	acceptance, annually
Timer reproducibility	coefficient of variation $\leq 5\%$	acceptance, annually
kVp accuracy	≤ 2 kVp	acceptance, tube change, annually
kVp reproducibility	≤ 1 kVp or coefficient of variation < 5%	acceptance, tube change, annually
Automatic exposure con	trol	
Reproducibility	coefficient of variation $\leq 5\%$	acceptance, tube change, annually
Minimum response time	≤ 0.1 second	acceptance, annually
Backup timer	either operator set or < 2000 mAs	acceptance, annually
Beam quality	$OD = 1.4 \pm 0.2$	acceptance, annually
Routine quality control	tests	
Assessment of image quality – step wedge radiograph – imaging of breast phantom		weekly weekly
Dose calculations		annually
Screens, films and cassettes - screen efficiency (≤ 10% va - general screen conditions	uriation)	every 3 to 6 months every 3 to 6 months
Film processor - sensitometry - temperature and other open	rating conditions	daily daily
Viewing boxes – intra– and inter–box consis image marking and ambient	stency of light output with time; light control capability	acceptance, annually

Source:

Adapted from ACPSEM Position Paper (18)

Table 5: Quality assurance test equipment

Item	Description and requirements
Electrometer	must measure in integrate mode, should be a 31/2 digit device
Ion chamber	thin window chamber with a flat response down to 10 keV leakage chamber ideally capable of measuring down to 0.02 μGy
kVp meter	must be capable of measurement down to 24 kVp with Mo anode, and accuracy of 1 kVp $$
Timer	accurate to 0.1 second
Star pattern	0.5 or 1 degree pattern
Filter	0.1mm, 0.3mm. Type 1100 A1
Phantoms	i) perspex step wedge ii) breast phantom with inclusions mimicking clinical conditions
Sensitometer	sensitivity to blue and green. Should have 21 steps
Densitometer	should give readings in the range 0 to 3.0 optical density units and have its own light source

Source: Adapted from ACPSEM Position Paper (18)

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Conclusions and recommendations

The Working Party considers that at present mammography is the only appropriate technology for breast cancer screening programs. It is the only technology with proven advantages over breast self–examination and clinical examination.

The Working Party recommends that the specifications for screening mammography units given in this report should be used as guidelines in the selection of units for screening programs in Australia.

The Working Party supports the adoption of the ACPSEM document *A quality assurance program for mass screening in mammography* as the official guidelines for quality control of equipment performance in screening mammography programs in Australia.

1

References

- 1. National Health Technology Advisory Panel. Screening mammography services. Australian Institute of Health, Canberra, March 1988
- 2. Colgan JP, O'Reilly PA. Statewide midline depth dose intercomparison between dedicated film–screen and xerox mammography units. *Australasian Radiology* 1984;28;372–375
- 3. ECRI. Mammography units. *Health Devices* 1989;18:3–53
- 4. Shapiro S, Venet W, Strax P, Venet L, Roeser R. Ten to fourteen-year effect of screening for breast cancer on mortality. *J Nat Cancer Institute* 1982;69: 349-355
- 5. Tabar L, Fagerberg CJG, Eklund G et al. Reduction in mortality from breast cancer after mass screening with mammography. *Lancet* 1985:829–832
- 6. Kopans DB. Non-mammographic breast imaging techniques: current status and future developments. *Radiol Clin North Am* 1987;25:961–970
- 7. US National Centre for Health Services Research and Health Care Technology Assessment. Reassessment of transillumination light scanning for the diagnosis of breast cancer. Health Technology Assessment Reports, US Department of Health and Human Services, 1988
- 8. Health and Public Policy Committee, American College of Physicians. The use of diagnostic tests for screening and evaluating breast lesions. *Ann Intern Med* 1985;103:143–6
- 9. Mushlin AI. Diagnostic tests in breast cancer. Ann Intern Med 1985;103:79-85
- 10. Turner DA, Alcorn FS, Adler YS. Nuclear magnetic resonance in the diagnosis of breast cancer. *Radiol Clin North Am* 1988;26:673–687
- 11. Tjandra JJ, McKenzie IFC. Murine monoclonal antibodies in breast cancer: an overview. *Br J Surg* 1988;75:1067–1077
- 12. Stacker SA, Thompson CH, Sacks NPM et al. Detection of mammary serum antigen in sera from breast cancer patients using monoclonal antibody 3E1–2. *Cancer Research* 1988;48:7060–7066
- 13. Hare WSC, Tjandra JJ, Russell IS, Collins JP, McKenzie IFC. Comparison of mammary serum antigen assay with mammography in patients with breast cancer. *Med J Aust* 1988;149:402–406
- 14. Beaman S, Lillicrap SC, Price JL. Tungsten anode tubes with K-edge filters for mammography. *Br J Radiol* 1983;56:721–727
- 15. McDonagh CP, Leake JL, Beaman SA. Optimum x-ray spectra for mammography: choice of K-edge filters for tungsten anode tubes. *Phys Med Biol* 1984;29:249-252
- 16. Jennings RJ, Eastgate RJ, Siedband MP, Ergun DL. Optimal x-ray spectra for screen-film mammography. *Med Phys* 1981;8:629–639
- 17. National Council on Radiation Protection and Measurements. *Mammography a user's guide*. NCRP, Bethesda, Maryland, USA. 1986
- ACPSEM position paper. A quality assurance program for mass screening in mammography. Australas Phys Eng Sci Med 1989;12:252–259
- 19. Feig SA. Mammography equipment: principles, features, selection. *Radiol Clin North Am* 1987;25:897–911
- 20. Haus AG. Recent advances in screen-film mammography. *Radiol Clin North Am* 1987;25:913–928
- 21. Chan HP et al. Ultra-high-strip-density radiographic grids: a new antiscatter technique for mammography. *Radiology* 1985;154:807–815
- 22. Tabar L, Haus AG. Processing of mammographic films: technical and clinical considerations. *Radiology* 1989;173:65–69

Appendix 1

Specifications of some mammography units available in Australia

Specifications of some mammography units available in Australia—continued

	Acoma ESP-200	Senographe 600TS	Senographe 600T	Serographe 500TS	Senographe 500T
Australian distributor	Solus Medical Imaging	GE Medical Systems	GE Medical Systems	GE Medical Systems	GE Medical Systems
Approx cost (\$A)	\$A89,000 standard unit	\$A95,000 with optional accesso- ries	\$A125,000 with optional accesso- ries	\$A90,000 with optional accesso- ries	\$A115,000 with optional accesso- nes
Power supply and generator type	single phase high fre- quency	single phase high fre- quency	single phase high fre- quency	single phase high frequency	single phase high frequency
Target material	molybdenum	molybdenum	molybdenum	molybdenum	molybdenum
Focal spot size (mm)	0.1 and 0.3	0.3	0.1 and 0.3	0.3	0.1 and 0.3
Maximum output	110mA	100mA	100mA	100mA	100mA
Filtration	molybdenum/alumi- nium	molybdenum<36kV aluminium>36kV	$molybdenum{<}36mV\\aluminium{>}36kV$	molybdenum<36kV aluminium>36kV	molybdenum<36kV aluminium>36kV
Auto exposure control - with microprocessor	yes yes	yes yes	yes yes	yes yes	yes yes
Magnification	1.5x or 2.0x	no	1.85x and 1.5x	no	1.85x
Compression device	motorised/manual adjustment	pneumatic	pneumatic	manual	manual
Grid type	moving	moving-optional	moving-optional	moving-optional	moving-optional
Film size	18x24, 24x30	18x24, 24x30	18x24, 24x30	18x24, 24x30	18x24, 24x30

Specifications of some mammography units available in Australia-continued

	Lorad D-450	Lorad M-II	Lorad Transpo 365	Lorad M-III	Elscint Man IS-3
Australian distributor	Picker Australia	Picker Australia	Picker Australia	Picker Australia	Elscint Aust
Approx cost	\$A78,000	\$A95,000	\$A115,000	\$A105,000	\$A80,000-\$A85,000 with options
Power supply and generator type	Power supply and gen-single phase high fre-single phase high fre-erator type quency (22.5kHz) quency (22.5kHz)	single phase high fre- quency (22.5kHz)	single phase high fre-single phase high fre- quency (22.5kHz) quency (22.5kHz)	single phase high fre- quency (22.5kHz)	single phase full wave
Target material	molybdenum	molybdenum	molybdenum	molybdenum	tungsten
Focal spot size (mm)	0.1 and 0.3	0.3 (M-IIS) 0.1 and 0.3 (MIE)	0.1 and 0.3	0.1 and 0.3	0.09 and 0.45
Maximum output	50mA	100mA	100mA	100mA	20mA
Filtration	molybdenum	molybdenum	molybdenum/alumininum	molybdenum	aluminium 0.45mm 22~30kVp 0.58mm 31~49kVp 1.62mm 50~60kVp
Auto exposure control - with microprocessor	yes yes	yes yes	yes yes	yes yes	optional no
Magnification	1.8x	1.8x	1.8x	1.8x	1.5x and 2.0x
Compression device	motorised/manual	motorised/manual	motorised/manual	motorised/manual	motorised
grid type	stationary and moving – optional	stationary and moving – optional	stationary and moving – optional	moving (stationary op-tional)	stationary or moving – optional
Film size	18x24, 24x30	18x24, 24x30	18x24, 24x30	18x24, 24x30	18x24, 24x30

Note: Costs included in this table are approximate and apply only at the time of preparation of this report. The optional accessones included in the quoted cost may vary from brand to brand

Specifications of some mammography units available in Australia-continued

	Elscint Mam-4	SoredexMamexDCMag Bernett MF-150	Bennett MF-150	Athena-HF	Astra
Australian distributor	Elscint Aust	Phoenix Scientific Industries	Phoenix Scientific Industries	Fischer Imaging Australia	Fischer Imaging Australia
Approx cost	\$A63,000-68,000	\$A92,000	\$A80,000	\$A78,000	\$A84,000-93,000
Power supply and gen-Single phase full wave erator type	Single phase full wave	single phase high frequency (70kHz)	single phase high frequency (100kHz)	high frequency (16–35kHz)	single phase high frequency
Target material	tungsten (molybdenum molybdenum optional)	molybdenum	molybdenum	molybdenum	molybdenum
Focal spot size (mm)	0.09 and 0.45	0.1 and 0.4 (DC-MAG) 0.15 and 0.4 0.4 (DC-S)	0.15 and 0.4	0.1 and 0.4 or 0.1 and 0.3	0.1 and 0.3 (0.3 Astra—S)
Maximum output (mA) 20mA	20mA	100mA	150mA	125mA	100mA
Filtration	aluminium	molybdenum	molybdenum	molybdenum	molybdenum/alumi- nium
Auto exposure control - with microprocessor	yes no	yes yes	yes yes	yes yes	yes yes
Magnification	1.5x and 2.0x	1.6 (DC-MAG)	1.5 and 1.7	1.5 or 1.8 optional	1.5 or 1.8 (not with Astra-S)
Compression device	manual	motorised with manual override	motorised with manual motorised with manual motorised and manual override	motorised and manual	motorised/manual fine adjustment
Grid type	stationary	moving	moving	moving and stationary – optional	moving -optional
Film size	18x24, 24x30	18x24, 24x30	18x24, 24x30	18x24, 24x30	18x24, 24x30

Specifications of some mammography units available in Australia—continued

	Instrumentarium/Ausonics Alpha III	Instrumentarium/Ausonics Alpha III plus	Merate Integrated System	Metaltronica Compact Mammo HF
Australian distributor	Medtel Australia	Medtel Australia	Mr M Xeno	Excelray Australia
Approx cost	\$A75,000	\$A90,000	Specifications for these units table as they have not been v	Specifications for these units have not been included in this table as they have not been verified
Power supply and generator single type	single phase high frequency	phase high frequency $$ single phase high frequency $$	3.	
Target material	molybdenum	molybdenum		
Focal spot size (mm)	0.1 and 0.4	0.1 and 0.35		
Maximum output (mA)	100mA	100mA		
Filtration	molybdenum	molybdenum		
Auto exposure control - with microprocessor	yes yes	yes yes		
Magnification	1.5x	1.6 (1.8 optional)		
Compression device	motorised and manual	motorised and manual		
Grid type	moving -optional	moving -optional		
Film size	18x24, 24x30	18x24, 24x30		