ACPSEM Position Paper

RECOMMENDATIONS FOR A DIGITAL MAMMOGRAPHY QUALITY ASSURANCE PROGRAM V4.0

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Abstract

In 2001 the ACPSEM published a position paper on quality assurance in screen film mammography which was subsequently adopted as a basis for the quality assurance programs of both the Royal Australian and New Zealand College of Radiologists (RANZCR) and of BreastScreen Australia. Since then the clinical implementation of digital mammography has been realised and it has become evident that existing screen-film protocols were not appropriate to assure the required image quality needed for reliable diagnosis or to address the new dose implications resulting from digital technology. In addition, the advantages and responsibilities inherent in teleradiology are most critical in mammography and also need to be addressed. The current document is the result of a review of current overseas practice and local experience in these areas. At this time the technology of digital imaging is undergoing significant development and there is still a lack of full international consensus about some of the detailed Quality Control (QC) tests that should be included in quality assurance (QA) programs. This document describes the current status in digital mammography QA and recommends test procedures that may be suitable in the Australasian environment. For completeness, this document also includes a review of the QA programs required for the various types of digital biopsy units used in mammography. In the future, international harmonisation of digital quality assurance in mammography and changes in the technology may require a review of this document. Version 2.0 represented the first of these updates and key changes related to image quality evaluation, ghost image evaluation and interpretation of signal to noise ratio measurements. In Version 3.0 some significant changes, made in light of further experience gained in testing digital mammography equipment were introduced. In Version 4.0, further changes have been made, most notably Digital Breast Tomosynthesis (DBT) testing and QC have been addressed. Some additional testing for conventional projection imaging has been added in order that sites may have the capability to undertake dose surveys to confirm compliance with diagnostic reference levels (DRLs) that may be established at the National or State level. A key recommendation is that dosimetry calculations are now to be undertaken using the methodology of Dance et al. These and other significant changes have been highlighted in the body of the paper and in the Appendices by the use of red text. Some minor changes to existing facility QC tests have been made to ensure the suggested procedures align with those most recently adopted by the Royal Australian and New Zealand College of Radiologists and BreastScreen Australia. Future updates of this document may be provided as deemed necessary in electronic format on the ACPSEM's website (https://www.acpsem.org.au/whatacpsemdoes/standards-position-papers and see also http://www.ranzcr.edu.au/quality-a-safety/radiology/practice-quality-activities/ mqap).

Key Words: mammography, digital, quality control, quality assurance, biopsy, digital breast tomosynthesis, DBT, diagnostic reference levels, DRLs[a]

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1 Introduction

1.1 Background

In 2001 the ACPSEM published a position paper entitled *Recommendations for a mammography quality assurance program*[1] which has formed the basis for quality assurance testing of mammographic equipment used for both mammographic screening and diagnosis. These recommendations have been adopted in Australia and New Zealand by the Royal Australian and New Zealand College of Radiologists and BreastScreen Australia and incorporated into their respective mammographic documents[2,3].

Since that time, digital mammographic units have been introduced into Australia and New Zealand and it has been recognised that these units, utilizing varying technologies, cannot be adequately assessed by the current quality assurance recommendations. A review of overseas experience with digital mammography quality assurance reveals a diverse set of situations. Mammographic units marketed in the USA have traditionally used company specific protocols individually approved by the FDA. The American College of Radiology (ACR) has recently developed a generic set of recommended quality assurance (QA) tests for digital mammography[4] and the Digital Mammography Imaging Screening Trial (DMIST) that has been reported[5-7]. The European community on the other hand have developed a generic set of recommendations for implementation by member states[8,9,89]. During the early stages of Australian and New Zealand experience in digital mammographic systems it was thought appropriate to adopt where possible ACR test recommendations, however these have been cross referenced to similar European Union test recommendations where possible and in some cases tests have been supplemented by the European Union protocol requirements. The International Atomic Energy Agency (IAEA) has also published a QA document for use by member states[62].

1.2 Scope of this Document

The early versions of this paper were written as a companion document to the 2001 position paper. It is not the intent of this document to alter any recommendations for screen-film mammographic systems previously described. Many tests used for digital mammographic systems are shared with screen-film systems and, while a brief description of the appropriate test is given below, the reader may wish to refer back to the 2001 paper[1] for a fuller discussion for particular tests.

The paper is intended to provide:

(a) A brief introduction to the types of mammography units described as full field digital mammography (FFDM) units, digital breast tomosynthesis (DBT) units, and those used for specimen biopsy.
(b) An overview of the role of the Medical Physicist in mammography QA at acceptance, annual and regular quality control (QC) testing.
(c) Recommendations for imaging system related QC procedures to be performed by facility staff, which are consistent with those prescribed by the Royal Australian and New Zealand College of Radiology (RANZCR)[61]. This latter document and its updates should be consulted for the detailed procedures necessary when performing some of these tests.
(d) Recommendations for performance evaluation of mammography imaging systems typically performed by the Medical Physicist. One section of the document discusses specific acceptance and equipment upgrade tests, normally not repeated annually, as well as annual tests that are performed at acceptance and then as a part of routine testing.
(e) Recommendations for quality assurance testing of stereotactic breast biopsy units.
(f) Recommendations for quality assurance testing of DBT units.

It must be appreciated that the challenges of digital imaging, and particularly those of mammography, are the subject of intense research and development with many bodies searching for a commonality of test procedures. Every attempt has been made in this paper to assess these developments, as they become available. However this paper recommends testing that is currently achievable and acceptable within the Australasian context, while supporting future test principles, which may be more useful with the advances in software, image phantoms and a consensus of methodologies.

2 Digital Mammography Equipment

2.1 Full Field Digital Mammographic (FFDM) Units

The term FFDM is intended to apply to any mammographic unit producing images in digital format with an image receptor capable of imaging a field size comparable to that of current screen-film systems, that is, 18 cm x 24 cm and preferably 24 cm x 30 cm. It specifically excludes film digitisers and obviously does not include the small field of view digital biopsy units. These latter are considered as a separate entity and are discussed in section 2.2. As of 2017 there remain four detector technologies available in the market place[10], which may satisfy the description of being a FFDM unit. They are Computed Radiography (CR), indirect flat panel arrays using CsI:Tl as the active detector material, direct flat panel arrays using a-Se as the detector, and scanning photon counting systems based on a silicon detector. All of the solutions are characterised by having a high dynamic range with the benefits of excellent low contrast detectability when compared with screen-film but this comes at the expense of reduced limiting spatial resolution.

Each of these technologies, and the emerging concept of DBT, which is showing encouraging results in clinical trials, will be reviewed briefly. It is also worth mentioning that contrast enhanced mammography and dedicated CT mammography technologies are also being developed but they have not yet reached a mature enough stage to need addressing in a quality assurance program.

2.1.1 Computed Radiography (CR)

Computed Radiography (CR) technology can be considered as an intermediate step from a screen-film system to a flat panel technology. The CR technology involves the use of phosphor plate cassettes which can be used on any suitable mammographic Bucky and associated x-ray system. In this way the CR system can 'stand alone'

and can be introduced to complement existing x-ray units, thus providing a less expensive method of achieving digital images. However such an approach retains many of the disadvantages of screen-film systems with no increase in patient throughput and the lack of integration between the image receptor and x-ray system that can be a vital part of flat panel arrays.

The physical principles of CR technology are well established[11]. In the context of FFDM, it should be made clear that the CR plates and readers commonly encountered in radiology departments are not adequate for mammography purposes as they suffer from relatively poor spatial resolution, primarily because of the lateral diffusion of laser light in the body of the phosphor. A number of CR units have been approved by the FDA in the United States for mammographic use. Of particular note is the unit from Fujifilm Medical Systems, Tokyo, Japan, which utilises an improved readout system achieved by the collection of stimulated light emissions from both sides of the plate (dual side read CR as illustrated schematically in Figure 1). The published results of an evaluation of mammographic detectors[12] demonstrates that dual side read devices have overcome some of the inherent x-ray absorption and light collection efficiency limitations seen in conventional CR systems with improvements in low frequency detective quantum efficiency (DQE) of 40%. More recently, other manufacturers have developed CR systems based on needle phosphor technology and these units seem to have improved performance compared with their predecessors[63,64]. Nevertheless, clinical use has established that in order to achieve acceptable image quality, CR systems operate at significantly higher doses compared with the digital solutions described in subsequent sections and referred to collectively as DR systems[75].

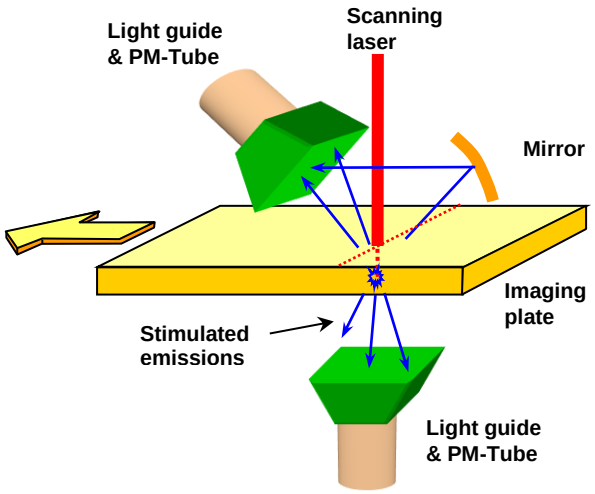

Figure 1. *Dual Sided CR reading. The Imaging plate (phosphor) has a transparent protective coating on both sides allowing the laser stimulated emissions to be collected by the optics for subsequent digitisation.*

It is therefore the view of the ACPSEM that only DR technology should be approved for future purchases of equipment for screening mammography in Australia and New Zealand and existing CR systems should be progressively replaced. Notwithstanding this advice, tests on CR units are outlined below and have been written to be as generic as possible.

2.1.2 Indirect Flat Panel Detectors

General Electric (General Electric Healthcare, Milwaukee, WI, USA), has developed digital flat panel detectors based on amorphous silicon (a-Si) coupled to a scintillator such as CsI:Tl (see Figure 2). The detection process can be considered in three distinct steps. First, the CsI scintillator absorbs the x-rays and converts them to light, just as it does in the input phosphor of an image intensifier. Then a low noise a-Si photodiode array absorbs the light and converts it to an electronic charge signal. Each photodiode corresponds to a single del in the image matrix. The charge at each del is read out using thin-film transistor (TFT) switches and turned into digital data using an Analogue to Digital Converter (ADC). Ideally, the magnitude of the digital signal is directly proportional to the x-ray intensity absorbed by the CsI:Tl scintillator directly above the del. Del sizes are typically 100 μm, which implies a detector limiting spatial resolution of approximately 5 lp/mm.

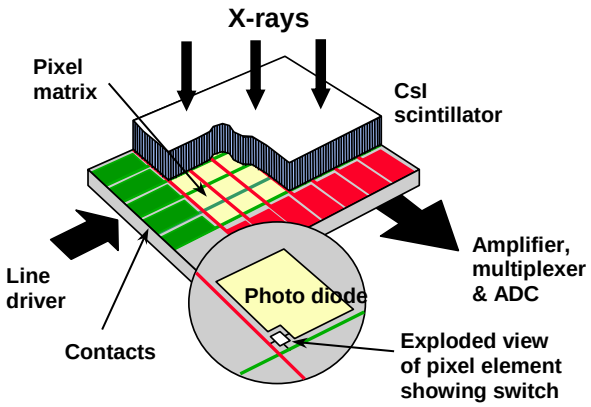

Figure 2. *The indirect flat panel detector based on a CsI-scintillator with a-Si switching diodes and TFT-read out. The x-rays absorbed in the CsI layer are first converted to light which is then converted to a charge signal by the photo-diodes and ultimately digitised.*

2.1.3 Direct Flat Panel Detectors

An alternative flat panel detector is that based on a-Se technology. This detector type utilises an a-Se array with a typical thickness of 250 μm to detect the x-rays directly and then converts them into a charge pulse map that is collected by a set of simple a-Si electrode pads. Since the charge is swept out of the a-Se volume under the influence of a high voltage (see Figure 3) lateral diffusion effects are minimal and the technology is claimed, at least in principle, to be superior in terms of its DQE and spatial resolution to the previously mentioned detectors. The del size ranges between 50 μm and 85 μm implying an approximate detector limiting spatial resolution of between 10 lp/mm and 6 lp/mm, respectively. While this detector could be used with a standard focused linear grid the Hologic unit (Hologic, Bedford, MA, USA) uses a unique hexagonal grid. This grid must complete an integral number of cycles during an exposure and this constraint is a determining factor in automatic exposure parameter selection including tube current.

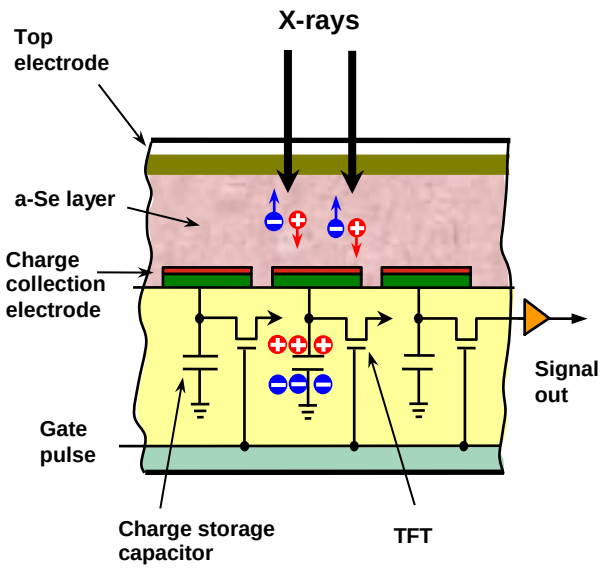

Figure 3. *The direct flat panel detector utilising a-Se as the x-ray absorber. When a voltage is applied across the a-Se layer, the charges produced are collected by the electrodes and digitised.*

2.1.4 Scanning Photon Counting Systems

A Swedish Company (Sectra Medical Systems, Linkoping, Sweden) developed a novel system called the MicroDose which is now marketed by Philips (Philips Healthcare, Hamburg, Germany). The unit is based on multiple scanning slit technology[15] (see Figure 4), which shares a degree of commonality with scanning CCD technology developed by Fischer Imaging (Fischer Imaging, Northglen, CO, USA) but which is no longer commercially available. However, it has the additional concept of single photon counting with energy discrimination allowing rejection of scattered photons and electronic noise (i.e. individual X- rays are detected as single events and a decision made to either accept or reject them on the basis of their energy). There are no intermediate conversion steps as x-ray energy is converted directly to charge in a crystal silicon detector, which is operated on edge to give excellent absorption efficiency (>90%) with a high fill factor (i.e. all detector material area is utilised). The image is made up of 4800 x 5200 dels covering a FOV of 24 x 26 cm^2 each of size 50 μm implying a nominal 10 lp/mm detector resolution. A key to the success of the unit is pre and post breast collimation with 28 thin fan beams producing an essentially zero scatter environment. Each fan beam, as defined by the pre breast collimator, has dimensions of 24 cm x 0.065 mm. As a result of this design, grids are not required and doses are typically less than a half of those obtained with screen film mammography.

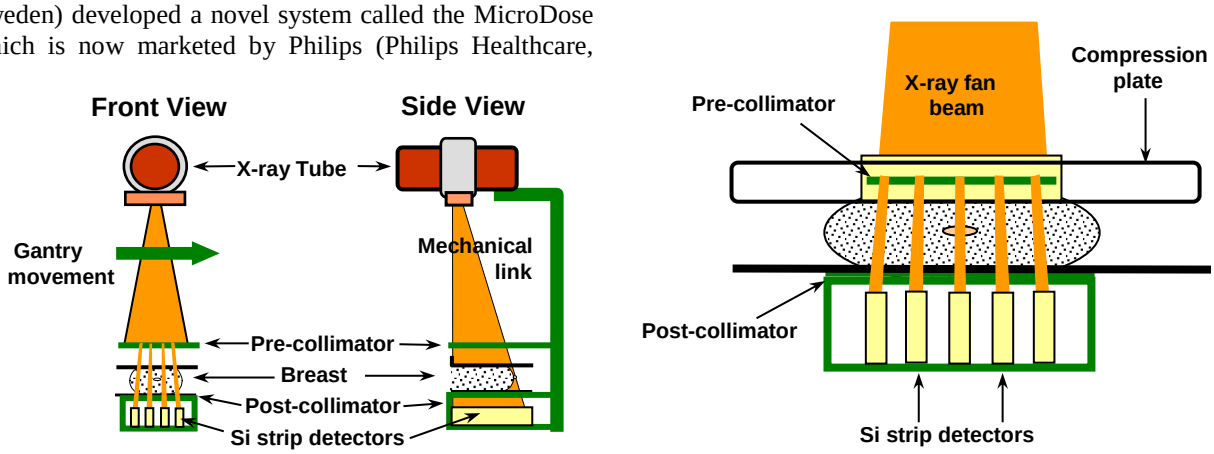

Figure 4. *Sectra/Philips Microdose Multi-slit scanning unit. Narrow slit collimators define fan beams that image part of the breast. Post breast collimators further reduce the impact of scatter. The multi-slit device moves across the breast ensuring that all breast tissue is imaged. The crystal-Si detector elements are also unique in that they collect and record the energy from discrete x-rays.*

2.1.5 Digital Breast Tomosynthesis (DBT)

One of the disadvantages of conventional 2D projection mammography is that overlying tissue, particularly if it is dense, can mask the appearance of suspicious lesions. Accordingly, most manufacturers are either investing in or have already produced technology capable of performing DBT. Figure 5 provides a schematic of what the process entails. In essence a number of low dose images are acquired at different angles around the breast. As the figure illustrates, the relative positions of details in the image changes with projection angle. Even with a limited number of views sufficient data is produced to allow the generation of a 3D data set from which images of thin slices of breast tissue may be reconstructed. DBT therefore offers improved visualization of lesions that would be otherwise masked and enables real lesions to be distinguished from those mimicked by superimposition of normal structures. These benefits have been realized clinically, with several studies on large screening populations reporting an increase in overall cancer detection rate and a reduction in recall rate when using DBT in addition to 2D digital mammography, compared to using 2D mammography alone[80-83]. The greatest gains in sensitivity were observed for younger women and those with heterogeneously dense breasts[83, 84].

The implementation of DBT technology is achieved in different ways by the manufacturers as summarised in Table 1. Some use a different detector from that used in conventional projection imaging. Most don't use a grid but the General Electric models use an unconventional grid whereby the grid lines are aligned parallel to the chest wall

and the movement is restricted to ≤ 2 mm perpendicular to the chest wall edge of the breast support. Some designs use a step and shoot style of exposure whilst others utilise a continuous movement of the x-ray tube head with the x-ray exposure pulsed during the movement. The angular range varies between manufacturers; generally speaking, a wider scan angle has the advantage of better depth resolution, but with longer scan times and increased radiation dose, unless the number of projections is reduced[85,86]. However, too few projections results in aliasing artefacts. Further, the type of image processing undertaken varies widely. Some offer filtered back projection (FBP), which has traditionally been used with CT image reconstruction, but just as CT has moved on to utilise iterative reconstruction, so we find the same thing occurring with DBT. The iterative technique is now generally regarded as being superior to FBP from an image artefact perspective, most especially when limited projection data is employed as in DBT[91].

At this point in time DBT is not yet regarded as a screening technology in Australasia. However, this situation may change following the outcome of a number of clinical trials. In the interim it may be used as an adjunct to conventional mammography in those cases requiring further workup. One concern regarding its use as a screening technology is the increase in radiation dose, since DBT has typically been used in addition to 2D mammography. However, several manufacturers have developed software that will allow the generation of synthesised 2D projection images from the tomosynthesis projections. This may replace the need for conventional projection mammography to be performed in addition to DBT. Testing with the ACR accreditation phantom clearly demonstrates that these synthesised 2D projection images are inferior in some respects to conventional 2D projection images. This should not be considered surprising as they are generally acquired using reduced resolution and, in most instances, without a grid or at least with a different type of grid. Notwithstanding this finding, initial clinical results have been promising, with no significant difference in cancer detection rates between DBT used in conjunction with conventional or synthesised 2D projection images [87, 88].

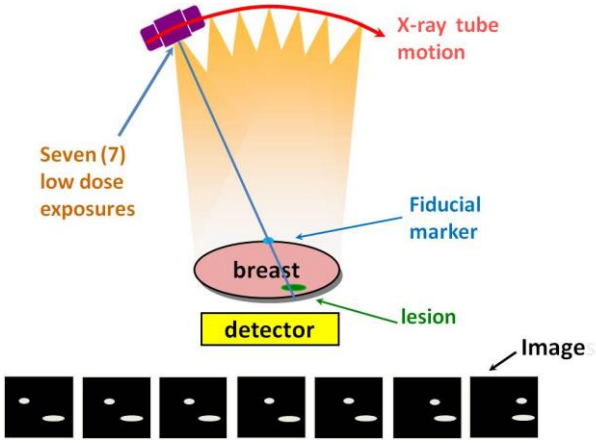

Figure 5. *The principle of DBT. The x-ray tube is rotated about the breast and several low dose images are acquired. In this figure, for clarity, only seven are shown. The relative positions of the fiducial marker and the lesion within the breast change in the image with angle. From these images a 3D data set is obtained from which images of thin slices of breast tissue may be reconstructed.*

Table 1 *DBT Models currently implemented in Australasia*[89]

Model	Scan angle (°)	# of views	X-ray tube movement & operation	Scan time (s)	Grid	Reconstruction algorithm
Hologic Selenia Dimensions 3D	±7.5	15	Continuous (pulsed)	3.7	No	FBP
Siemens Mammomat Inspiration	±23	25	Continuous (pulsed)	<25	No	Iterative/FBP**
GE Senoclaire*	±12.5	9	Step & shoot	8	Yes	Iterative
GE Pristina	±12.5	9	Step & shoot	6	Yes	Iterative
Fuji Amulet Innovality	±7.5 or ±20	15	Continuous (pulsed)	4 or 9	No	Iterative/FBP**

*Uses motorised tomosynthesis device (MTD) in lieu of the normal Bucky used for 2D imaging
**Both options are offered

2.1.6 Digital Image Display Systems

Advances in image display have been just as critical as have image detectors for digital mammography to achieve clinical acceptability. The work of the AAPM is universally accepted as being pre-eminent in this field[16,17]. Displays utilise either cathode ray tubes (CRT), albeit rarely now, liquid crystal displays (LCD) or variants thereof and are classified as either primary or secondary. The ACPSEM recommends that all future tenders for primary and secondary workstations specifically exclude CRT displays. Primary display systems are those used for the interpretation of medical images (in this case mammographic) by the radiologist, while secondary systems are those used by other medical personnel for quality control purposes or after the interpretation report is rendered[17]. The interpretation and reporting of digital mammography examinations must be carried out on monitors with a minimum resolution of 4.2 MP, a maximum pixel pitch of 0.2 mm and a luminance ratio (LR) (ratio of maximum to minimum brightness) ideally of approximately 350, the mammographic image being displayed in monochrome[90,93]. Further in the case of image

storage or transfer a lossless compression must be used to allow full image quality for image interpretation. Experience has also indicated that the monitors used on the acquisition device must also be of relatively high quality in order to ensure that movement artefact is not missed by radiographers when performing basic QC on the images. Accordingly, the ACPSEM recommends that such monitors be at least 3 MP, and should preferably be gray scale rather than colour monitors with sufficient bit depth to demonstrate the ramps in the TG18-QC test pattern continuously. This means that both the primary and secondary displays (specifically the one on the acquisition workstation) must conform to the DICOM 3.14 Grayscale Standard Display Function (GSDF). Conformance to the GSDF ensures that the perception of contrast is the same in all regions of an image, irrespective of the background luminance. It should also ensure that the image looks the same on all calibrated monitors. Vendor QC software has become increasingly sophisticated and is useful for establishing or confirming the status of display monitors.

2.1.7 Automatic Exposure Control (AEC)

As noted by Pisano and Yaffe[10], digital mammography image brightness and contrast are controlled by adjusting the window and level controls of the image display workstation quite independently of image acquisition. Thus, the AEC is not required for this purpose but rather to ensure that the dose to the breast is not excessive and that the signal difference to noise ratio (SDNR)[b] is acceptable. This has implications for the type of QC measurements that are undertaken with digital mammography units (see sections 3.2.14 and 4.3.4). Further, the sophistication of the AEC varies between unit types. All systems determine the technique factors, with the exception of the mAs (and possibly the kVp), from lookup tables in response to the breast thickness as indicated by the breast paddle position. Some systems then utilise information direct from the image detector obtained with a short trial exposure to modify the technique factors based on an estimate of breast density. The exposure (mAs) is terminated when the integrated detector signal at the selected region reaches an acceptable level. In all cases the position of the breast paddle is critical to the AEC process emphasising the importance of correct breast thickness measurement. Innovative methods to utilise detector signals in AEC determination for scanning technologies are currently under consideration[18,19]. In the Philips/Sectra scanning system, for example, information from the leading detector line is utilised to adjust the scan velocity during the scan[18].

2.2 System Types Included as Biopsy Mammographic Units

Stereotactic breast biopsy units are mammographic units, or attachments to mammographic units, that allow identified sections of the breast to be sampled for diagnostic or treatment purposes. Film based systems cause long waiting times for patients while film processing takes place and have been superseded by digital biopsy systems. These systems can be either dedicated biopsy units (usually with prone tables) or attachment units (usually upright with the patient seated) connected to existing mammographic units. In the case of dedicated units the full range of tests described will need to be undertaken, however for mammographic units with attachments, many of the prescribed tests will already be completed in routine testing of either a screen-film or digital mammographic unit.

The detectors used have a limited coverage (typically 5 cm x 5 cm) and for the "attachment" units may either be a sub section of the digital detector used in FFDM applications, or form part of the attachment unit itself. In this latter case, and in the case of dedicated prone units, the detectors commonly use a single CCD chip technology. At least two different implementations of the technology are available. Siemens Medical Solutions now market a unit (previously developed by Fischer Imaging) using tapered fibre optics to couple light from a Kodak Min R screen to the CCD array. Lorad Medical Systems (a subsidiary of Hologic) uses conventional lenses in their design. In both instances, the CCD array is 1024 x 1024 (note that a 512 matrix can also be selected and this is more commonly used clinically – doses can be quite high using the 1024 array) and both systems have demonstrated spatial resolution of between 5 and 10 lp/mm. Diagnosis may be made from soft copy or from hard copy.

2.3 The Role of the Medical Physicist

Acceptance testing gives the purchaser of complex equipment the opportunity to determine if equipment installed performs to the standard specified. Digital equipment allows instantaneous feedback on the radiographic process. Information such as patient dose must be verified along with the optimisation of image quality, the correct configuration of processing algorithms and display devices and the correct transfer of digital data.

The tests described below form a minimum set of tests that should be conducted annually. These tests should be performed according to displayed technique factors that are used clinically. As well as providing a report to indicate corrective action by a qualified service person, the medical physicist should also make recommendations that may improve image quality and/or reduce patient dose. The facility or radiographer tests should also be reviewed, with assistance given when test procedures are not clearly understood by radiographic staff.

3 Facility Quality Control Procedures (2D Mode)

3.1 Introduction

As in screen/film mammography, facility quality control procedures for digital mammography systems are essential for ensuring production of high quality mammography images. Failure to implement adequate QC procedures has proven to reduce the image quality significantly which may result in lower detection rates for breast cancers. The effectiveness of the QC program is reliant on the correct performance of the QC procedures, results being

[b] *SDNR was previously referred to as the contrast to noise ratio (CNR). SDNR terminology is now preferred*[6,24]

charted/recorded and compared with previous results or set limits and appropriate corrective action being taken when needed [2,3,61] The routine control procedures to be performed by facility staff are listed in Appendices 1a and 1b and further discussion of the testing is provided in the following section.

3.2 Procedure Recommendations

3.2.1 Viewing Conditions

Viewing conditions are extremely critical when presenting high quality mammography images for interpretation. The ambient light levels and reflections can affect the quality of displayed mammography images (hard copy and soft copy) through artefacts and loss of image quality including loss of perceived contrast[5,7,17,22]. The ACPSEM recommends that a visual inspection of ambient lighting conditions be made daily[61] by facility staff to ensure conformance with the acceptable viewing condition configuration determined by the medical physicist at acceptance testing. Ideally, third monitors, which may be used for providing worklists and other associated tasks on some diagnostic workstations, should be blanked out to keep light to acceptable levels. When assessing viewing conditions for viewboxes (hard copy interpretation) a visual inspection of uniformity of brightness and confirmation of the presence and operation of masking must also be made. To be effective this requires clinical departments to have a tube replacement policy which specifies tri phosphor phosphorescent tubes or equivalent and ensures that all viewboxes have tubes of the same colour and intensity. This may require all tubes in a viewbox to be replaced simultaneously.

3.2.2 Image Plate Erasure (CR only)

CR Image plates are sensitive to scattered and naturally occurring radiation sources and if left unused for long periods of time will store energy absorbed from these sources. It is recommended that all CR image plates be subjected to erasure procedures on a daily basis as per manufacturer's instructions. Fuji Medical Systems refer to this as a "secondary" erasure but they also require a "primary" erasure to be performed on a weekly basis.

3.2.3 Full Field Artefact Evaluation & System Check (DR systems only)

The standard test block of PMMA covering the complete image receptor should be imaged using clinically relevant technique factors and the image viewed on the acquisition monitor. Zoom and roam should be used to check for possible detector faults such as dead dels. The test should be undertaken on a daily basis[61,62]. This test is designed to detect changes in the performance of the entire imaging chain including the x-ray system and the detector. If hard copy interpretation is undertaken then a printed image must be produced

The mean pixel value in the image is measured using a 4 cm^2 ROI positioned centrally along the long axis of image receptor and 6 cm in from the chest wall. The mean pixel value and the mAs must be within ±10% of the baseline value (provided a consistent choice of kVp, anode and filter is used). The "for presentation" or processed image must be used to make this measurement[c].

Additionally, the "for presentation" image must be examined using clinically relevant window/level settings and observed to be free from clinically significant:

- Blotches or regions of altered noise appearance.
- Grid lines or breast support structures.
- Bright or dark pixels.
- Dust artefacts mimicking calcifications
- Stitching or registration artefacts.
- Any processing artefacts (if applicable).

3.2.4 Monitor QC

In digital mammography the monitor is the primary means of interpretation and as such provides the vital link between the image acquisition system and the image reader. These display devices are susceptible to maladjustment and drift and often their QC is overlooked[7]. Monitors used for interpretation and those attached to the acquisition workstations must be tested regularly to ensure that displayed images are a true representation of the "for presentation image" sent from the acquisition system. It is recommended that all monitors used for acquisition or interpretation have the TG 18-QC test pattern displayed on them each week[7,9,17]. Evaluation by the same person on a routine basis is recommended. The ACPSEM recommends that the provision by the vendor of the TG18-QC test pattern, rather than the older SMPTE test pattern, be included in the tender process and the pattern should be preloaded on the mammography system prior to acceptance testing. The TG 18-QC test pattern image displayed at a scale of 1:1 must be evaluated to ensure that:

- Borders are visible,
- lines are straight,
- squares appear square,
- the ramp bars should appear continuous without any contour lines,
- there is no smearing or bleeding at black-white transitions,
- all corner patches are visible,
- squares of different shades from black to white are distinct,
- all high contrast resolution patterns and at least two low contrast patterns are visible in all four corners and the centre
- the 5% and 95% pixel value squares are clearly visible,
- the pattern is centred in the active area,
- no disturbing artefacts are visible and
- the number of letters visible in the phrase "Quality Control" for the dark, mid-gray and light renditions is at least eleven.

The TG 18-QC test pattern image must be evaluated under optimal viewing conditions as specified in section 3.2.1

[c] *Unfortunately, with the Philips/Sectra L30/L50 systems the placement of ROIs with a processed image is not possible so this procedure must be undertaken with a raw image.*

and typical viewing distances should be employed when assessing resolution test patterns. Additional test patterns should be viewed as prescribed by the monitor manufacturer's QC program

3.2.5 Monitor/Viewbox Cleaning

The monitor/viewbox is the final device used in presenting high quality mammography images for interpretation. The cleanliness of the monitor/viewbox can have an effect on the quality of the mammography images that are displayed. The ACPSEM recommends weekly cleaning of monitors and viewboxes to ensure they are free of dust, fingerprints and other marks that might interfere with image interpretation. The manufacturer's specific instructions should be adhered to when choosing cleaning agents.

3.2.6 Printer Area Cleanliness

Where printers are used to produce images for interpretation it is important to ensure dust-related artefacts are not introduced on to the images. It is recommended that weekly cleaning of areas where film magazines are loaded and film is printed be undertaken, in order to maintain a clean, dust free environment.

3.2.7 Image Quality Evaluation

Although there are a number of test objects available for this purpose the ACPSEM currently recommends retaining the ACR Accreditation phantom for image quality evaluation because of its current widespread availability and use in screen film mammography[1]. However, for sites wishing to purchase a new phantom, the ACPSEM recommends the recently released ACR digital mammography phantom, referred to as the ACR DM phantom (e.g. the Gammex Model 145 or CIRS Model 086). This phantom has been designed with tighter specifications and is certainly more sensitive to imaging equipment changes in performance. Regardless of which phantom is used, the "for presentation" or processed image may be assessed, using the zoom and modest adjustments of the window/level functions available in order to visualise the specks and fibres. The masses should be scored without the need for zooming.

As with its use in screen film mammography there are a number of key procedural elements which are relevant in acquiring the phantom image:

- Maintain light contact between the compression paddle and the phantom surface.
- Position the phantom consistently. Centred along the long axis of the image receptor and flush with the chest wall is recommended.
- Use a consistent selection of clinically relevant kVp and target/filter combinations.
- Select the density control setting in current clinical use (if applicable).
- Use a consistent AEC detector position where this is manually selected
- For CR use a designated test cassette and imaging plate that is in routine clinical use. To avoid variations in image quality caused by image fading it is suggested that the plate be read at a fixed time delay (say 30 seconds) after irradiation.
- If hardcopy images are used for reporting or if this image is to be used for a measure of signal difference to noise ratio (SDNR) (see section 3.2.9), the acrylic contrast disc must also be used with the ACR phantom (not necessary with the ACR DM phantom). It is preferable to place this on, rather than under, the paddle to minimise the chance of causing damage to the latter.

Apart from the evaluation of the phantom image the technique factors associated with the image acquisition must be recorded and it is suggested that a control chart be employed for this purpose. Previously, the ACPSEM had recommended that for DR systems the mean pixel value and signal to noise ratio (SNR) in a reproducible region of interest (ROI) of standard size of approximately 100 mm^2 should be measured using the workstation tools. This requirement has now been supplanted by the requirement to measure the SDNR as described below in section 3.2.9).

For CR units, the SDNR is not easily obtained, due to the absence of ROI tools, in some units, but the exposure indicator, or a parameter related to it (see below), must be recorded. If reporting is performed from hard copy the optical density in a reproducible part of the phantom image (e.g. the centre) must be measured.

When visually scoring the details present in the phantom images care should be taken to ensure consistency of viewing conditions and also that these conditions reflect those used to read clinical mammograms. This applies to both soft and hard copy where applicable. Ideally, image quality scoring should be undertaken by the same person, if possible. With the ACR Accreditation phantom the ACPSEM now believes that, using the RANZCR scoring system[1] a score of at least 5 fibres, 3.5 speck groups and 4 masses must be achieved in the digitally acquired image. This is a tighter requirement than that currently in place for screen film mammography. Ideally, 4 speck groups should be visualised but field testing has established that significant variations in scoring of specks can arise when different ACR phantom units are utilised, this variation is attributable to manufacturing tolerances and aging of the wax insert test object. **With the new ACR DM phantom, the equivalent minimum acceptable scores are 4 fibres, 3 speck groups and 3 masses**.

Ideally, image quality should be scored on the modality used for reading clinical images i.e. the reporting monitors or the printed copy if hardcopy is used for reporting. However, this may not always be practicable, especially if images are sent to a separate site for reading. In this case, it is acceptable to score the phantom on the acquisition work station but it is best practice if the image is also scored on a reporting monitor at least once a month to check that PACS causes no image deterioration. Furthermore, there is significant variation in the resolution of acquisition monitors supplied by each vendor. If the ACR phantom score (particularly speck groups) is not acceptable on the acquisition monitor, it should be verified that it is satisfactory on the reporting monitors.

When evaluating the performance of CR systems, the significance of variations in the exposure indicator requires some comment as the specification of an acceptable tolerance depends on the equipment manufacturer and, in some instances, on the choice of algorithm used in the image acquisition. The basic premise is that the air kerma (dose) to the plate must not change with time by greater than ±10%. The equivalences in terms of the exposure indicator are given in Appendix 6.

3.2.8 Detector Calibration – Flat Field Test (DR Systems only)

This test ensures that the detector is properly calibrated, the image is uniform over the entire field of view, and that a high and consistent level of image quality is maintained. The test must be carried out in accordance with the manufacturer's methodology[61]. The outcome of the test is a simple pass or fail.

3.2.9 Signal Difference to Noise Ratio (DR Systems only)

When screen-film was used, one of the important parameters for image quality was contrast. However, digital detectors have a much wider dynamic range and therefore wider exposure latitude. Combined with image processing and the ability to adjust the contrast and brightness of the image, this means that the important parameter is not simply contrast but a new parameter called the signal difference to noise ratio (SDNR). The ACPSEM considers that the way to optimise a digital mammography system is to achieve established minimum target SDNR values as a function of breast thickness. Medical physicist annual testing will confirm if this is the case (see section 4.3.4). However, the ACPSEM now believes an important routine test is to ensure that the SDNR for a single phantom thickness remains approximately constant over time. The test must be carried out weekly in accordance with the manufacturer specific methodology as described in the RANZCR QA document[61] or using the ACR phantom with PMMA contrast disc on the paddle. **If the new ACR DM phantom is utilised for this measurement the SDNR is measured using the negative contrast disc inherent to the phantom.** In either case, **t**he basic requirement is that the SDNR vary from the baseline value by less than ±20%.

3.2.10 Printer QC

In order to produce high quality mammography images for interpretation the printer used must be monitored to ensure it is functioning optimally. This should involve higher resolution and maximum density settings than are usually found in non mammographic situations. Monitoring for changes in geometric distortion, contrast visibility, resolution, optical density range and artefacts will ensure that high quality images are produced. The TG 18-QC, rather than superseded SMPTE, test pattern[16,17] (Figure 6) is used widely for examining these parameters[7].

It is recommended that the TG 18-QC test pattern be printed monthly on each dry printer (daily or as used for wet printers), to confirm that:

- Borders are visible,
- lines are straight,
- all corner patches are visible,
- squares of different shades from black to white are distinct,
- all high contrast resolution patterns are visible in all four corners and the centre,
- the 5% and 95% pixel value squares are clearly visible,
- no disturbing artefacts are visible,
- the number of letters visible in the phrase "Quality Control" for the dark, mid-gray and light renditions is at least eleven.

Also measurements must be made of the mid density (MD) and density difference (DD) to ensure they are within ± 0.15 OD of their baseline values. Additionally the Base +Fog (B+F) must be within ± 0.03 OD, and maximum density (D_{max}) within ± 0.10 OD, of their respective baseline values. Further, the B+F should be ≤ 0.25 OD and D_{max} ≥3.4 OD. The TG 18-QC test pattern image must be evaluated under optimal viewing conditions as specified in section 3.2.1. Charts plotting the temporal variation of the above parameters will facilitate the observation of significant trends.

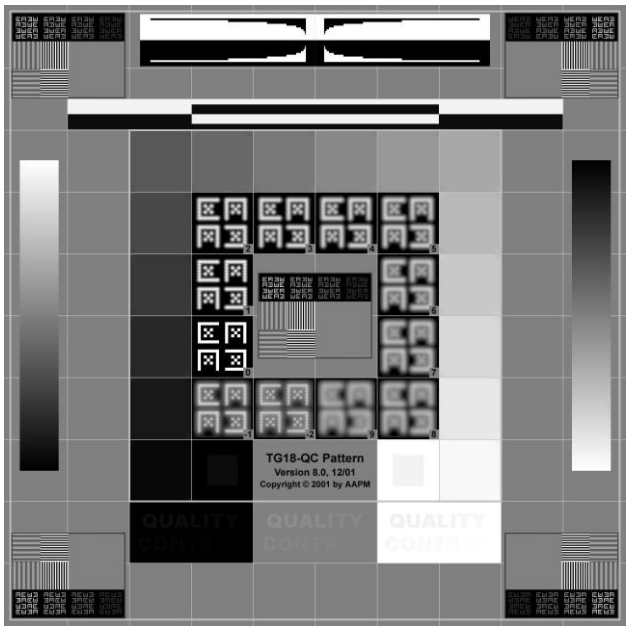

Figure 6 *TG18-QC test pattern.*

3.2.11 Mechanical Inspection & Breast Thickness Indication

As in screen/film mammography the facility staff must perform an overall mechanical inspection of the digital mammography system and associated components[5]. The inspection should be carried out monthly to ensure there are no hazardous, inoperative, out of alignment or improperly operating items on the system. As part of this process, particular care must be taken to ensure that the machine indicated compressed breast thickness remains within tolerance, that is within ± 5 mm of the actual thickness at the manufacturer's specified compression and specified paddle (see also section 2.1.7).

3.2.12 Repeat Analysis

The overall procedure will be as per existing mammography recommendations[1,3], however if reject images cannot be digitally stored it is recommended that a log be kept for the examination reject analysis period. However some new categories for repeat causes may need to be created for digital mammography (e.g. software failures, blank images, non-appearance of images on the acquisition station, although an exposure was made, etc.)[4].

3.2.13 Image Receptor Homogeneity

Whilst there is general agreement that the evaluation of image receptor homogeneity should be undertaken routinely there are some differences as to the methodology that might be employed and the standards of performance that might be expected[4,9]. In some cases the test methodology may be dictated by the manufacturer's software which may provide a totally automated measure of homogeneity. In all cases the image of a standard PMMA test block covering the entire image receptor is obtained. The PMMA block must be free of imperfections, dust and dirt. It is recommended for DR units that five ROIs, each of approximately 100 $mm^{2,}$ are specified; one centrally located and the other four placed near the corners of the image with their outer boundaries 20 mm from the image margins. The analysis must be performed on "for processing" (unprocessed or raw) image data, if possible, using the manufacturer's recommended calibration technique factors, and simply requires the extraction of mean pixel values from each of the five ROIs and determining if the mean pixel value for any ROI differs from that for the central ROIs by more than ±**10**%. For CR units the evaluation should be restricted to a consideration of three ROIs placed in a line parallel to the chest wall and 20 mm from it to avoid issues associated with the heel effect. The mean pixel values for the three ROIs must not differ by more than ±10%.

For all systems the maximum variation in the mean pixel value of the central ROI between successive QC measurements should be less than ±10%.

Meeting the above specification may be problematical if the PMMA block is not uniform. If this is found to be the case then in order to exclude failure due to such non uniformities a second image should be obtained with the block rotated 180° between exposures. The average of the mean pixel values in each of the comparable ROIs is then used in the analysis.

If the software required for these calculations is not available, as is the case for some CR units, a visual inspection of the image using a narrow window may be all that can be done.

3.2.14 AEC Calibration Test

The AEC calibration testing involves obtaining images of PMMA blocks of thickness 2 cm, 4 cm and 6 cm **in contact and magnification mode, if applicable.** Ideally, the blocks should completely cover the detector (as this also enables artefact evaluation), but if not, they should be positioned in a consistent manner (e.g. flush with the chest wall). Clinically relevant AEC exposure factors must be used, as displayed on the technique chart. In some systems, the chosen thicknesses of PMMA above may correspond to one or more switching points in the AEC selection procedure for determining the technique factors. This may make for difficulties in achieving consistency and the problem can be exacerbated if inconsistent application of compression leads to variations in the machine displayed thickness. For CR units the designated "test" cassette must be employed and the exposure indicator recorded.

While the EU guidelines[9] for image assessment uses calculation of signal to noise ratios (SNRs), in practice difficulties arise because of the need for pixel offsets[d] to be applied and the lack of available software. Accordingly, the recommended set of measurements proposed is:

- For DR systems the mean pixel value in a specified ROI in each image is measured using a 4 cm^2 ROI positioned centrally along the long axis of image receptor and 6 cm in from the chest wall[9].
- For CR systems the exposure indicator is recorded. To avoid variations in the exposure indicator caused by image fading it is suggested that the plate be read at a fixed time delay (say 30 seconds) after irradiation.

It is recommended for DR units that the mean pixel value be within ±10% of the baseline value for the respective PMMA thickness. The unprocessed or raw image must be used to make this measurement.

Similarly for CR units, the basic requirement is that the average dose to the plate for each of the three thicknesses of PMMA be within ±10% of the baseline value for that thickness. Appendix 6 should be consulted to see what this means in terms of the manufacturer specific exposure indices.

Additionally, the "for presentation" image must be examined using clinically relevant window/level settings and observed to be free from clinically significant:

- Blotches or regions of altered noise appearance.
- Grid lines or breast support structures.
- Bright or dark pixels.
- Dust artefacts mimicking calcifications
- Stitching or registration artefacts.
- Any processing artefacts (if applicable)).

3.2.15 Compression

The requirements are as per existing mammography recommendations[1] but with the measurement methodology simplified to the extent that the site need only confirm that the mammography unit digital readout of the compression force meets these specifications.

[d] *Some manufacturers add a constant number to the value of the signal assigned to each pixel. This is referred to as the pixel offset value*.

3.2.16 Test Equipment Calibration

As per existing mammography recommendations[1]

3.2.17 Cassette Image Plate Condition & Interplate Sensitivity Variation (CR only)

Apart from the visual inspection of images of a uniform test object such as 4 cm of PMMA for artefacts, this test is analogous to the uniformity of screen speed test of screen-film mammography conducted semi-annually. The QC "test" cassette/plate is irradiated using clinical relevant AEC settings and processed on three separate occasions to confirm repeatability of the x-ray tube output. To avoid variations in the exposure indicator, or its surrogate, caused by image fading each plate must be read at a fixed time delay (say 30 seconds) after irradiation. All other plates are then irradiated in turn and the exposure indicator of each plate is recorded. The basic specification is that the dose to any image plate must differ from the mean for that size by less than ±5%. Appendix 6 should be consulted to see what this means in terms of the manufacturer specific exposure indices.

3.2.18 Maintenance and Fault Logging

As per existing mammography recommendations[1].

3.2.19 Infection Control of Breast Imaging Equipment

Before each examination as per existing mammography recommendations[1].

4 Medical Physics Testing and Equipment Performance (2D Mode)

4.1 Introduction

Both acceptance and annual testing are essential for digital mammographic units, the major difference being the extent of the testing being undertaken. Acceptance testing should be significantly more thorough. Digital mammographic units may be configured and operated in a wide range of exposure settings. It is the view of the ACPSEM that units be tested in the manner they are used clinically. It is therefore essential that the Medical Physicist determines what the clinical configuration and usage of the unit is before testing begins. Of particular concern is determining the mode of diagnostic reporting that is in use; that is, if the image is presented on a monitor or on a film/viewbox. If the mode is ambiguous then both display systems must perform to the required standard.

4.2 Acceptance and Equipment Upgrade only Procedure Recommendations

The acceptance and equipment upgrade procedures to be performed by the medical physicist are listed in Appendix 2 and further discussion of the testing is provided in the following sections.

4.2.1 Focal Spot Size

System resolution is dictated by both the focal spot size and image receptor resolution. In a non-digital system the limiting resolution, as measured by a line pair test object, is a good indicator of system resolution. This is not the case in a digital system where the receptor resolution is usually limited by the receptor detector element (del) size. It is however still essential that the system Modulation Transfer Function (MTF) not be compromised by an inappropriately large focal spot size. The ACPSEM therefore recommends, in line with the European recommendations[9], that the focal spot of the system be determined at acceptance. This may be achieved through a limiting resolution measurement on film or CR imaging plate as described previously[1,9] although this will become increasingly difficult with the demise of printed film. Thus, in line with the International Electrotechnical Commission (IEC) principles of accepting certified documentation in lieu of the results of physical measurements at accreditation[20,21], provision of documentation demonstrating IEC certification verifying the focal spot size[21] is acceptable for this test.

4.2.2 Leakage Radiation

The ACPSEM recommends[1] that testing be performed at acceptance and tube change to meet the minimum leakage requirements specified in the Australian and New Zealand standard[27]. Further the ACPSEM recommends that the leakage measured at 30 cm from the focal spot using 30 kVp shall be ≤0.01 mGy/100 mAs[28].

4.2.3 Transmission Through Breast Support

The ACPSEM[1] supports the specification in the relevant Australian and New Zealand standard[27] that the maximum permitted air kerma transmitted through the breast support be 1 μGy per exposure. Acceptable methods for testing for compliance with this specification, that remain valid for CR based systems, are partially outlined in AS/NZS IEC 60601.1.3:2015[27]. For DR systems the requirement is waived unless specifically required by State or National Regulatory bodies.

4.2.4 Missed Tissue at Chest Wall

This test is specified as an acceptance only test, however it is a simple test that can be incorporated into the image quality phantom test. The aim is to determine the amount of tissue not imaged between the edge of the breast support and the imaged area. This may be achieved with the use of a phantom (the ACR recommend a 40 mm thick PMMA block with a top and bottom vertical flange at breast wall side) with distance markers at fixed distances from the chest wall on the breast support side. Alternatively, some units indicate the image field area on the breast support which, after determining the accuracy of this indication, allows vernier callipers to be used to measure the distance to the edge of the breast support. If the acquisition workstation has image measurement capabilities one simple method involves taping a coin so that it is flush with the breast support, performing a low dose exposure and then measuring the extent to which the coin is not fully imaged. The ACPSEM supports the limit of 5 mm as the maximum amount of missed tissue in contact mode[78]. For magnification mammography a slightly weaker limit of 7 mm is acceptable but not desirable.

4.2.5 Plate Fogging (CR only))

This test assures that the storage locations for CR cassettes are sufficiently shielded to prevent fogging artefacts. One cassette is selected and erased. A coin is then taped to the cassette which is left in the storage area with the coin facing the tube for a significant time, for example the complete acceptance testing period. The cassette is then

read using minimal screen processing and no post processing. Some units may allow quantitative evaluations in terms of their exposure indicator being within pre-determined specifications. In any event, the image of the coin must not be visible in the image even when a narrow window is used for viewing purposes.

4.2.6 Modulation Transfer Function

The modulation transfer function (MTF) is recognised as the best indicator of equipment system resolution. It can be measured with either of two methods. The first uses either the Fourier transform of a point spread function, line spread or edge response function (ERF)[29]. The second approach uses a bar pattern phantom and the application of the Coltman transform[30]. A variation of the latter methodology has been described by Droege and Morin[31] and is currently favoured in the IEC acceptance testing document[32]. Recently the use of the ERF has been generally discussed in the literature for MTF measurement in mammography[5,33,34] and advocated by another IEC document[35]. The test requires a square test object with sides of at least 50 mm long. It should be mounted on a backing plate, large enough to cover the entire detector. The ACR suggest 0.8 mm of aluminium is suitable for this purpose. The test object may be made of a variety of materials such as Niobium[33] (27 μm thick), stainless steel[35] (80 μm thick) or brass with tungsten or lead [34]. The test object should be placed on the image receptor so that it makes an angle to the pixel rows or columns of between 1° and 3°. An image should be acquired using the same technique factors that would be relevant for the ACR Accreditation phantom except that the mAs should be increased by a factor of between two and four. The DICOM image is then processed with software (see references above for details) to give the MTF. The test procedure should be repeated with the test object raised above the image receptor by 40 mm.

4.2.7 Threshold Contrast Visibility

The threshold contrast detail phantom test uses the CDMAM 3.4 phantom. This phantom has been adopted in Europe as the basis of image quality assessment and relies on the theory that digital images are ultimately quantum noise limited. This premise has been challenged recently by work that illustrates that clinical projection images are in fact limited by structured noise from the parenchymal pattern of tissue[36,37]. The reality of this is clearly demonstrated with the good low contrast visibility achievable through DBT. The current utilisation of the CDMAM phantom has also recently been investigated with the difficulties in the scoring of the phantom demonstrated[38,39]. It is believed that automatic reading of the phantoms may alleviate the problems experienced with this phantom although such software[72] may introduce inherent scoring biases.

The ACPSEM therefore does not advocate the use of the CDMAM phantom for quality control, however it suggests that selected large centres continue to monitor and investigate the use of this phantom as it a very sensitive test of noise limited systems.

4.2.8 Spatial Linearity and Geometric Distortion

A convenient way to observe any spatial non-linearity and geometric distortion is to image a film/screen contact mesh pattern with light compression. The mesh may need to be placed asymmetrically on the imaging device in order to avoid Moire effects in the image arising from sampling frequency issues. The image is viewed in magnified mode using magnify and roam tools and any distortion is readily evident, although the assessment is somewhat subjective.

4.2.9 Distance Calliper Accuracy

Confirmation of the system distance callipers, and hence pixel size by implication, may be undertaken by imaging steel rulers of known length placed parallel to and at 90° to the chest wall. The rulers should be placed in direct contact with either the breast support or a CR cassette, depending on the indicated circumstances. Direct measurement in the image using the measurement tools should confirm the distance accuracy to better than 2%. In some instances, a small correction for magnification effects may be required to correct the distances measured in the images to the manufacturer's reference plane. For example, with the Hologic Selenia Dimensions 2D (Hologic, Bedford, MA, USA) the reference plane is 22.5 mm above the breast support. Thus, in this instance, where the source to breast support distance is 675 mm, a multiplicative correction factor of 1.034 should be applied. Ideally, distance measurements should be undertaken at the reporting workstation in **contact mode and in each clinically used magnification mode** to confirm that there are no issues with the transfer of dimensions to PACS as such problems have been noted in the literature[66]. When that is not possible the images must be evaluated at the acquisition workstation or exported to another workstation and evaluated with a DICOM viewer.

4.2.10 Monitor Installation and Viewing Conditions

Special attention should be paid to the monitor installation and viewing conditions for display systems. As previously noted the ACPSEM believes it is essential that monitors used for primary assessment of the mammographic image be used in monochrome mode and be capable of displaying at least 4.2 MPs at a pixel pitch of 0.2 mm[90,93]. Further, those used on the acquisition device for QC should be capable of displaying at least 3 MP. The luminance range must be measured with an appropriately calibrated (or traceable) photometer. The maximum luminance must be >450 cd/m^2 for a primary display device[43] and > 250 cd/m^2 for a secondary display device used for QC (e.g. acquisition monitor)[93]. The maximum luminance of two or more diagnostic monitors on a workstation must be matched to within 5%. This requirement also applies to two viewing windows within the one large monitor. The luminance ratio (LR), measured as the ratio of the maximum luminance (L_{max}) to the minimum luminance (L_{min}) must be large for good image contrast; however, an excessively large LR will exceed the range of the adapted human visual system. The LR must be greater than 250 with an LR of approximately 350 seen as most effective. This can be achieved with an L_{max} of 450 cd/m^2 and an L_{min} of approximately 1.3 cd/m^2. For monitors with greater luminance L_{min} should be proportionately larger to maintain approximately the same LR[93]. Since the contrast

response of the adapted human visual system is poor in very dark regions, the L_{min} should not be extremely low. L_{min} values of less than 1 cd/m^2 are not desirable[93]. Whilst optimising the maximum and minimum luminance values, it is important to ensure that the monitor meet all the required criteria, when viewing the TG 18-QC test pattern, as outlined in Appendices 3a and 3b. The ambient lighting must not exceed 20 lux.

Monitor tests are commonly achieved through the viewing of test patterns that can be obtained directly from the AAPM TG-18 website http://deckard.duhs.duke.edu/~samei/tg18.htm. However they may be supplied or installed by the monitor supplier and are specific to the monitors used. The use of non-matched test patterns results in aliasing which prevents the proper assessment of monitor devices. In many cases the patterns are already incorporated into manufacturer specific QC programs with daily, weekly or monthly testing frequencies specified. At acceptance, all tests should be performed in accordance with the AAPM recommendations[16,17] Special attention is needed in a Picture Archiving and Communication System (PACS) or when the workstation and display devices are not from the same vendor as the primary digital imaging system. Tests unique to commissioning of a new monitor might include noise (TG18-AFC), veiling glare (TG18-GV, GVN, GVs), chromaticity, electronic cross talk (LCD only) (TG18-LPH-02) pixel defects (LCD only) (TG18-UN10 and TG18-UN80) and display noise (TG18-AFC) as well as tests detailed in section 4.3.14 (see also reference 73).

At the very least, the ***Luminance response*** must be measured at acceptance (if issues are reported) to check whether a display is calibrated to the DICOM Grayscale Standard Display function (GSDF). Conformance with the GSDF ensures the image will appear similar on different viewing stations and on printed film. The test patterns TG18-LN12-01 through to TG18-LN12-18 are used to determine this function using a photometer[43,73]. The TG18-QC pattern may also be used but each grayscale square should be zoomed and centred.

To reduce image glare the walls of the reporting room should be painted with a non-reflecting material and should be in a dedicated area to ensure appropriate ambient lighting. To assess specular reflection observe the display when turned off, from typical positions for interpretation under normal ambient. At a distance of about 30 to 60 cm within an angular view of ±15° no specular reflections, such as high contrast objects including patterns on the viewer's clothing should be seen. If light from a film illuminator or window for example are seen, the position of the display device is not appropriate. If patterns such as an identification badge on a white shirt etc. are seen, the ambient illumination in the room should be reduced.

The effect of diffusely reflected light on image contrast may be observed by alternately viewing the low-contrast patterns in the TG18-AD test pattern in near total darkness and in normal ambient lighting, determining the threshold of visibility in each case. A dark cloth placed over both the display device and the viewer may be helpful for establishing near total darkness. The pattern should be examined from a viewing distance of 30 cm. The threshold of visibility for low-contrast patterns in the TG18-AD test pattern should not be different when viewed in total darkness and when viewed in ambient lighting conditions. If the ambient lighting renders the "dark-threshold" not observable, the ambient illuminance on the display surface may be causing excess contrast reduction, and the room ambient lighting needs to be reduced.

4.3 Annual Test Procedure Recommendations

The annual test procedures to be performed by medical physicist are listed in Appendices 3a and 3b and further discussion of the testing is provided in the following sections. A subset of these tests must also be undertaken following significant equipment upgrade such as x-ray tube or detector replacement, AEC adjustment or any other change that might influence image quality or patient dose. The specific tests to be undertaken being dictated by the nature of the upgrade. These repeat physics assessments must be performed prior to any patient examinations. Additional testing would not be necessary following replacement of minor components such as a hard drive or computer mouse that do not have any impact on image quality and patient dose.

4.3.1 Mammography Unit Assembly Evaluation

The mammography x-ray unit must be inspected to confirm correct function of column rotation, vertical drives, locks and indicators and to identify any miscellaneous safety related issues (e.g. jam risk, system stability, loose cabling etc.) as described elsewhere[1,2]. Evaluation of thickness display accuracy should be included using PMMA thicknesses ranging from 2 to 8 cm under a compression force of 70 to 90 N. Care should be taken to avoid any scratching of either the compression paddle or the breast support. Some manufacturers advise the use of semi circular or triangular PMMA blocks. These shapes have the advantage of applying a more realistic pressure pattern to the paddle but will affect the measurement performance of the paddle, as will the use of spring loaded or flexible paddles. A tolerance of ±5 mm for the thickness display accuracy is recommended for conventional paddles.

The clinical operational settings should be clearly displayed on a technique chart adjacent to the console as is the case for screen-film mammography[1]. This should include **magnification and implant** settings as appropriate.

The displayed image information from the DICOM header[24] of any randomly selected patient image should be verified for the correct display of relevant parameters such as institution name, patient name, patient ID number, projection and technique factors, acquisition time and date. This should be also checked after software upgrades. Unfortunately, when CR is used as the image processing device the DICOM tags for the technique factors will not be populated unless a Protocol Bridge (Livingston Products Inc., Wheeling, Illinois, USA) is installed. For screening centres this is a mandatory requirement[3].

4.3.2 Collimation and Alignment Assessment

The importance of maximum x-ray coverage of the mammographic film has been covered elsewhere[1]. This requirement may not be as essential with true digital receptors where any unexposed sections of the image receptor are commonly processed digitally to create a fully dark background to the mammographic image. However, when assessing a digital mammography system it remains important to ensure that the entire image receptor can be irradiated. When assessing a system using CR as the image receptor account should be taken of the variation in CR plate position in the cassette and any latitude in the position of the cassette in the image receptor holder.

In early versions of the position paper a formal requirement was placed on the alignment between the x-ray and light fields. The ACPSEM believes this is no longer necessary. One requirement that is retained is the proviso that the x-ray field extend to the edge of the image receptor at the chest wall but not extend beyond the breast support by more than 2 mm[78]. This requirement can be established most simply with a fluorescent screen.

Finally, correct alignment of the front edge of the compression paddle is important. If the outer paddle edge is positioned more than one percent beyond the image receptor edge on the chest wall margin the amount of breast tissue missed by the paddle position will exceed that allowed by the missing tissue test. Alternatively, if the paddle edge falls within the image area, breast tissue in the image will be obscured. A very simple method for determining the position of the paddle with respect to image receptor is to physically measure the overhang of the paddle with respect to the breast support with a ruler and add this measurement to the missing tissue value (see section 4.2.4). When checking the alignment of flexible paddles, particular care must be exercised as the alignment will vary significantly depending on the amount of compression applied. It is suggested that little or no compression force be applied or the paddle be positioned parallel to the breast support.

4.3.3 System Resolution / MTF

While the system resolution of a screen film system is typically constrained by both the focal spot size and the image receptor resolution, digital system limiting resolution in mammography is effectively constrained by the del size (see section 4.2.1). Thus, the use of a limiting resolution test pattern in the digital case typically yields only partial resolution information whereas measurement of the MTF will give more complete information about system performance. Thus, the preferred technique, which remains optional, is to measure the system MTF. The use of a metal straight edge, placed on top of 40 mm of PMMA, with appropriate software is recommended. Alternative test objects, such as bar pattern objects, with appropriate software may be used. As digital mammography QC becomes standardised it is expected that test tools and software will be provided with the mammographic equipment. If this is not the case the MTF can be obtained using an exported DICOM image of a suitable test object using third party software.

Notwithstanding the above, if the MTF cannot be measured easily the limiting resolution must be measured using a resolution pattern placed on 40 mm of PMMA. In either case, measurements must be undertaken in both contact and magnification mode.

4.3.4 Automatic Exposure Control System Performance Assessment / Signal Difference to Noise Ratio

The AEC is perhaps the most important component of the digital mammography system as it controls the dose and image quality of the system. Some of the AEC tests, such as reproducibility, backup timer and/or security cut-out require no real change from the screen-film situation[1], while the concept of thickness compensation is essentially superseded by measures of dose and image quality as a function of object thickness. The case of CR is an exception, where the host mammographic unit requires calibration to facilitate appropriate exposure settings for different object thicknesses. The function of the density control (if applicable) is also different in that the range of mAs values provided should be much greater than that for screen-film mammography as the main requirement now is to change the level of image noise. Specifically, the density control must be capable of changing the mAs from the value used normally by -25% to +50%.

At acceptance testing, the DR equipment vendor must provide the manufacturer's recommended target pixel values and allowable tolerance for a range of PMMA absorber thicknesses. In some systems, the AEC is designed to maintain an essentially constant MPV over the thickness range, in which case a single target value is appropriate.

When testing CR systems, to ensure constancy and to avoid variations in the exposure indicator, or its surrogate, caused by image fading it is suggested that the plate be read at a fixed time delay (say 30 seconds) after irradiation.

For systems that produce film images for diagnosis the optical density must comply with the standards for film screen mammography.

<u>Signal Difference to Noise Ratio (SDNR)</u>

The assessment of image quality is primarily achieved with the measurement of the SDNR. This measurement requires a uniform phantom with a test object of slightly varying attenuation. The simplest is a test object consisting of an aluminium foil of thickness 0.2 mm and dimensions 10 mm x 10 mm[9]. Images of this test object are made **under AEC** with 2, 4 and 6 cm thicknesses of PMMA. The technique factors must be recorded as it is important that these are the same or very similar factors are utilised in the determination of the mean glandular dose as described in section 4.3.11[e].

[e] *With the Al test object of 10 mm × 10 mm the ROIs used in the analysis should be ~ 0.25 cm^2.*

In each **"for processing" or raw** image the mean pixel value (MPV) and standard deviation (SD), respectively are calculated for a ROI located in a uniform part of the phantom (PV_b, SD_b) and in an area where the Al foil is located (PV_{Al}, SD_{Al}). Both ROIs should be centred on a line parallel to and 6 cm **(3 cm for magnification images)** from the chest wall to minimise the impact of the heel effect and ideally the image pixel values should be linearised with respect to dose before the SDNR as defined below is calculated. The SDNR is defined as[9]:

$$SDNR = \frac{PV_b - PV_{Al}}{\sqrt{[(SD_b^2 + SD_{Al}^2)/2]}}.$$

The European specification[9] requires that the measured SDNR be at least 110%, 100% and 90% of the minimum acceptable SDNR with 4 cm PMMA (designated as $SDNR_{accept}$) with 2 cm, 4 cm and 6 cm of PMMA as a test object, respectively. For each model of mammography system, the value of $SDNR_{accept}$ is unique and has been established from experience in Europe by reference to imaging performance with the CDMAM test object mentioned in section 4.2.7. Table 2 provides a list of digital mammography units with recommended values of the parameter $SDNR_{accept}$ for use in contact mammography.

Recent experience suggests that these values are also universally applicable in magnification mode with DR units but not with CR units. Accordingly, the required specification for the SDNR for 6 cm PMMA imaged in magnification mode with CR is relaxed but it must still be at least **65%** of $SDNR_{accept}$.

Some further comment is required about the process of establishing compliance with the acceptable limits. Testing should initially be undertaken using the AEC settings normally used clinically by the site in question. If the medical physicist finds non-compliance then they must undertake further testing to establish AEC settings that will provide compliance. Any recommended changes must be clearly communicated to the site in their report.

In most CR systems it may be difficult to extract meaningful statistics relating to ROIs because of the inadequacies of workstation software. Under these circumstances, it will be necessary to export uncompressed, unprocessed, DICOM images to a USB stick or compact disc for subsequent analysis with freeware image analysis programs[24,25,65]. It had previously been suggested that image data should be linearised first with respect to dose before the SDNR is calculated. Recent experience suggests that provided the contrast object is relatively thin, the SDNR calculated from the unprocessed, non-linearised CR data is a very good approximation to the true SDNR calculated with linearised data. Note that in contact mode, the target SDNR values in the range 2 cm to 6 cm PMMA must be achieved by the AEC without recourse to the operator intervening in the selection of the density control setting. However, if a host mammographic unit allows a change in density control with thickness to be pre-programmed then this is an acceptable means to achieve the required outcome. On the other hand, in magnification mode operator adjustment of the density control to achieve the acceptable SDNR values, whilst not desirable, is allowed. Thus, if testing establishes that the density control must be adjusted manually as the thickness changes in magnification mode then the medical physicist must notify the site that a technique chart for magnification mode reflecting this fact must be posted on the operator's console.

It is important to note that the acceptable SDNR values referred to in Table 2 must be obtained within the dose constraints discussed in section 4.3.11 and also within the exposure time limits specified for imaging of 6 cm PMMA in section 4.3.12.

Table 2 *DR and CR manufacture specific values of $SDNR_{accept}$ with 4 cm PMMA. They are derived from published values (see Reference 26).*

Manufacturer	Model	$SDNR_{accept}$
Fuji	Amulet	5.5
	Amulet fs	6.6
	Innovality	6.6
General Electric	2000D	8.1
	DS	8.1
	Essential	11.6
	Senoclaire (normal Bucky & MTD**)	11.6
	Pristina	11.6*
Hologic	Selenia (Mo or W anode)	4.35
	Selenia Dimensions 2D & 3D	4.1
Philips	MammoDiagnost DR	4.4
Philips/Sectra	L30 (v 8.3 software & higher)	5.1
	L50 (v 9.0 software)	4.6
Planmed	Clarity	7.5*
Siemens	Novation	4.8
	Inspiration	4.5
	Inspiration PRIME	5.3
Agfa	CR 85-X with MM 3.0 plate	11.1
Konica	Regius 190 with RP-6M plates	10.4
	Regius 190 with RP-7M plates	8.0
	Regius 190 with CP-1M plates	6.0
Fuji	Profect CS with HR-BD plates	8.9
Carestream	DirectView with EHR-M2 plates	7.8
	DirectView with EHR M3 plates	10.2
	DirectView with SNP-M1 plates	7.0*
Philips	Eleva Cosima X with Fuji HR-BD plates	8.9*

*Provisional values: ** Motorised Tomosynthesis Device

Systems such as the GE Senoclaire (GE Medical Systems Buc, France) use a different Bucky (called Motorised Tomosynthesis Device or MTD) when being used in DBT Mode. However, they also can acquire conventional projection images with the MTD in lieu of the normal Bucky. Under these circumstances the MTD must be subjected to full assessment of the AEC as noted above and meet the minimum SDNR values given in Table 2.

Finally, regardless of system type, it is important to establish that the AEC does not allow excessive exposures. A security cut-out mechanisms shall be present and either

terminate the exposure within 50 ms (or within 5 mAs) or restrict the maximum deliverable mAs under any circumstances to ≤500 mAs ideally and certainly to ≤800[78] or less as dictated by regulatory requirements.

4.3.5 Image Uniformity and Artefact Evaluation

Image uniformity includes a measure of (i) spatial, (ii) temporal uniformity of image detector or image plate response to radiation and, in the case of CR technology, (iii) the uniformity of response of each cassette/image plate within the clinical set of utilised plates. This last requirement is analogous to the screen cassette uniformity test conducted with screen –film as the image receptor[1]. The procedure for all three uniformity measures is essentially similar with a standard test PMMA block of thickness 40 mm covering the entire image receptor being exposed under the same AEC conditions with which the unit has been calibrated. If a mammography DR system is utilised by the clinical site for assessment then both contact and magnification modes must be evaluated.

To assess the spatial uniformity qualitatively the image is simply viewed with a display window width of 10% of the mean pixel value. Preferably, uniformity can be assessed quantitatively for DR units by measuring the mean pixel value (with pixel offset value subtracted). The ROI size recommended in the European protocol[9] is 100 mm^2. Apart from the central one, all ROIs should be placed about 20 mm from the image margins. The maximum deviation in the mean pixel value for each ROI must be less than **±10%** of the mean pixel value for the central ROI. To exclude failure due to non-uniformity of the block, the block can be rotated 180 degrees and a repeat measure taken. With CR units the heel effect is not usually corrected for and the procedure may be simplified slightly by requiring that the mean pixel value and SNR be evaluated using just three ROIs placed on a line approximately 20 mm from and parallel to the chest wall. The mean pixel values for the three ROIs must not differ by more than **±10%**[43]. Should the left or right SNR values drop significantly below the central SNR, it is an indication of possible damage to the CR plate(s) and it may be appropriate to consider replacement of the plate(s). With new plates the SNR variation should be <15%.

Temporal uniformity or system response stability is assessed by comparing the SNR from the central ROI with that from previous measurements. A maximum deviation of less than ±10% in SNR is required, except when the system has undergone a software upgrade which could account for any abrupt change.

For CR cassettes it is also necessary to assure that the image response does not vary between cassette/image plates. In this case the image post processing must be turned off as much as possible. The basic criteria for inter cassette/image plate uniformity is **±5% in terms of mAs or dose to the plate**. A comparison of the exposure indicator, or its surrogate, for all plates is appropriate as discussed in the technologist's section (see section 3.2.17 and Appendix 6).

If more than one cassette size is utilised in the practice then the tolerances (see Appendix 6) must apply to each size separately with the further proviso that the difference in the average dose to the imaging plate for the two sizes is less than 20%. Appendix 6 should be consulted to see what this means in terms of the manufacturer specific exposure indices.

Image artefacts can interfere with the detection of cancers and also be the source of false positive image interpretations.

Usually images obtained whilst testing image receptor uniformity with PMMA test objects may be suitable for identifying and assisting in the elimination of some artefacts. Images must be free of blotches or regions of altered noise patterns, free from grid lines or breast support structures and bright or dark pixels.

Further, artefacts unique to digital detectors may arise. Specifically, detector element failures can occur. The manufacturers should provide access to a "dead pixel map" which indicates which del values are not based on their own reading. This should be inspected by the medical physicist at each visit and compared with earlier maps. No specific limits apply at this point in time but future requirements are likely to be based on limiting the number of defective dels in a defined area to a maximum percentage. In the interim, the manufacturer's specification should apply.

4.3.6 Image Quality Evaluation

The ACPSEM accepts the use of the ACR Accreditation phantom (e.g. the RMI 156 or equivalent) for base line image quality evaluation but with the additional proviso that, using the RANZCR scoring system[1], a score of at least 5 fibres, 3.5 speck groups and 4 masses must be achieved in the digitally acquired image at a mean glandular dose (MGD) of ≤ 2.0 mGy for that phantom. Ideally, 4 speck groups should be visualised but field testing has established that significant variations in scoring of specks can arise when different ACR phantom units are utilised, This variation is attributable to manufacturing tolerances and aging of the wax insert test object.

Notwithstanding the above, if sites or individual physicists wish to purchase a new phantom, the ACPSEM now recommends the recently released ACR digital mammography phantom, referred to as the ACR DM phantom. This phantom has been designed with tighter specifications and is certainly more sensitive to imaging equipment changes in performance. **With the new ACR DM phantom, the equivalent minimum acceptable scores are 4 fibres, 3 speck groups and 3 masses**. **An additional requirement is that the SDNR measured with the negative contrast object in the phantom must be ≥ 2.0. Note that the SDNR measurement must be performed using a "raw" or "for processing" image.**

4.3.7 Ghost Image Evaluation

A ghost image represents the remnants of a previous image arising either as a result of the detector memory (DR systems) or incomplete erasure (CR systems). Both

qualitative and quantitative (preferred) evaluations may be undertaken depending on the capability of the acquisition workstation.

A 4 cm thick PMMA block is positioned such that half the detector or CR cassette is covered and an exposure is made using typical exposure factors under manual control (e.g. 28 kVp, 50 mAs). This creates the ghost image. For DR systems a second exposure is taken, after a delay of about a minute, at the same clinical settings but with the PMMA block completely covering the detector. For CR systems the cassette is erased using the normal readout cycle before the second exposure is undertaken with the geometry described in the previous sentence.

The ghost image evaluation involves determining the mean pixel value (PV_i) in two ROIs in the second image. The two ROIs are placed equidistant from the boundary defining where the PMMA and no PMMA regions existed in acquiring the ghost image. The noise (SD) is also measured in the ROI that corresponds to the region that would have been under the PMMA in the ghost image formation. The Ghost Image Factor is then defined by:

$$\text{Ghost Image Factor} = |(PV_1 - PV_2)|/SD$$

and must be less than 2.0.

4.3.8 System Linearity & Noise Analysis

The response of DR systems to air kerma variations should be linear. To test this, the "for processing" (unprocessed or raw) images of a 40 mm PMMA block covering at least the central part of the detector must be acquired under manual control at a clinically relevant kVp and target/filter combination (i.e., those selected under AEC for 40mm PMMA). The range of mAs values selected should cover the clinically useful range (e.g. 5 to 300 mAs). The air kerma (K) is measured by placing a dosimeter on or next to the PMMA and approximately 60 mm from the chest wall in the irradiated field in a position that will not influence the subsequent image measurements. Images are viewed and a ROI is drawn centrally along the long axis and approximately **60** mm from the chest wall. The mean pixel value (with pixel offset value subsequently subtracted) and standard deviation (SD) are recorded.

For DR systems a plot of mean pixel value (MPV) against the K is drawn and linearity tested by noting the square of the correlation coefficient (R^2). A reasonable specification is to require that this plot must have $R^2 > 0.99$[4,9]. In a change from early versions of this paper the ACPSEM now recommends that some limited analysis of image noise is appropriate. This is done by plotting the SD^2 against the MPV and fitting a quadratic function of the form:

$$SD^2 = a_0 + a_1\,MPV + a_2\,MPV^2$$

where a_0, a_1, and a_2 represent the relative contributions of electronic, quantum and structure noise, respectively[63,64,9.74]. It should be noted that where manufacturers include a PV offset in their images then this offset must first be subtracted from the measured pixel values before the above plot is undertaken. The R^2 value from this fit must be > 0.99 and the fitted parameters should not change significantly from one test to the next.

Similar test procedures apply for CR systems except that the response to air kerma variations depends on the system. In all cases the exposure indicator is recorded for each image, which must be acquired with the same cassette on each occasion. The extraction of mean pixel values and standard deviations may be problematic at best. In any event, it is simpler to confirm linearity by examining the dependence of the exposure indicator on the ESAK. The appropriate plot (see Appendix 6) of exposure indicator against the ESAK must have an R^2 value of >0.99. There remains no specific requirement to perform any noise analysis, as discussed above, on CR systems although this is an option that remains at the discretion of the medical physicist.

4.3.9 Generator Performance

Previously, the ACPSEM had recommended that kVp performance be evaluated on an annual basis. This is no longer felt to be necessary once it has been established at acceptance testing. However, since it remains a regulatory requirement in some jurisdictions it is retained as an optional test and is certainly warranted when the x-ray tube is changed or if HVL or measured dose values appear problematical.

A minimum of **three** manually selected exposures is recommended to assess the reproducibility of kVp. These exposures should be made using a kVp and target/filter combination that is in routine clinical use. The COV must not exceed 0.02 for kVp reproducibility.

The kVp accuracy must be measured across the entire range of kVps used clinically. The measured kVp must be within ± 5% of the specified value.

4.3.10 Beam Quality or Half Value Layer

An accurate measurement of half value layer (HVL) is required to allow estimation of the MGD. At a routine evaluation the HVL (with compression paddle in the beam) must be measured for target/filter and kVp settings related to MGD calculations (see section 4.3.11) and also at values related to establishing compliance with DRLs (see also section 4.3.9). At acceptance, the evaluation should be extended to include at least one kVp at all possible target/filter combinations as this may be required for subsequent dose audits.

The ACPSEM[1] requirements for the HVL with the paddle in the beam are as follows:

$$(kVp/100) + 0.03 \leq HVL < (kVp/100) + C$$

where C = 0.12 mm Al for Mo/Mo
= 0.19 mm Al for Mo/Rh
= 0.22 mm Al for Rh/Rh
= 0.23 mm Al for Rh/Ag
= 0.30 mm Al for W/Rh
= 0.32 mm Al for W/Ag
= 0.25 mm Al for W/Al.

If the unit is used for biopsy purposes with an open paddle, at acceptance, the HVL should be measured at 28 kVp for all available target/filter combinations with the paddle

removed from the beam. HVLs measured under these conditions must comply with the requirements of IEC 61223-3-2, 2007[32].

4.3.11 Mean Glandular Dose

The measurement of Mean Glandular Dose (MGD) is essential to the assessment of the performance of the imaging system as a whole. The measurement is used to ensure that the system complies with dose limits specified by accrediting and/or regulatory bodies, and to allow comparisons between systems. The measurement of MGD should ideally be undertaken for a range of breast thicknesses as, in many cases, the unit displays an MGD for each procedure, and also because the dose value is crucial to determining whether the AEC of a digital system is optimised.

As noted previously the MGD is calculated from the incident air kerma to a breast phantom together with suitable conversion factors that vary with beam quality, breast thickness and breast glandularity[1,45]. A number of studies have evaluated breast glandularity[46-52] with the UK adopting the studies of Young et al and Beckett et al as a basis for their dosimetry protocol[53]. There is reasonable agreement between most of the studies in the breast thickness range of 3 to 6 cm thick, however at thicknesses above 6 cm the UK glandularity values are considerably lower than the results from Germany[50], the US[46,48] and Australia[49]. The European protocol has adopted the UK dosimetry model and has further converted thicknesses of PMMA into breast equivalent thickness and corresponding glandularity[8,53].

Although recent work by Yaffe et al[75] and Vedantham et al[76] have demonstrated that the volumetric glandularity is more typically in the range of around 20%, depending somewhat on the glandularity definition, breast thickness, age, weight, and the ethnicity of the women surveyed, the ACPSEM believes that for simplicity and for QC purposes, the MGD should be measured for a 50% glandular, 50% adipose breast (henceforth referred to as 50:50) unless otherwise stated[45]. Further, that dose indicators displayed for mammographic exposures should be verified, as far as possible, over a range of thicknesses for both contact and magnification modes as appropriate. Such verification may be done with breast phantom material simulating a 50:50 breast, but with a 5 mm layer of adipose material on the top and bottom of the phantom. However, for ease of testing it is preferred that PMMA be utilised. Published data[54] converting PMMA block thicknesses to equivalent 50:50 breast material thickness may then be utilised to calculate the MGD. Specifically, the relationship between PMMA and breast tissue equivalent thickness may be expressed by the equation:

Breast thickness (mm) = 1.047×PMMA thickness (mm) + 1.78.

In a departure from previous versions of this document, and following on from the lead of the ACR[4], the ACPSEM now recommends the adoption of the dosimetry formalism by Dance et al[53,54,69,77,92] for the estimation of the MGD. This formalism has been adapted for specific application in the UK and European dosimetry protocols, the IAEA Quality Assurance for Mammography program[62] and the current ACR protocol[4]. Further this formalism is recommended by the ICRU[45] and the IAEA[94] and the tables in those publications are compatible with our use. Whilst doses estimated by either the Dance model or that of Wu et al[55,56,57] differ only marginally, the Dance methodology allows for greater flexibility and ease of calculation within a spreadsheet. The full dose formulation of Dance for mammography is given in the equation below:

$$MGD = K.g.c.s$$

where K is the incident air kerma measured at the entrance surface of the breast, the g-factor converts K into MGD for a standard breast irradiated with x-ray beams generated from molybdenum/molybdenum (Mo/Mo) target/filter combination, the c-factor would correct for breast glandularity other than 50% but is set to unity in the present application and the s-factor corrects for the x-ray energy spectrum generated by target/filter combinations other than Mo/Mo.

Care must be taken to correct any measured incident air kerma values by the inverse square law to the height of the breast equivalent thickness, not to the PMMA entrance level.[f] Also, measurement of the incident air kerma should be conducted in close contact with the compression paddle to mirror the Dance Monte Carlo simulation setup. For consistency of practice and simplicity, the ACPSEM does not recommend the use of spacers, as advocated in the UK and European protocols, to equate the thickness of the PMMA phantom to that of the equivalent breast model for dosimetry. Practical experience has suggested that the addition of spacers would not contribute to any major dosimetric differences owing to the adaptation of the 50:50 breast assumption and the fact that current QC measurements only concern PMMA phantoms of thicknesses up to 6 cm.

The following dose limits apply. For 20 mm and 60 mm PMMA, the MGD must be less than 1 mGy and 4.5 mGy, respectively. For the ACR Accreditation phantom or the new ACR DM phantom the MGD must be ≤2 mGy.

If measuring MGD for magnification mammography, caution should be taken in applying the conversion factors published for the contact geometry and the physicist is referred to the work of Liu et al[59].

Modern DR mammographic equipment records a value for the mean glandular dose in a DICOM structure of each mammographic image and this value is also displayed on the acquisition workstation monitor and may be issued in a structured dose report in future. The validity of such values should be checked by the medical physicist for a range of

[f] *In principle, this recommendation does not contradict the UK, European and IAEA protocols which state that the incident air kerma should be measured at the upper surface of the PMMA phantom. It is worth noting that specific correction factors have been implicitly applied in the above protocols to relate the incident air kerma measured with PMMA phantoms to that of the equivalent breasts. In the present recommendation, however, no such corrections have been made.*

breast types and thicknesses. Following on from the lead of the ACR[4], the ACPSEM recommends that the displayed/recorded MGD values must agree with estimates from the Dance model, discussed above, to better than 25%. It is noted that increasingly electronic dose related data is gathered for dose information statements, therefore it is of importance that the veracity of such information be established.

Importantly, the ACPSEM believes that sites need to undertake dose surveys to allow comparison of their doses with State or National diagnostic reference levels (DRLs). In order to facilitate this it is necessary that x-ray output and HVL measurements must be undertaken at a number of kVps and target filter combinations indicative of techniques used to image breasts of average thicknesses in the range 55 to 65 mm. This may mean that additional measurements above and beyond those outlined above may need to be undertaken. Table 3 provides a guide to possible required measurements for DR systems. For CR systems the actual requirement will need to be made on an individual basis dependent on the CR manufacturer and the x-ray unit used with the CR system. Whilst Robson[44] has developed simple power laws that may be applied to generate output and HVL values based on measurements at a single kVp the ACPSEM recommends that actual measurements should be undertaken if at all possible.

Table 3 *Guide to possible techniques required for output and HVL measurements with DR units*

Manufacturer	Model	Target /filter	kVp
Fuji	All models	W/Rh	30, 31
General Electric	All models except for the Pristina	Rh/Rh	29
	Pristina	Rh/Ag	34
Hologic	All models	W/Rh	30, 31
Philips	MammoDiagnost DR	W/Rh	28, 30
Philips/Sectra	L30 & L50	W/Al	32, 35
Siemens	Novation	W/Rh	28
	Inspiration	W/Rh	28, 30
	Inspiration Prime	W/Rh	28, 30

4.3.12 Exposure Time

In the earlier position paper[1] it had been a requirement that the radiation output rate be measured to confirm that it was sufficiently high to keep clinical exposure times within a reasonable range. The requirement to have short exposure times remains important for both contact and magnification digital imaging. However, rather than measuring the output rate, it is now felt that a sufficient requirement is to measure the exposure time[g], or infer it by observing the required mAs, under AEC operation using clinically relevant technique factors (kVp, anode/filter combination etc.) to image 6 cm of PMMA and dividing by the known tube current, specified in the technical manual. The technique factors employed in this test must be consistent with those used in the assessment of the SDNR and the MGD (see sections 4.3.4 and 4.3.11). It is suggested that the exposure time required, for fine and broad focus modes of operation, be less than 3.5 seconds and two seconds, respectively. This provision is waived for the scanning slot technologies.

4.3.13 Viewbox Luminance and Room Illuminance (Hardcopy only)

As in screen film mammography every effort must be made to keep ambient lighting as low as possible as outlined elsewhere.

4.3.14 Monitor Luminance and Viewing Conditions

It is essential to check the monitor installation in detail with the use of the TG18 test pattern series[9,16,17,62] prior to conducting any image quality assessments of x-ray images as has been mentioned previously (section 3.2.4). All relevant test patterns[17] should be viewed and if even subtle departures from the expected appearance are seen, further investigation with the appropriate technician is required. This may reveal set up errors or deficiencies. Special attention is needed in a Picture Archiving and Communication System (PACS) or when the workstation and display devices are not from the same vendor as the primary digital imaging system.

Ambient lighting conditions are more critical for monitor viewing due to the lower luminance levels provided by monitors. Any windows in the viewing room should be covered to exclude daylight. Room lighting should be indirect. Care should be taken that no direct illumination from room lighting or other sources falls directly on a monitor (including the acquisition monitor). The ambient lighting must be measured and be less than **20 lux**.

Geometric distortion (CRT displays), contrast visibility and display artefacts are tested using the TG18-QC test pattern, while a range of test patterns can be used to check image resolution. The screen should be cleaned before assessment.

Luminance range must be measured with an appropriately calibrated (or traceable) photometer. The maximum luminance must be >450 cd/m^2 for a primary display device and > 250 cd/m^2 for a secondary display device used for QC (e.g. acquisition monitor)[93]. The maximum luminance of two or more diagnostic monitors on a workstation must be matched to within 5%. This requirement also applies to two viewing windows within the one large monitor. The luminance ratio (LR), measured as the ratio of the maximum luminance (L_{max}) to the minimum luminance (L_{min}) must be large for good image contrast; however, an excessively large LR will exceed the range of the adapted human visual system. The LR must be greater than 250 with an LR of approximately 350 seen as most effective. This can be achieved with an L_{max} of 450 cd/m^2 and an L_{min} of approximately 1.3 cd/m^2. For

[g] *If the exposure time is to be measured directly then it should be done using a manual exposure that matches the mAs needed for the AEC controlled exposure. This avoids the inclusion of the trial exposure which if included will give the impression of an erroneously long exposure time.*

monitors with greater luminance L_{min} should be proportionately larger to maintain approximately the same LR[93]. Since the contrast response of the adapted human visual system is poor in very dark regions, the L_{min} should not be extremely low. L_{min} values of less than 1 cd/m^2 are not desirable[93]. Whilst optimising the maximum and minimum luminance values, it is important to ensure that the monitor meet all the required criteria, when viewing the TG 18-QC test pattern, as outlined in Appendices 3a and 3b.

Luminance uniformity should also be checked using test patterns TG18-UNL10 and TG18-UNL80. The maximum deviation of a display device should be less than 30% $(L_{max}-L_{min})/L_{centre}<0.3)$.

4.3.15 Printer (Hardcopy)

The initial set up of the printer is critical and must be examined closely to ensure correct installation. In particular the laser spot used for scanning must be on the lowest setting and the maximum optical density must be at least 3.4. The full range of TG18 test patterns should be printed from each workstation that services the printer (usually at least the acquisition and reporting workstations). Careful examination of these images may reveal subtle errors in the printer set up or the transfer look up tables.

Test patterns are used to test ***geometrical distortion***, ***contrast visibility***, ***printer artefacts, density response and uniformity***. Conformance with the GSDF can be determined by printing the TG18-PQC test pattern[9,16,17] and measuring the optical densities of the marked regions[73].

4.3.16 Exposure Indicator Calibration & Image Fading (CR systems only)

The exposure indicator (EI) is used clinically by radiographers as a guide to confirm that the image is acceptable. Accordingly, the ACPSEM believes that the EI calibration must be established on an annual basis. Each manufacturer has its own procedure for confirming the EI calibration and their methodology must be followed closely. In essence the CR plate is irradiated directly (i.e. out of Bucky) with a known dose and then read out after a fixed time delay. Note that the measurement should be undertaken at a dose relatively close to the specified dose of 175 μGy and the EI then normalised to this dose to confirm the calibration. The accompanying Table 4 summarises the techniques used to undertake the test and provides allowed tolerances.

It is also useful when performing the calibration test to confirm the extent to which the EI changes with the time delay between exposure and readout – this is called fading. Experience suggests that fading, which may be defined as the absolute change in EI when the readout time delay is changed from 1 minute to 5 minutes, should be minimal and should the relevant value in the last column of Table 4 be exceeded then the test should be repeated with a different CR plate to confirm the outcome. Plates exhibiting excessive fading should be removed from service.

Table 4 *Exposure Indicator Calibration Tolerances for a dose to plate of 175 μGy using Mo/Mo spectrum. Absolute EI value and calibration conditions based on manufacturer recommendations.*

Manufacturer	Exposure Indicator	Calibration conditions	EI value	Fading
Fuji,	S#	25 kVp, no paddle, readout time 10 min, use QC Test / sensitivity	120±20	<12
Konica	S#	As per Fuji but use Mammo Test Phantom	120±20	<12
Philips	S#	As per Fuji but use Test Sens Hi Matrix	120±20	<12
Carestream	EI	28 kVp, 2 mm Al, readout time 5 min, Pattern raw	2300±100	<45
Agfa	SAL, SAL log, PVIlog16	28 kVp, 2 mm Al, readout time 105 sec, Flat field	1130±100 21600±1000 41100±1300	<60 <450 <600

5 Biopsy testing: Facility procedures

5.1 Introduction

The tests for biopsy units discussed in this section are based, in part, on the ACR 1999 manual[60]. It is also assumed that film based units are no longer employed and that CR technology is not used for biopsy procedures. As highlighted in the ACR manual a key issue when using biopsy units is the establishment of technique charts, whether an AEC is available or not. With digital receptors inappropriate technique factors may lead to either noisy images (due to inadequate x-ray intensity) or saturated detector systems (due to excessive x-ray intensity). The correct use of technique charts should ensure minimal repeat rates arising from these causes. Accordingly, the usefulness of the posted technique chart should be reviewed at least semi-annually as part of the site QC.

5.2 Procedure Recommendations

Three different configurations of units may be encountered in the field; (i) 'integrated', where the same detector is used for mammography and biopsy use, (ii) 'separate image receptor' where an x-ray system common to mammography but with a different image receptor assembly is used, and (iii) 'stand alone' where full testing must be completed. As such, it must be anticipated that in some cases little or no additional QC testing may be required for biopsy units whilst in other instances variations to the basic tests outlined in section 3 should be expected. However, the following site QC tests:

- Viewing Conditions (see section 3.2.1)
- Artefact Evaluation (see section 3.2.3)
- Monitor QC (see section 3.2.4)
- Monitor/Viewbox Cleaning (see section 3.2.5)

- Printer Area Cleanliness (see section 3.2.6)
- Printer QC (see section 3.2.10)
- Compression (see section 3.2.15)
- Test Equipment Calibration (see section 3.2.16)

should mirror those discussed previously and summarised in Appendices 1a and 4. *Maintenance and fault logging* and *infection control of breast imaging equipment* should be treated as per existing mammography recommendations for screen-film units[1].

Specific requirements or variations for other tests are discussed briefly below.

5.2.1 Stereotactic Accuracy Confirmation

Localisation accuracy confirmation must be performed prior to patient use on each day that the biopsy unit is used. The ACPSEM recommends calibration in air as per the ACR manual[60] unless the manufacturer specifies an alternative technique using a suitable localisation phantom. The required accuracy, in air or using a suitable localisation phantom, is that the indicated needle tip coordinates be within ± 1 mm of the actual preset needle position in each direction (horizontal, vertical and depth)[78].

If the biopsy unit fails this test possible sources of error must be investigated. Possible causes could include a wobbly needle guide, a bent needle, a gap between the biopsy device and its holder, inappropriate needle type or incorrect *throw* length data entered into the computer[60].

5.2.2 Image Quality Evaluation

The image quality evaluation of biopsy units may be carried out as described in section 3.2.7. However, the use of the ACR Accreditation phantom makes this task clumsy with small FOV units. Rather, the ACPSEM recommends the use of the ACR "mini" digital stereotactic phantom (e.g. the NA 18-250 or equivalent) for image quality evaluation but with the additional proviso that a score of at least 3 fibres, 3 speck groups and 2.5 masses must be achieved in the digitally acquired image using the RANZCR scoring system[60]. This is equivalent to the standard used for FFDM and with ACR requirements[60]. Note that if the RMI 156S phantom is used, it is important to recognise that it contains one less speck group and one less mass. Thus, an acceptable score with the RMI 156S phantom is 3 fibres, 2 speck groups and 1.5 masses. In other respects the procedure is similar to that discussed in section 3.2.7.

5.2.3 Mechanical Inspection

In addition to the general inspection features carried out on FFDM units it is recommended that the following checks be undertaken:

- The image receptor and compression plate biopsy window is demonstrated to be free of wobble
- The vernier table drive and needle guide is rigid and is demonstrated to be free of wobble
- The localisation system zeroes coordinates properly, and
- The biopsy device is properly immobilised to prevent recoil.

5.2.4 Repeat Analysis

The issues noted in section 3.2.12 apply but it should be observed that the analysis should be performed semi-annually and be based on a sample of at least 150 patients. It should include all images for a patient procedure. A repeat rate of <20% should be achieved [60].

5.2.5 Image Receptor Homogeneity

Of necessity, because of the small FOV some biopsy units have, the procedure discussed in section 3.2.13 must be modified slightly. It is suggested that the four ROIs placed at the corners of the image be located approximately 10 mm, rather than 20 mm, from the image margins on units with a FOV of less than 100 mm square. Some *separate image receptor* systems do not allow the placement of ROIs on the image so that a visual inspection using an appropriately adjusted level and narrow window is all that may be possible.

5.2.6 AEC Calibration Test (Technique Chart Adequacy)

The procedure outlined in section 3.2.14 may be applied in slightly modified form. Clinically relevant technique factors must be used to obtain images of PMMA blocks of thickness 2 cm, 4 cm and 6 cm. The technique factors may be selected by the AEC, or from a technique chart or from a combination of the two. The PMMA blocks should be positioned in a consistent manner (e.g. flush with the chest wall). The mean pixel value in a specified ROI in each image is measured using a 4 cm^2 ROI positioned centrally. The same specification as for FFDM units applies. That is, it is recommended that the mean pixel value be within ±10% of the baseline value for the respective PMMA thickness. Some *separate image receptor* systems, do not allow positioning of ROIs on the image. In that case, it is suggested that the mean pixel value from the entire image area meet the above specification. Further, it may be necessary to infer this mean pixel value by noting the default gray scale level at which the image is displayed. For systems depending totally or in part on technique charts a failure to meet the above provisions should indicate that an adjustment to the technique charts is warranted.

6 Biopsy testing: Medical Physics Tests

6.1 Introduction

The tests discussed in this section are, in part, based on the ACR 1999 manual[60] but with due recognition of the fact that major developments have occurred in the intervening time. Further, every effort has been made to ensure that testing procedures and requirements specified for biopsy units are consistent with those previously specified for FFDM. As previously noted, it is also assumed that film based units will be no longer employed and that CR technology is not used for biopsy procedures.

Much of section 4 applies directly to the testing of biopsy units, however because of the small size of the detector, the existence of three different configurations (see section 5.2) and other specialised features some new tests and separate considerations may apply. For example, stand alone biopsy equipment must be tested fully.

6.2 Acceptance and Equipment Upgrade only Procedure Recommendations

The ACPSEM recommends that the following acceptance test procedures:

- Focal spot size (see section 4.2.1)
- Leakage radiation (see section 4.2.2)
- MTF evaluation (see section 4.2.6)
- Spatial linearity & geometric distortion (see section 4.2.8)

should be performed on biopsy units. The methodology and performance criteria should mirror those discussed previously and summarised in Appendices 2a and 5. Tests for *missed tissue at chest wall, transmission through breast support* and *threshold contrast visibility* are not recommended at this point in time.

6.3 Annual Test Procedure Recommendations

The following annual test procedures for FFDM units:

- System resolution (see section 4.3.3)
- Ghost image evaluation (see section 4.3.7)[h]
- System linearity (see section 4.3.8)[i]
- kVp performance (see section 4.3.9)
- Beam quality or half value layer (see section 4.3.10)
- Mean glandular dose (see section 4.3.11)
- Exposure time (see section 4.3.12)
- Viewbox luminance and room illuminance (hardcopy only – see section 4.3.13)
- Monitor luminance and viewing conditions (see section 4.3.14), and
- Printer (hardcopy – see section 4.3.15)

should be undertaken on biopsy units. The methodology and performance criteria should mirror those discussed previously and summarised in Appendices 3a and 5.

Specific requirements or variations for other tests are discussed briefly below.

6.3.1 Mammography Unit Assembly Evaluation

In addition to the features of the general inspection carried out on FFDM units, as noted in section 4.3.1, it is recommended that the medical physicist undertake the following checks on biopsy units:

- Technique charts are confirmed to be in place. This applies to units both with and without AEC. Charts must be visibly displayed near the console clearly indicating the settings used for varying procedures and breast types.
- The x-ray tube angular locations are positively locked and inadvertent movement from them cannot take place
- The image receptor and compression plate biopsy window is demonstrated to be free of wobble
- The vernier table drive and needle guide is rigid and is demonstrated to be free of wobble
- The localisation system zeroes coordinates properly, and
- The biopsy device is properly immobilised to prevent recoil.

6.3.2 Collimation and Alignment Assessment

For small FOV units the ACPSEM supports the fundamental requirement that the FOV defined by the biopsy window or collimator is aligned centrally with the digital image receptor and that the x-ray field may extend beyond the edge of the image receptor by no more than 5 mm on all four sides, where all distances are referred to the plane of the image receptor[60].

The most convenient procedure to confirm compliance involves taping four coins on the compression paddle tangent to the edges of the biopsy window. A loaded film-screen cassette is placed directly behind the compression paddle and an exposure is taken (e.g. Mo/Mo 25 kVp and 10 mAs). The definition of the x-ray field with respect to the biopsy window may be established from the image of the coins in the film image and the position of the coins with respect to the image receptor in the digital image defines the alignment of the biopsy window with the image receptor. From distance measurements on the film and digital receptor, after due correction for magnification effects, the alignment of image receptor with the x-ray field can be inferred for each of the four edges.

Increasingly, confirming compliance does present some potential difficulties in the purely digital world. In the absence of film it is not clear how to best perform this test. Certainly, the digital image will allow confirmation that the biopsy window is centred appropriately or not. However, the alignment of the image receptor with the x-ray field cannot easily be established without film. A visual test with a fluorescent screen, in lieu of the screen-film cassette, is unlikely to provide the required accuracy as the required measurements are a few mm at best. Although expensive, Gafchromic film offers some possibility of success. It may be that a qualitative assessment is all that can be achieved in most circumstances.

6.3.3 Automatic Exposure Control System Performance Assessment / SDNR

Whenever possible, the methodology for determining the SDNR as a function of PMMA thickness, as outlined in sections 4.3.4, should be adopted with only minor changes. In particular, the ROIs defining where the SDNR is to be calculated should be placed parallel to the chest wall and centrally in the image along the anode-cathode axis on those units with a FOV of less than 100 mm square. The SDNRs should be measured at acceptance and monitored annually.

For *separate image receptor* systems, that do not allow the extraction of standard deviations, the SDNR cannot be

[h] *For some image receptor systems, that do not allow positioning of ROIs on the image, a quantitative measure of ghosting cannot be undertaken.*

[i] *This test can be performed on all units where the mean pixel value for part or all of image can be extracted. However, the detector used to monitor the air kerma may influence the measurement so it may be necessary to employ mAs as a surrogate for air kerma*

obtained. Instead, the mean pixel value for each of the three PMMA thicknesses is measured in the absence of the Al foil. It is recommended that the mean pixel value, and the SDNR, in those instances where it can be measured, be within ±10% of the previously measured value for the respective PMMA thickness.

Finally, for those units that depend totally or in part on the use of technique charts, the images must be obtained using the clinically relevant techniques as posted on those technique charts. For such systems a failure to comply, with either the tolerances on the SDNR or mean pixel value, indicates that an adjustment to the technique charts is warranted.

6.3.4 Image Uniformity and Artefact Evaluation

Of necessity, because of the small FOV some biopsy units have, the procedure discussed in section 4.3.5**Error! Reference source not found.** for determining image uniformity in FFDM must be modified slightly. It is suggested that the four ROIs placed at the corners of the image be located approximately 10 mm, rather than 20 mm, from the image margins on units with a FOV of less than 100 mm square. Some *separate image receptor* systems do not allow the placement of ROIs on the image so that a visual inspection using an appropriately adjusted level and narrow window is all that may be possible.

In other respects, the ACPSEM believes the procedure and requirements specified in section 4.3.5 should apply.

6.3.5 Image Quality Evaluation

The image quality evaluation of biopsy units may be carried out as described in section 4.3.6. However, the use of the ACR Accreditation phantom makes this task clumsy with small FOV units. Rather, the ACPSEM recommends the use of the ACR "mini" digital stereotactic phantom (e.g. the NA 18-250 or equivalent) for image quality evaluation but with the additional proviso that a score of at least 3 fibres, 3 speck groups and 2.5 masses must be achieved in the digitally acquired image using the RANZCR scoring system[60]. This is equivalent to the ACR requirements[60]. Note that if the RMI 156S phantom is used, it is important to recognise that it contains one less speck group and one less mass. Thus, an acceptable score with the RMI 156S phantom is 3 fibres, 2 speck groups and 1.5 masses. It needs to be emphasised that the image quality requirements outlined above must be achieved with a MGD of ≤ 2.0 mGy.

6.3.6 Mean Glandular dose

The mean glandular dose must be assessed using the method shown in section 4.3.11 but for the exposure conditions used for biopsy operation. While strictly speaking biopsy units are not constrained to meet the dose limits for contact mammography as specified in section 4.3.11, it is strongly recommended they adhere to these requirements. Additionally, it is recommended that occasional surveys of the number of exposures taken per patient for a biopsy procedure be undertaken.

6.3.7 Localisation accuracy

Previously the ACPSEM had followed the ACR[60] in recommending that a radiographer experienced in biopsy procedures perform a localisation using a gelatine biopsy phantom or equivalent. Since the manufacturers have now developed specific localisation tests that must be undertaken prior to any biopsy the ACPSEM now recommends that the assessor must merely verify that the test is performed routinely by the radiographer and that the results are within manufacturer set limits (see also section 5.2.1). The assessor must confirm this by inspecting the results.

7 Digital Breast Tomosynthesis (DBT): Facility QC

7.1 Introduction

Every effort has been made to ensure that testing procedures and requirements specified for DBT units are consistent with those previously specified for 2D FFDM. In fact, with a few notable exceptions little or no additional QC testing may be required for DBT units whilst in a few instances variations to the basic tests outlined in section 3 should be expected. This section, and the testing summarised in Appendix 7, addresses only those QC initiatives where additional or different requirements are recommended. It should be noted that the manufacturers may require some machine specific QC testing to be done that is additional to those tests discussed here.

7.2 Procedure Recommendations

7.2.1 Image Uniformity and Artefact evaluation

As in section 3.2.3 the standard test block of 4 cm PMMA covering the complete image receptor should be imaged using clinically relevant technique factors under AEC. The test should be undertaken on a daily basis (or on those days when DBT is to be utilised if less frequently) and the mAs should be within ±10% of the baseline value, provided a consistent choice of kVp, anode and filter is used.

The central reconstructed and projection images from their respective series should be inspected for clinically significant artefacts and non-uniformity. The images should be viewed on the acquisition monitor using a narrow window and sufficient magnification to achieve at least 1:1 resolution. Further magnification and roaming of the image can be used if necessary. The images should appear uniform with no ghosting or areas of conspicuous features or noise. Faulty pixels, which may appear as distinctive bright or dark spots, lines, columns or clusters, must not be evident. Some artefacts may resemble the appearance of masses, fibres or specks, similar to those seen on the image of the ACR Accreditation phantom. If necessary scroll through all the images in the respective series.

Slight shadows of up to 10 mm on the edges of the detector (except the chest wall) may be visualised during these tests. On Siemens Inspiration units the high voltage contact of the detector will be visible as a single white square in the corner of the image. This is normal and is not an image artefact.

7.2.2 Image Quality Evaluation

As noted in section 3.2.7, either the ACR Accreditation phantom (without the contrast disc for DBT) or the recently released ACR DM phantom may be used for image quality evaluation. Regardless of which phantom is used, the procedure is the same. In some instances, the DBT acquisition can be combined with 2D FFDM mode using the so called "Combo mode".

There are a number of key procedural elements which are relevant in acquiring the phantom image:

- Maintain light contact between the compression paddle and the phantom surface.
- Position the phantom consistently. Centred along the long axis of the image receptor and flush with the chest wall is recommended.
- Use a consistent selection of clinically relevant kVp and target/filter combinations chosen under AEC.

The slice from the reconstructed data set which best displays the phantom speck details is utilised for scoring purposes. Typically, this should be the slice that is 37±2 mm above the breast support if the ACR accreditation phantom is used and 34±2 mm above the breast support if the ACR DM phantom is used. Image zoom and modest adjustments of the window/level functions may be undertaken in order to best visualise the specks and fibres. The masses should be scored without the need for zooming.

The usual radiographic settings (kVp, Target/filter and mAs), compressed breast thickness, and the slice number used for scoring must be recorded. The mAs must be within ±10% of baseline (for the same kVp and target filter combination and compressed breast thickness) and the position of the slice used for scoring should be within ±1 mm of that from previous measurements.

With the ACR Accreditation phantom, 4 fibres, 3 speck groups and 3 masses must be visualised. With the new ACR DM phantom, the equivalent minimum acceptable scores are 2 fibres, 1 speck group and 2 masses.

7.2.3 Detector Calibration-Flat Field Test

Some units may require no additional calibration requirements for DBT above and beyond those undertaken for 2D FFDM. Others (e.g. GE Senoclaire, GE Medical Systems, Buc, France) will require additional QC checks as different hardware or different target/filter combinations may be utilised in image acquisition. Importantly, and with all units, the detector calibration must be carried out in accordance with the manufacturer's methodology. The outcome of the test is a simple pass or fail.

7.2.4 AEC Calibration Test

For DBT the assessment of the AEC is simpler than for 2D FFDM, largely because most systems do not readily allow for quantitative analysis (i.e. extraction of meaningful pixel values). Thus, all that is required is to obtain images of 2 cm, 4 cm and 6 cm PMMA blocks that cover the entire detector using clinically relevant radiographic settings. Along with the kVp and target/filter combination, the mAs, for each PMMA thickness, must be recorded and the latter value should not vary from baseline by more than ±10%.

7.2.5 Breast Thickness Indication

Some units (e.g. GE Senoclaire, General Electric Medical Systems, Buc, France) utilise a special Bucky for DBT acquisition, and since compressed breast thickness remains a key factor in determining the AEC technique factors for image acquisition, it is important to confirm the accuracy of the machine indicated compressed breast thickness in these circumstances. The indicated thickness must be within ± 5 mm of the actual thickness at the manufacturer's specified compression and specified paddle.

8 Digital Breast Tomosynthesis (DBT): Medical Physics Tests

8.1 Introduction

The test procedures to be performed by the medical physicist are listed in Appendix 8 and further discussion of the testing is provided in the following sub-sections.

8.1.1 Collimation and Alignment Assessment

The collimation and compression paddle alignment requirements are not dissimilar to those previously outlined in section 4.3.2. The ACPSEM believes the key requirement is the proviso that the x-ray field extend to the edge of the image receptor at the chest wall but not extend beyond the breast support by more than 2 mm[78,89]. As with 2D FFDM acquisition, this requirement can be established most simply with a fluorescent screen. The lateral and rear alignments may be difficult to establish because of how the DBT acquisitions are undertaken. Therefore, a less stringent requirement that the x-ray beam is merely contained within the breast support table and its surrounding structure seems adequate. This can also be done with fluorescent screens or self-developing film.

8.1.2 Compressed Breast thickness

Since compressed breast thickness remains a key factor in determining the AEC technique factors for image acquisition, it is important to confirm the accuracy of the machine indicated compressed breast thickness in those circumstances where different hardware (e.g. Bucky) is used for the DBT acquisition as opposed to the 2D projection image acquisition. The indicated thickness must be within ± 5 mm of the actual thickness at the manufacturer's specified compression and specified paddle.

8.1.3 Missed Tissue

With regard to the missing tissue at the chest wall, the basic requirements outlined in section 4.2.4 apply and must be confirmed in DBT mode of acquisition even if the same Bucky is utilised as in the traditional projection imaging mode of operation. That is, the missing tissue at the chest wall must be $\leq$ 5 mm[89].

Because of the manner in which the DBT images are acquired it is also important to confirm that the full thickness of compressed breast tissue is actually imaged[89]. This may be established quite simply, in parallel with the missed tissue at chest wall test, if the latter is undertaken using two radio-opaque rulers or similar objects, provided

they are very thin, placed on the breast support and the top surface of a 40 mm PMMA test block, respectively. It is then a simple matter of scrolling through the reconstructed DBT image stack to confirm that both test objects are adequately visualised.

8.1.4 Distance Calliper Accuracy

When mammography units are used in the DBT mode the situation with regard to calliper calibration is changed. Now, as part of the reconstruction process, the height of each reconstructed slice above the breast support is known and accurate corrections for magnification can be made in software to any estimates of distances within that slice. Accordingly, the ACPSEM believes that any distance measurements made within a slice must be accurate to ±2% regardless of the slice position. Confirmation can usually be made by doing measurements on images of the ACR Accreditation phantom (or the new ACR DM phantom) and comparing them with the relevant physical dimensions of the phantom. Given the importance of the accuracy of these measurements clinically, and the frequent update in software that takes place over time, the ACPSEM also believes that this test must be undertaken annually rather than just at acceptance as had previously been recommended for 2D FFDM mode of operation.

8.1.5 AEC System Performance Assessment

The AEC assessment is a simplified version of that described in section 4.3.4. Since some models do not allow for the extraction of pixel values from raw reconstructed images the quantitative testing involving the calculation of SDNR values outlined in that section is waived. Thus, all that is required is to obtain images of 2 cm, 4 cm and 6 cm PMMA blocks that cover the entire detector using clinically relevant radiographic settings. Along with the kVp and target/filter combination, the mAs, for each PMMA thickness, must be recorded and the mAs should not vary from the previous test value by more than ±10%.

Note that in some instances (e.g. the GE Senoclaire), when special hardware is used to acquire conventional 2D projection images, the full requirements of section 4.3.4 must be satisfied.

8.1.6 Image Uniformity and Artefact Evaluation

As in section 4.3.5 the standard test block of 4 cm PMMA covering the complete image receptor should be imaged using clinically relevant technique factors for DBT under AEC. The mAs must be within ±10% of the previous measured value, provided a consistent choice of kVp, anode and filter is used.

The central reconstructed and projection images from their respective series should be inspected for clinically significant artefacts and non-uniformity. The images should be viewed on the acquisition monitor using a narrow window and sufficient magnification to achieve at least 1:1 resolution. Further magnification and roaming of the image can be used if necessary. The images should appear uniform with no ghosting or areas of conspicuous features or noise. Faulty pixels, which may appear as distinctive bright or dark spots, lines, columns or clusters, must not be evident. Some artefacts may resemble the appearance of masses, fibres or specks, similar to those seen on the image of the ACR Accreditation phantom. If necessary, scroll through all the images in the respective series.

Slight shadows of up to 10 mm on the edges of the detector (except the chest wall) may be visualised during these tests. On Siemens Inspiration units (Siemens Healthcare, Erlangen, Germany) the high voltage contact of the detector will be visible as a single white square in the corner of the image. This is normal and is not an image artefact.

8.1.7 Image Quality Evaluation

As noted in section 4.3.6, either the ACR Accreditation phantom (without the contrast disc for DBT) or the recently released ACR DM phantom may be used for image quality evaluation. Regardless of which phantom is used, the procedure is the same. In some instances, the DBT acquisition can be combined with FFDM mode using the so called "Combo mode".

There are a number of key procedural elements which are relevant in acquiring the phantom image:

- Maintain light contact between the compression paddle and the phantom surface.
- Position the phantom consistently. Centred along the long axis of the image receptor and flush with the chest wall is recommended.
- Use clinically relevant kVp and target/filter combinations chosen under AEC for the acquisition.

The slice from the reconstructed data set which best displays the phantom speck details is utilised for scoring purposes. This should typically be the slice that is 37±2 mm above the breast support if the ACR accreditation phantom is used and 34±2 mm above the breast support if the ACR DM phantom is used. Image zoom and modest adjustments of the window/level functions may be undertaken in order to best visualise the specks and fibres. The masses should be scored without the need for zooming.

The usual radiographic settings (kVp, Target/filter and mAs), compressed breast thickness, and the slice number used for scoring must be recorded. The mAs must be within ±10% of the previous result (for the same kVp and target filter combination and compressed breast thickness) and the position of the slice used for scoring should be within ±1 mm of that recorded in the previous assessment.

With the ACR Accreditation phantom, 4 fibres, 3 speck groups and 3 masses must be visualised. With the new ACR DM phantom, the equivalent minimum acceptable scores are 2 fibres, 1 speck group and 2 masses.

8.1.8 Beam Quality or Half Value Layer

The methodology and requirements outlined in section 4.3.10 apply with one important change to note. Both the Fuji Innovality (FujiFilm Medical Systems, Tokyo, Japan) and the Hologic Selenia Dimensions 3D (Hologic, Bedford, MA, USA) use 0.7 mm of Al added filtration when acquiring images with DBT. Accordingly, the

tolerance on HVL must be raised. An appropriate requirement for the HVL expressed in mm of Al with paddle in the beam for these units to meet is:

$$(kVp/100) + 0.03 \leq HVL < (kVp/100) + 0.31.$$

8.1.9 Mean Glandular Dose

Sechopoulos et. al[67,68] have published a dosimetric methodology for DBT that can be used in conjunction with the standard American College of Radiology dosimetric techniques[55-57]. This has been expanded upon by the American Association of Physicists in Medicine[79]. A similar approach has been developed by Dance et al[69] for use with European dosimetry models. Recent measurements and simulation appear to indicate that the increased MGD from the use of DBT as opposed to conventional projection FFDM systems varies with breast thickness and glandularity with a range of increases from about 10% to 75% for a 50% glandular breast[71]. In any event, in keeping with earlier comments made in section 4.3.11, the ACPSEM recommends adopting the Dance methodology. The dosimetry equation introduced earlier requires a minor modification for DBT, viz.:

$$MGD_{Tomo} = K_{Total}.g.c.s.T$$

where MGD_{Tomo} is the estimated mean glandular dose from a DBT acquisition, K_{Total} is the incident air kerma measured at the entrance surface of the breast with a zero degree projection utilizing the total mAs from all projections, and the *T*-factor corrects for the dosimetric implication from the oblique irradiations from the projections[69,92]. The *gcs*-factors have been defined earlier.

The ACPSEM believes that the same dose limits that apply to 2D FFDM are applicable in the DBT mode of acquisition with one exception. Experience has demonstrated that some units cannot meet the 1 mGy MGD requirement when imaging 20 mm of PMMA. Accordingly, it is recommended that for 20 mm and 60 mm PMMA, the MGD must be less than 1.2 mGy and 4.5 mGy, respectively. For the ACR Accreditation (or ACR DM) phantom the MGD limit of ≤2 mGy remains.

9 Acknowledgments

We acknowledge those who assisted in the writing of this latest version of the paper through discussions and review: Alex Merchant, Stewart Midgley, Tim Ireland and Mike Irvine.

10 Appendices

Appendix 1a Summary of Recommendations for Facility QC Procedures for DR units in 2D mode

Procedure	Recommended Control-Limits/Requirements	Minimum Frequency	Key Procedure Elements	Recommendations for Record Keeping[jj]
Viewing Conditions	Appropriate viewing conditions All viewbox lamps must be operational and appropriate masking available	Daily	Visual inspection of ambient lighting conditions to ensure conformance with acceptable viewing condition configuration (see text for detail). Visual inspection of viewboxes for uniformity of brightness. Confirmation of presence and operation of masking for viewboxes.	Checklist/logbook entry showing: • Date performed • Person performing task
Full Field Artefact Evaluation	mAs = baseline ± 10% Mean pixel value in image = baseline ± 10% There must be no evidence of: • Structures that are more conspicuous than the objects in the phantom used for weekly testing. • Blotches or regions of altered noise appearance. • Observable grid lines or breast support structures. • Bright or dark pixels. • Dust artefacts mimicking calcifications • Significant stitching or registration artefacts	Daily	• Expose a uniform thickness of PMMA using clinically relevant technique factors. • Image must be acquired in "processed" or "for presentation" form • Measure mean pixel value in 4 cm^2 ROI positioned centrally along long axis of image and 6 cm from chest wall • View image on acquisition monitor using zoom and roam to check for possible detector faults • Print image if interpretation performed using hard copy.	Records showing: • Date test was performed. • Person performing test. • Test results • kVp, target/filter and mAs

[jj] All written/electronic QC records should be retained for a minimum of one year unless otherwise indicated by local Regulatory requirements. Images used to assess image quality with the ACR Accreditation or ACR DM phantom should be retained for a minimum of one month.

Procedure	Recommended Control-Limits/Requirements	Minimum Frequency	Key Procedure Elements	Recommendations for Record Keeping[j]
Monitor QC (Monitors used for interpretation and attached to the acquisition workstation)	Borders must be visible, lines must be straight, squares must appear square, the ramp bars should appear continuous without any contour lines, there must be no smearing or bleeding at black-white transitions, all corner patches must be visible, squares of different shades from black to white must be distinct, all high contrast resolution patterns and two low contrast patterns must be visible in all four corners and in the centre, the 5% and 95% pixel value squares must be clearly visible, pattern must be centred in the active area and no disturbing artefacts must be visible on the displayed TG18-QC test pattern. The number of letters visible in the phrase "Quality Control" for the dark, mid-gray and light renditions must be ≥11.	Weekly	1. Display TG18-QC test pattern. 2. Ensure viewing conditions are acceptable. 3. Use window-width set to maximum and window-level set to half of maximum.	Records showing: • Date test was performed. • Person performing test. • Monitor identification. • Monitor settings. • Test results
Monitor Cleaning	Monitor screens must be free of dust, fingerprints and other marks that might interfere with image interpretation	Weekly	Clean all monitor screens gently with lint-free cloth as per manufacturer's instructions.	Checklist/logbook entry showing: • Date performed • Person performing task
Printer area Cleanliness (if applicable)	Clean and dust free environment	Weekly	Wet cleaning of printer area floor and open shelves. Inspect and clean air intake filters on the film printer.	Checklist/logbook entry showing: • Date performed • Person performing task

Procedure	Recommended Control-Limits/Requirements	Minimum Frequency	Key Procedure Elements	Recommendations for Record Keeping[j]
Image Quality Evaluation	mAs = baseline ± 10% For hard copy reporting optical density = baseline ±20% and must be in the range of 1.60 to 2.0. The ability to clearly visualise 5 fibres, 3.5 speck groups (4 is desirable) & 4 masses in an image of an ACR Accreditation phantom or Alternatively: the ability to clearly visualise 4 fibres, 3 speck groups & 4 masses in an image of the new ACR DM phantom	Weekly	Obtaining the phantom image: 1. Use of ACR Accreditation phantom or new ACR DM phantom. 2. Use of a consistent AEC detector position where this is manually selected 3. Light contact between the compression paddle and the phantom surface. 4. Consistent positioning of the phantom. 5. Consistent selection of clinically relevant kVp and target/filter combinations. 6. Selection of the density setting in current clinical use (if applicable). Evaluating the phantom image (preferably on reading workstation or on printed copy if hardcopy reporting used): 1. Use "for presentation" image with zoom and modest adjustment of window/level functions to score fibres and specks 2. Use consistent (baseline) viewing conditions that reflect those used to read actual mammograms. 3. Image quality scoring by the same person, if possible 4. Measure optical density in reproducible part of phantom image if hardcopy reporting. 5. Use of a control chart to record results.	Record numerical mAs values and image quality scores Control chart showing: • Plots of mAs, image quality score/s, and OD if applicable • ≥ 25 results. • Clearly marked control limits. • Baseline values • Radiographic settings (kVp, target/filter combination, density setting and SID) • Remarks e.g. corrective action. Phantom images identifying: • Date • The X-ray system • The technique factors.
Detector Calibration – Flat Field Test	Pass or Fail	Weekly or as per manufacturer's requirements	Follow manufacturer's specific procedure	Checklist/logbook entry showing: • Date performed • Person performing task
Signal Difference to Noise Ratio (SDNR)	SDNR = baseline ± 20%	Weekly	Preferably follow manufacturer procedure. Alternatively: 1. Use the "for presentation" image obtained with either the ACR Accreditation or ACR DM phantom for image quality purposes but with PMMA disc on paddle (if using the ACR DM phantom there is a negative contrast disc in the phantom) 2. Measure the mean pixel value (MPV_1) and SD in a small ROI next to PMMA disc (or negative contrast disc in the ACR DM phantom) 3. Measure mean pixel value (MPV_2) in ROI centred in disc 4. Calculate SDNR = ($MPV_1 - MPV_2$)/SD	Records showing: • Date test was performed. • Person performing test. • x-ray system identification. • kVp, target/filter, AEC mode and mAs. • Test results

Procedure	Recommended Control-Limits/Requirements	Minimum Frequency	Key Procedure Elements	Recommendations for Record Keeping[j]
Printer QC (if applicable)	Borders must be visible, lines must be straight, all corner patches must be visible, squares of different shades from black to white must be distinct, all high contrast resolution patterns must be visible in all four corners and the centre, the 5% and 95% pixel value squares must be clearly visible, and no disturbing artefacts must be visible on the printed TG18-QC test pattern. The number of letters visible in the phrase "Quality Control" for the dark, mid-gray and light renditions must be ≥11.The mid density (MD) and density difference (DD) = baseline ± 0.15 Base + fog (B+F) = baseline ± 0.03 & ≤0.25 D_{max} = baseline ±0.10 & ≥3.4	Monthly for dry lasers and daily or as used for wet lasers	1. Print the TG18-QC test pattern. 2. Check visibility and distortion of several items used for evaluating the quality of the image. 3. Check for disturbing artefacts. 4. Measure MD, DD, B+F and D_{max}.	Control charts & records showing: • Date test was performed. • Person performing test. • Printer identification. • Test results
Mechanical Inspection	Indicated breast thickness accurate to ±5 mm No hazardous, inoperative, out of alignment or improperly operating items on the system. All items listed on the visual check list have received a pass.	Monthly	1. Confirm accuracy of thickness indication 2. Visual inspection of the system to ensure safe and optimum operation.	Checklist/logbook entry showing: • Date inspection performed • Inspection results • Person performing test
Repeat Analysis	Repeat rate <3% (<2% preferred)[3]	Quarterly	1. Inclusion of images from at least 250 consecutive client examinations. 2. The ability to determine repeat rates attributable to a range of equipment faults and positioning errors.	Worksheet/logbook entries showing all results/calculations.
Image Receptor Homogeneity	Maximum deviation in mean pixel value in ROI < ±10% of mean pixel value in central ROI. Maximum variation of the mean pixel value in central ROI between successive quarterly images < ±10%.	Quarterly or more frequently if recommended by the manufacturer	1. Use manufacturer's protocol and test block if available; otherwise 2. Image a standard test block at clinical settings. 3. On the "for processing" image, draw 100 mm^2 square or circular ROIs in the centre and four corners 4. If the mean pixel value of a ROI deviates by more than 15% from the mean pixel value in the central ROI, the detector gain map may require re-calibration 5. If required, to exclude failure due to non-uniformities in the standard test block, rotate latter by 180^o and repeat measurement.	Records showing: • Date test was performed. • Person performing test. • x-ray system identification. • kVp, target/filter, density setting and mAs. • Test results

Procedure	Recommended Control-Limits/Requirements	Minimum Frequency	Key Procedure Elements	Recommendations for Record Keeping[j]
AEC Calibration Test	Mean pixel value for each of 2, 4 and 6 cm PMMA within 10% of baseline values	Quarterly	1. Assess for both contact and magnification modes. 2. Use PMMA thickness between 2 and 6 cm covering complete image receptor 3. Use clinical AEC settings (kVp, target/filter and mode) 4. Measure mean pixel value in 4 cm^2 ROI positioned centrally along axis and 6 cm from chest wall 5. Examine image for clinically significant artefacts	Records showing: • Date test was performed. • Person performing test. • X-ray system identification. • kVp, target/filter, AEC mode and mAs. • Test results
Compression	Maximum motorised compression force in range 150 - 200 N	Six monthly	Confirm machine indicated compression force meets requirements	Checklist/logbook entry showing: • Date test performed • Test results • Person performing test
Test Equipment Quality Control				
• *Densitometer calibration check*	Optical density measurement accurate to within: ± 0.03 (0 -3.0 OD) ± 3% (3.0 - 4.0 OD)	Six monthly	Verification of accuracy using an optical density calibration strip traceable to an accepted standard	Checklist/logbook entry showing: • Date test performed • Test results • Person performing test
Maintenance & Fault Logging	Separate logbooks for each imaging system including diagnostic monitors & film printer if relevant.	As required	Dated entries describing fault encountered and/or maintenance performed.	Logbooks with dated and initialled entries.
Infection Control of Breast Imaging Equipment	Clean equipment	Before each examination	Cleaning using alcohol swipes, or as per manufacturer's recommendations and/or suitable infection control advice	Nil.

Appendix 1b Summary of Recommendations for Facility QC Procedures for CR Units

Procedure	Recommended Control-Limits/Requirements	Minimum Frequency	Key Procedure Elements	Recommendations for Record Keeping[k]
Viewing Conditions	Appropriate viewing conditions All viewbox lamps must be operational and appropriate masking available	Daily	Visual inspection of ambient lighting conditions to ensure conformance with acceptable viewing condition configuration (see text for detail). Visual inspection of viewboxes for uniformity of brightness. Confirmation of presence and operation of masking for viewboxes.	Checklist/logbook entry showing: • Date performed • Person performing task
Image Plate Erasure	Erasure of energy absorbed from scattered radiation or naturally occurring radiation by CR image plates before they are used.	Daily/Weekly	On a daily basis or if left unused for more than 8 hours, all CR image plates must be subjected to an erasure (following manufacturer's instructions). On a weekly basis all Fuji CR image plates must be subjected to a primary erasure.	Logbooks with dated and initialled entries.
Monitor/Viewboxes Cleaning	Monitor screens and viewboxes must be free of dust, fingerprints and other marks that might interfere with image interpretation	Weekly	Clean all monitor screens and viewboxes gently with lint-free cloth as per manufacturer's instructions.	Checklist/logbook entry showing: • Date performed • Person performing task
Monitor QC (Monitors used for interpretation and attached to the acquisition workstation)	Borders must be visible, lines must be straight, squares must appear square, the ramp bars should appear continuous without any contour lines, there should be no smearing or bleeding at black-white transitions, all corner patches must be visible, squares of different shades from black to white must be distinct, all high contrast resolution patterns and two low contrast patterns must be visible in all four corners and the centre, the 5% and 95% pixel value squares must be clearly visible, pattern must be centred in the active area and no disturbing artefacts must be visible on the displayed TG18-QC test pattern. The number of letters visible in the phrase "Quality Control" for the dark, mid-gray and light renditions must be ≥11.	Weekly	1. Display TG18-QC test pattern. 2. Ensure viewing conditions are acceptable. 3. Use window-width set to maximum and window-level set to half of maximum.	Records showing: • Date test was performed. • Person performing test. • Monitor identification. • Monitor settings. • Test results
Monitor Cleaning	Monitor screens must be free of dust, fingerprints and other marks that might interfere with image interpretation	Weekly	Clean all monitor screens gently with lint-free cloth as per manufacturer's instructions.	Checklist/logbook entry showing: • Date performed • Person performing task

[k] All written/electronic QC records should be retained for a minimum of one year unless otherwise indicated by local Regulatory requirements. Images used to assess image quality with the ACR Accreditation or ACR DM phantom should be retained for a minimum of one month.

Procedure	Recommended Control-Limits/Requirements	Minimum Frequency	Key Procedure Elements	Recommendations for Record Keeping[k]
Printer area Cleanliness (if applicable)	Clean and dust free environment	Weekly	Wet cleaning of printer area floor and open shelves. Inspect and clean air intake filters on the film printer.	Checklist/logbook entry showing: • Date performed • Person performing task
Image Quality Evaluation	mAs = baseline ± 10% Dose to plate = baseline ±10% Exposure indicator (see Appendix 6 for manufacturer dependent tolerances) For hard copy reporting optical density = baseline ±20% and must be in the range of 1.60 to 2.0. The ability to clearly visualise 5 fibres, 3.5 speck groups (4 is desirable) & 4 masses in an image of an ACR Accreditation phantom or The ability to clearly visualise 4 fibres, 3 speck groups & 3 masses in an image of an ACR DM phantom	Weekly	Obtaining the phantom image: 1. Use an ACR Accreditation phantom or the new ACR DM phantom. 2. Use of a designated test cassette and imaging plate that is in routine clinical use. 3. Use of a consistent AEC detector position where this is manually selected 4. Light contact between the compression paddle and the phantom surface. 5. Consistent positioning of the phantom. 6. Consistent selection of clinically relevant kVp and target/filter combinations. 7. Selection of the density setting in current clinical use. 8. Consistent time delay between plate irradiation and readout. Evaluating the phantom image (preferably on reading workstation or on printed copy if hardcopy reporting used): 1. Use "for presentation" image with zoom and modest adjustment of window/level functions to score fibres and specks 2. Use of consistent viewing conditions that reflect those used to read actual mammograms. This applies to both soft and hard copy 3. Image quality scoring by the same person, if possible. 4. Measure optical density in reproducible part of phantom image if hardcopy reporting. 5. Use of a control chart to record results.	Record numerical mAs values and image quality scores Control chart showing: • Plots of mAs, exposure indicator, image quality score/s and OD if applicable • ≥ 25 results. • Clearly marked control limits. • Baseline values • Radiographic settings (kVp, target/filter combination, density setting and SID) • Remarks e.g. corrective action. Phantom images identifying: • Date • The x-ray system • The technique factors.

Procedure	Recommended Control-Limits/Requirements	Minimum Frequency	Key Procedure Elements	Recommendations for Record Keeping[k]
Printer QC	Borders must be visible, lines must be straight, all corner patches must be visible, squares of different shades from black to white must be distinct, all high contrast resolution patterns must be visible in all four corners and the centre, the 5% and 95% pixel value squares must be clearly visible, and no disturbing artefacts must be visible on the printed TG18-QC test pattern. The number of letters visible in the phrase "Quality Control" for the dark, mid-gray and light renditions must be ≥11 The mid density (MD) and density difference (DD) = baseline ± 0.15 Base + fog (B+F) = baseline ± 0.03 & ≤0.25 D_{max} = baseline ±0.10 & ≥3.4	Monthly for dry lasers and daily or as used for wet lasers	1. Print the TG18-QC test pattern. 2. Check visibility and distortion of several items used for evaluating the quality of the image. 3. Check for disturbing artefacts. 4. Measure MD, DD, B+F and D_{max}.	Control charts & records showing: • Date test was performed. • Person performing test. • Printer identification. • Test results
Mechanical Inspection	Indicated breast thickness accurate to ±5 mm No hazardous, inoperative, out of alignment or improperly operating items on the system. All items listed on the visual check list have received a pass.	Monthly	1. Confirm accuracy of thickness indication 2. Visual inspection of the system to ensure safe and optimum operation .	Checklist/logbook entry showing: • Date performed • Inspection results • Person performing task
Repeat Analysis	Repeat rate <3% (<2% preferred)[3]	Quarterly	1. Inclusion of images from at least 250 consecutive client examinations. 2. The ability to determine repeat rates attributable to a range of equipment faults and positioning errors.	Worksheet/logbook entries showing all results/calculations.
Image Receptor Homogeneity	Maximum difference in mean pixel value between any two ROIs < ±10% Maximum variation of the mean pixel value in central ROI between successive QC images < ±10%.	Quarterly or more frequently if recommended by the manufacturer)	1. Use manufacturer's protocol and test block if available; otherwise 2. Image a standard test block at clinical settings. 3. Use 'test' cassette 4. Perform measurements on the "for processing" (unprocessed) image, if possible, using a 100 mm^2 square or circular ROI. Three ROIs are placed at the left, right and centre on a line 20mm back from chest wall. 5. If the mean pixel value of any two ROIs differ by more than 10% from each other, the CR unit's shading correction may require re-calibration or imaging plate(s) may require replacement 6. If ROI analysis is not possible, do a visual inspection at narrow window width. 7. If required, to exclude failure due to non-uniformities in the standard test block, rotate by 180^o and repeat measurement	Records showing: • Date test was performed. • Person performing test. • x-ray system identification. • kVp, target/filter, density setting and mAs. • Test results

Procedure	Recommended Control-Limits/Requirements	Minimum Frequency	Key Procedure Elements	Recommendations for Record Keeping[k]
AEC Calibration Test	Dose to plate for each of 2, 4 and 6 cm PMMA = baseline ±10% See Appendix 6 for equivalent manufacturer specific exposure index requirements	Quarterly	1. Assess for both contact and magnification modes. 2. Use PMMA thickness between 2 and 6 cm covering complete cassette 3. Use clinical AEC settings (kVp, target/filter and mode including density setting) 4. Use a designated test cassette and imaging plate that is in routine clinical use 5. Use a consistent AEC detector position where this is manually selected. 6. Consistent positioning of the PMMA. 7. Consistent time delay between plate irradiation and readout.	Records showing: • Date test was performed. • Person performing test. • X-ray system identification. • kVp, target/filter, AEC mode and mAs. • Test results
Compression	Maximum motorised compression force in range 150 - 200 N	Six monthly	Confirm machine indicated compression force meets requirements	Checklist/logbook entry showing: • Date test performed • Test results • Person performing test
Test Equipment Quality Control • *Densitometer calibration check*	Optical density measurement accurate to within: ± 0.03 (0 -3.0 OD) ± 3% (3.0 - 4.0 OD)	Six monthly	Verification of accuracy using an optical density calibration strip traceable to an accepted standard	Checklist/logbook entry showing: • Date test performed • Test results • Person performing test
Cassette/Image Plate Condition and Inter Plate Sensitivity Variation	Clean and dust free cassettes & image plates No major inhomogeneities on the images See Appendix 6 for manufacturer specific tolerances on interplate variations	**Six monthly**	1. Cassette/image plate cleaning as per manufacturer's recommendations 2. Image a standard test block at clinical settings. 3. Pre-processing should be turned off as much as possible and no post processing must be applied. 4. Evaluate for artefact on both film (if applicable) and monitor	Records showing: • Date test was performed. • Person performing test. • kVp, target/filter, AEC mode. • Exposure indicator and mAs for each plate.
Maintenance & Fault Logging	Separate logbooks for each imaging system, including diagnostic monitors, & film printer if relevant.	As required	Dated entries describing fault encountered and/or maintenance performed.	Logbooks with dated and initialled entries.
Infection Control of Breast Imaging Equipment	Clean equipment	Before each examination	Cleaning using alcohol wipes, or as per manufacturer's recommendations and/or suitable infection control advice	Nil.

Appendix 2 Summary of Recommendations for Medical Physics Testing only at Acceptance or Equipment Upgrade in 2D Mode

Procedure	Performance Requirements / Guidelines	Routine Testing Guidelines	Key Procedure Elements
Focal Spot	• ≥ 11 lp/mm for line-pair bars perpendicular to anode-cathode axis and • ≥ 13 lp/mm for line-pair bars parallel to anode-cathode axis. OR complies with IEC 60336[21] for 0.3 and 0.1 mm focal spot sizes	Not required unless tube has been changed.	As per section 4.2.1 or IEC 60336[21]
Leakage Radiation	• ≤ 1 mGy/hr at 1m from focus and • ≤0.01 mGy/100 mAs @ 30 kVp & 30 cm from focus	Not required unless tube has been changed or system relocated.	As per AS/NZS IEC 60601.1.30.1.3[27]
Transmission Through Breast Support	≤0.001 mGy @ max kVp and mAs	Not required unless change made to image receptor system.	As per AS/NZS IEC 60601.1.3[27]
Missed Tissue @ Chest Wall	Width of missed tissue at chest wall ≤ 5 mm in contact mode and ≤ 7 mm in magnification mode.	Not required unless tube has been changed or change made to image receptor system or system relocated.	
Plate Fogging (CR only)	Image of coin must not be visible.	Not required unless changes in storage of cassettes have occurred	Monitor during acceptance testing
MTF	Bench mark testing, compare to manufacturer's specification.	Not required unless tube has been changed or change made to image receptor system.	As per IEC 62220-1-2[35]
Threshold Contrast Visibility		Not required unless tube has been changed or change made to image receptor system.	Use CDMAM phantom[1]
Spatial Linearity & Geometric Distortion		Not required unless change made to image receptor system.	Use wire mesh tool.
Distance Calliper Accuracy	Measured dimensions of ruler in image must be within 2% of true dimensions in plane specified by manufacturer Check both contact and magnification modes	Not required unless change made to image receptor system.	Use steel rulers. Determine dimensions in image, ideally using reporting workstation.

[1] This test allows digital systems to be benchmarked against European standards[9].

Appendix 3a Summary of Recommendations for Medical Physics Annual Testing of DR Units in 2D Mode

Procedure	Performance Requirements / Guidelines	Routine Testing Guidelines	Acceptance & Additional Tests
Mammography Unit Assembly Evaluation	Correct and safe function of system components. Thickness display accuracy within ± 5 mm, note: Flexi paddles will not comply (manufacturer recommendation varies ~ 11-12 mm for flexi paddles). Reproducible to 2mm. Verify DICOM image header for correct display of parameters.	Confirm function of all motorised components, warning lights, displays etc. Evaluate system for any miscellaneous safety risks etc. DICOM verification required after software upgrades	As per routine tests.
Collimation & Alignment Assessment			
• *x-ray field / Image receptor alignment*	The x-ray field shall irradiate the image receptor fully but not extend beyond the breast support on the chest wall edge of the image receptor by more 2 mm.	Assess alignment for each target/geometry combination.	As per routine tests.
• *Paddle / Image alignment*	The chest wall edge of the compression paddle shall be aligned just beyond the chest wall edge of the image receptor such that it does not appear in the image. In addition, the compression paddle shall not extend beyond the chest wall edge of the image by more than 1% of the SID.	Assess alignment for all clinically relevant Bucky/paddle/target/geometry combinations.	As per routine tests.
System Resolution/ MTF	Compare to baseline values, variation less than 10%	Measure MTF using system software if possible. Otherwise measure limiting resolution: 1. Use a 4cm PMMA block or equivalent. 2. Place resolution pattern on PMMA 3. Measure both parallel and perpendicular to chest wall 4. Repeat for Magnification mode if applicable.	Establish base line values
AEC System Performance Assessment			
• *Reproducibility*	Coefficient of variation (COV) for both absorbed dose and mAs for at least three phototimed exposures of a test object shall be better than or equal to 0.05.	1. Use a 4cm PMMA block or equivalent. 2. Assess COV for each AEC detector at a typical clinical kVp.	As per routine tests.
• *Compensation & SDNR System Performance Assessment*	Compare SDNR values to baseline and to the minimum acceptable values for 4 cm PMMA ($SDNR_{accept}$): • $SDNR_{2cm} > 1.1 \times SDNR_{accept}$ • $SDNR_{4cm} > SDNR_{accept}$ • $SDNR_{6cm} > 0.9 \times SDNR_{accept}$	1. Assess the most commonly used AEC modes for contact and magnification geometry. 2. Use 0.2 mm Al foil as contrast test tool and measure SDNR for 2, 4 and 6 cm PMMA (also see section on glandular dose). Note: measurements are to be undertaken on "for processing" (unprocessed) images	Establish baseline values. Assess all available AEC modes for contact and magnification geometries.
• *Density control (if applicable)*	The density control must be capable of changing the mAs from the value used normally by -25% to +50%	Assess change in mAs for at least two density settings either side of the usual clinical setting using 4 cm of PMMA	Assess change in mAs across full range of density settings.
• *Back-up timer /security cut-out*	Security cut-out mechanisms shall be present & terminate the exposure within 50 ms or within 5 mAs, otherwise the back-up timer should terminate the exposure at ≤500 mAs and must terminate the exposure at ≤800 mAs.	Use lead sheet or other heavily attenuating material to intercept beam and confirm that the back-up timer security cut-out functions within specified limits.	Confirm that the back-up timer/security cut-out functions within specified limits.

Procedure	Performance Requirements / Guidelines	Routine Testing Guidelines	Acceptance & Additional Tests
Image Uniformity & Artefact	• Max. deviation of mean pixel value < ± 15% of mean pixel value for central ROI • Max. deviation in SNR as a function of time is ± 10%. • There must be no evidence of blotches or regions of altered noise appearance, observable grid lines or breast support structures, bright or dark pixels	1. Assess for 40 mm PMMA covering complete detector. 2. Use five ROIs (one central, with the other 4 approximately 20 mm from any edge) each of 100 mm^2. 3. Measurements performed on unprocessed image 4. Exclude phantom non uniformity by rotating block 180° and repeating. 5. Repeat in magnification mode if applicable	Assess also at 20 mm and 60 mm
Detector Element Failure	Limits currently not established. Must monitor independent of manufacturer. Inspect bad pixel map.	A mammographic screen-film mesh can be used to determine if correction for bad columns successful.	Bad pixel map must be available at any time, independent of manufacturer.
Image Quality Evaluation	The ability to clearly visualise 5 fibres, 3.5 speck groups (4 is desirable) & 4 masses in an image of an ACR Accreditation phantom or the ability to clearly visualise 4 fibres, 3 speck groups & 3 masses in an image of the ACR DM phantom. Additionally, with the ACTR DM phantom the SDNR with contrast object ≥2.0.	Use typical clinical settings. Measure MPVs and SDs in relevant ROIs of ACR DM phantom so that SDNR may be calculated.	As per routine testing
Ghost Image Evaluation	"Ghost image" factor < 2.0	Assess using 40 mm PMMA (see section 4.3.7 for testing guidelines).	As per routine testing
System Linearity & Noise Analysis	• Linearity plot versus ESAK: R^2>0.99 • SD^2 plot versus MPV: R^2>0.99 • Noise parameters: Compare to baseline results	1. Use standard test block (e.g. 4 cm PMMA) at typical clinical beam settings. 2. Measure ESAK at 6 cm from chest wall 3. Measure mean pixel value and SD in ROI placed 6 cm from chest wall. 4. Plot mean pixel value as a function of ESAK. 5. Plot SD^2 as a function of MPV corrected for any pixel offset.	Baseline measurements at clinical kVp, also at max and min clinical kVps for all target filter combinations
Generator Performance			
• *kVp, reproducibility*	COV ≤ 0.02 for a minimum of three exposures.	Assess kVp reproducibility at a typical clinical kVp value.	As per routine testing.
• *kVp accuracy*	Measured kVp shall be within ± 5% of the specified value over the clinically relevant range	Assess kVp accuracy over the clinically relevant range in, at most, 2 kVp increments Note: The kVp need only be verified for one target filter combination per kVp, however the kVp meter must be calibrated for that particular target/filter combination.	Assess kVp accuracy over clinically relevant range in 1 kVp increments.

Procedure	Performance Requirements / Guidelines	Routine Testing Guidelines	Acceptance & Additional Tests
Beam Quality	(kVp/100) + 0.03 ≤HVL< (kVp/100) +C where C = 0.12 mm Al for Mo/Mo = 0.19 mm Al for Mo/Rh = 0.22 mm Al for Rh/Rh = 0.23 mm Al for Rh/Ag = 0.30 mm Al for W/Rh = 0.32 mm Al for W/Ag = 0.25 mm Al for W/Al	Measure the HVL required for Mean Glandular Dose calculations and for establishing compliance with DRLs (see section 4.3.11 for details).	As per routine tests plus measure HVL at 28 kVp for all target/filter combinations, with the compression paddle removed if unit used for biopsy purposes with open paddle.
Mean Glandular Dose	• ≤2.0 mGy for a 4.2 cm 50% adipose, 50% glandular breast (i.e. ACR Accreditation phantom or ACR DM phantom). • <1 mGy for 2.0 cm PMMA (2.3 cm 50% adipose, 50% glandular breast) • < 4.5 mGy for 6.0 cm PMMA, (6.5 cm 50% adipose, 50% glandular breast) • the displayed MGD values must agree with calculated values to ≤25%.	Assess for an AEC controlled exposure using typical clinical settings using ACR Accreditation phantom (or ACR DM phantom) and also for 20 mm and 60 mm PMMA. Additional dose (and HVL) measurements may be necessary to confirm compliance with DRLs (see section 4.3.11)	As per routine tests.
Exposure Time	For all clinically relevant SID settings the maximum exposure time when irradiating 6 cm PMMA must be less than 3.5 seconds and 2 seconds for fine and broad focus, respectively.	1. Assess for both contact and magnification modes. 2. Use 6 cm of PMMA 3. Use clinically relevant technique factors for this PMMA thickness consistent with SDNR and MGD measurements 4. Record mAs and infer the exposure time from tube rating or measure directly using a manual exposure matched to mAs needed for AEC initiated exposure.	As per routine tests.
Viewbox Luminance and Room Illuminance (Hardcopy only)	• Viewing area illuminance ≤ 50 lux • Viewbox luminance ≥ 3000 cd/m^2	Assess viewing conditions for all viewers	As per routine tests.
Monitor Luminance & Viewing Conditions	• Image interpretation must not be done on a monitor of less than 4.2 mega pixels • Luminance ratio approximately 350:1 • Maximum luminance >450 cd/m^2 & maximum luminance of paired monitors matched to ≤5% • Minimum luminance preferably not less than 1 cd/m^2 • Ambient light < 20 lux • In PACS situations images must be stored with lossless compression.	1. Measure luminance ratio under clinical lighting conditions 2. Confirm luminance uniformity 3. Confirm no cross-talk & pixel defects	As per routine testing with the additional requirement of checking GSDF. Monitor or workstation may have comprehensive QC program which needs to be validated.
Monitor Performance	• No smearing artefact, ramps without terracing. • Lines straight, boxes square, active display centred, borders complete • Squares of different shades from black to white must be distinct and small squares in corners of each clearly discernible • Free from artefact • The number of letters visible in the phrase “Quality Control” for the dark, mid-gray and light renditions must be ≥11.	1. Test patterns to be displayed at full resolution 2. Test under clinical lighting conditions 3. Use TG18-QC test pattern.	As per routine testing. Monitor or workstation may have comprehensive QA program

Procedure	Performance Requirements / Guidelines	Routine Testing Guidelines	Acceptance & Additional Tests
Printer (Hardcopy only)	• B+F = baseline ± 0.03 & ≤0.25 OD • D_{max} = baseline ±0.10 & ≥3.4 OD • The number of letters visible in the phrase "Quality Control" for the dark, mid-gray and light renditions must be ≥11.	Print TG18-QC test pattern as per weekly printer QC test	As per routine tests.

Appendix 3b Summary of Recommendations for Medical Physics Annual Testing of CR Units

Procedure	Performance Requirements / Guidelines	Routine Testing Guidelines	Acceptance & Additional Tests
Mammography Unit Assembly Evaluation	Correct and safe function of system components. Thickness display accuracy within ± 5 mm, reproducible to 2mm. Verify DICOM image header for correct display of parameters.	Confirm function of all motorised components, warning lights, displays etc. Evaluate system for any miscellaneous safety risks etc. DICOM verification required after software upgrades	As per routine tests.
Collimation & Alignment Assessment			
• *x-ray field / image /breast-support alignment*	The x-ray field shall irradiate the image receptor fully but not extend beyond the breast support on the chest wall edge of the image receptor by more than 2 mm.	Assess alignment for largest collimator in clinical use for each Bucky/target combination. For magnification geometry only assess chest wall alignment.	As per routine tests.
• *Paddle / Image alignment*	The chest wall edge of the compression paddle shall be aligned just beyond the chest wall edge of the image receptor such that the chest wall compression paddle does not appear in the image. In addition the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than 1% of the SID	Assess alignment for all clinically relevant Bucky/paddle/geometry combinations.	As per routine tests.
System Resolution/ MTF	Compare to baseline values, variation less than 10%	Measure MTF using system software if possible. Otherwise measure limiting resolution: 1. Use a 4cm PMMA block or equivalent. 2. Place resolution pattern on PMMA 3. Measure both parallel and perpendicular to chest wall 4. Repeat for Magnification mode if applicable.	Establish base line values
AEC System Performance Assessment			
• *Reproducibility*	Coefficient of variation (COV) for both absorbed dose and mAs for at least three phototimed exposures of a test object shall be better than or equal to 0.05.	1. Use a 4cm PMMA block or equivalent. 2. Assess COV for each AEC detector at a typical clinical kVp.	As per routine tests.
• *Compensation & SDNR System Performance Assessment*	Compare SDNR values to baseline and to the minimum acceptable values for 4 cm PMMA ($SDNR_{accept}$): • $SDNR_{2cm} > 1.1 \times SDNR_{accept}$ • $SDNR_{4cm} > SDNR_{accept}$ • $SDNR_{6cm} > 0.9 \times SDNR_{accept}$ Note: For Magnification mode this last requirement is relaxed to: $SDNR_{6\ cm} > 0.65 \times SDNR_{accept}$	1. Assess the most commonly used AEC modes for contact and magnification geometry. 2. Use clinical AEC settings (kVp, target/filter and mode including density setting) 3. Use a designated test cassette and imaging plate that is in routine clinical use 4. Use a consistent AEC detector position where this is manually selected. 5. Use 0.2 mm Al foil as contrast test tool and measure SDNR for 2, 4 and 6 cm PMMA (also see section on glandular dose). Note: measurements are to be undertaken on "for processing" (unprocessed) image 6. Consistent time delay between plate irradiation and readout. 7. Record exposure indicator for each PMMA thickness 8. Measure film density for each image if applicable.	Establish baseline values. Assess all available AEC modes for contact and magnification geometries. Assess both 18x24 cm^2 & 24x30 cm^2 Buckys.

Procedure	Performance Requirements / Guidelines	Routine Testing Guidelines	Acceptance & Additional Tests
• *Density control*	The density control must be capable of changing the mAs from the value used normally by -25% to +50%	Assess change in mAs for at least two density settings either side of the usual clinical setting using 4 cm of PMMA	Assess change in mAs across full range of density settings.
• *Back-up timer / security cut-out*	Security cut-out mechanisms shall be present & terminate the exposure within 50 ms or within 5 mAs, otherwise the back-up timer should terminate the exposure at ≤500 mAs and must terminate the exposure at ≤800 mAs.	Use lead sheet or other heavily attenuating material to intercept beam and confirm that the back-up timer / security cut-out functions within specified limits.	Confirm that the back-up timer/security cut-out functions within specified limits.
Image Uniformity & Artefact	Max. deviation of mean pixel value < ± 10% of mean pixel value for central ROI Max. deviation in SNR of central ROI as a function of time is ± 10%. No major inhomogeneities on the images	1. Assess for 40 mm PMMA covering complete CR plate. 2. Use three ROIs each of ~100 mm^2 placed on a line parallel to and approximately 20 mm from chest wall	Assess also at 20 mm and 60 mm
Uniformity of Cassette/Image Plate Response	Maximum mAs variation <±5% between all plates of one size. Maximum mAs variation <±20% between plates of different sizes. See Appendix 6 for manufacturer dependent allowed tolerances on the exposure indicator	Assess for 40 mm PMMA covering complete CR plate.	As per routine testing
Image Quality Evaluation	The ability to clearly visualise 5 fibres, 3.5 speck groups (4 is desirable) & 4 masses in an image of an ACR Accreditation phantom or the ability to clearly visualise 4 fibres, 3 speck groups & 3 masses in an image of the ACR DM phantom. Additionally, with the ACR DM phantom the SDNR with contrast object ≥2.0.	Use typical clinical settings. Measure MPVs and SDs in relevant ROIs of ACR DM phantom so that SDNR may be calculated.	As per routine testing
Ghost Image Evaluation	"Ghost image" factor < 2.0	Assess using 40 mm PMMA (see section 4.3.7 for testing guidelines).	As per routine testing
System Linearity & Noise Analysis	Compare to baseline results and note requirement for linearity (see text and Appendix 6) has R^2>0.99. Noise analysis remains optional.	1. Use standard test block (e.g. 4 cm PMMA) at typical clinical beam settings. 2. Use the same cassette/image plate for all exposures. 3. Record exposure indicator. 4. Plot exposure indicator as a function of ESAK (see Appendix 6).	Baseline measurements at clinical kVp, also at max and min clinical kVps for all target filter combinations
Generator Performance			
• *kVp, reproducibility*	COV ≤ 0.02 for a minimum of three exposures.	Assess kVp reproducibility at a clinical kVp value.	As per routine testing.
• *kVp accuracy*	Measured kVp shall be within ± 5% of the specified value over the clinically relevant range	Assess kVp accuracy over the clinically relevant range in, at most, 2 kVp increments	Assess kVp accuracy over clinically relevant range in 1 kVp increments.

Procedure	Performance Requirements / Guidelines	Routine Testing Guidelines	Acceptance & Additional Tests
Beam Quality	[(kVp/100) + 0.03] ≤HVL< [(kVp/100) +C] where C = 0.12 mm Al for Mo/Mo = 0.19 mm Al for Mo/Rh = 0.22 mm Al for Rh/Rh = 0.23 mm Al for Rh/Ag = 0.30 mm Al for W/Rh = 0.32 mm Al for W/Ag = 0.25 mm Al for W/Al	Measure the HVL required for Mean Glandular Dose calculations and for establishing compliance with DRLs (see section 4.3.11 for details).	As per routine tests plus measure HVL at 28 kVp for all target/filter combinations, with the compression paddle removed if unit used for biopsy purposes with open paddle.
Mean Glandular Dose	• ≤2.0 mGy for a 4.2 cm 50% adipose, 50% glandular breast (i.e. ACR Accreditation phantom or ACR DM phantom). • <1 mGy for 2.0 cm PMMA (2.3 cm 50% adipose, 50% glandular breast) • < 4.5 mGy for 6.0 cm PMMA, (6.5 cm 50% adipose, 50% glandular breast)	Assess for an AEC controlled exposure using typical clinical settings using ACR Accreditation phantom (or ACR DM phantom) and also for 20 mm and 60 mm PMMA. Additional dose measurements may be necessary to confirm compliance with DRLs (see section 4.3.11)	As per routine tests.
Exposure Time	For all clinically relevant SID settings the maximum exposure time when irradiating 6 cm PMMA must be less than 3.5 seconds and 2 seconds for fine and broad focus, respectively.	1. Assess for both contact and magnification modes. 2. Use 6 cm of PMMA 3. Use clinically relevant technique factors for this PMMA thickness consistent with SDNR and MGD measurements 4. Record mAs and infer the exposure time from tube rating or measure directly using a manual exposure matched to mAs needed for AEC initiated exposure.	As per routine tests.
Viewbox Luminance and Room Illuminance (Hardcopy only)	• Viewing area illuminance ≤ 50 lux • Viewbox luminance ≥ 3000 nit	Assess viewing conditions for all viewers	As per routine tests.
Monitor Luminance & Viewing Conditions	• Image interpretation must not be done on a monitor of less than 4.2 mega pixels • Luminance ratio approximately 350:1 • Maximum luminance >450 cd/m^2 & maximum luminance of paired monitors matched to ≤5% • Minimum luminance preferably not less than 1 cd/m^2 • Ambient light < 20 lux. • In PACS situations images must be stored with lossless compression	1. Measure luminance ratio under clinical lighting conditions 2. Confirm luminance uniformity 3. Confirm no cross-talk & pixel defects	As per routine testing with the additional requirement of checking GSDF. As per routine testing. Monitor or workstation may have comprehensive QC program which needs to be validated.
Monitor Performance	• No smearing artefact, ramps without terracing. • Lines straight, boxes square, active display centred, borders complete • Squares of different shades from black to white must be distinct and small squares in corners of each clearly discernible • Free from artefact • The number of letters visible in the phrase “Quality Control” for the dark, mid-gray and light renditions must be ≥11.	1. Test patterns to be displayed at full resolution 2. Test under clinical lighting conditions 3. Use TG18-QC test pattern.	As per routine testing. Monitor or workstation may have comprehensive QA program

Procedure	Performance Requirements / Guidelines	Routine Testing Guidelines	Acceptance & Additional Tests
Printer (Hardcopy only)	• B+F = baseline ± 0.03 & ≤0.25 OD • D_{max} = baseline ±0.10 & ≥3.4 OD • The number of letters visible in the phrase "Quality Control" for the dark, mid-gray and light renditions must be ≥11.	Print TG18-QC test pattern as per weekly printer QC test	As per routine tests.

Appendix 4 Summary of Recommendations for Facility QC for Biopsy units

Procedure	Minimum Frequency	Fully integrated digital/biopsy unit	Digital mammography with add on image system	Stand alone biopsy system
Viewing Conditions	Weekly	Previously covered[m]	Previously covered	See section 3.2.1
Monitor QC	Weekly	Previously covered	ssa[n]	See section 3.2.4
Monitor Cleaning	Weekly	Previously covered	ssa	See section 3.2.5
Image Quality Evaluation	Weekly	ssa	ssa	See section 3.2.7 Note may use ACR 'mini' digital stereotactic phantom – see text.
Printer QC (if applicable)	Weekly	Previously covered	ssa	See section 3.2.10
Mechanical Inspection	Monthly	ssa	ssa	See section 3.2.11 Note Additionally image receptor and compression plate/ biopsy window must be free of wobble; Vernier drive and needle guide rigid and wobble free, localisation system zeros and biopsy device properly immobilised – see text.
Repeat Analysis	Quarterly	ssa	ssa	See section 3.2.12
Image Receptor Homogeneity	Quarterly[o]	Previously covered	ssa	See section 3.2.13 Note; procedure should be modified as seen in text.
AEC Calibration Test	Quarterly	ssa	ssa	See section 3.2.14 Procedure may vary for different types of units – see text.
Compression	Six monthly	ssa	ssa	See section 3.2.15
Test Equipment Quality Control Densitometer calibration check	Six monthly	Previously covered	Previously covered	See section 3.2.16
Maintenance & Fault Logging	As required	ssa	ssa	See section 3.2.18
Infection Control of Breast Imaging Equipment	Before each examination	Previously covered	Previously covered	See section 3.2.19
Stereotactic Accuracy Confirmation	Prior to first use on day of procedures	ssa	ssa	Localisation within ±1 mm. Procedure as per manufacturer's recommendations; Checklist/logbook entry showing: Date test performed Test results Person performing test

[m] Test previously completed as part of mammography tests
[n] Ssa – see stand alone biopsy units
[o] Or more frequently if recommended by the manufacturer

Appendix 5 Summary of Recommendations for Medical Physics Testing for Biopsy units

Procedure	Frequency	Fully integrated digital/biopsy unit	Digital mammography with add on image system	Stand alone biopsy system
Focal Spot	acceptance	Previously covered[p]	Previously covered	See section 4.2.1
Leakage Radiation	acceptance	Previously covered	Previously covered	See section 4.2.2
MTF	acceptance	Previously covered	ssa[q]	See section 4.2.6
Spatial linearity & Geometric Distortion	acceptance	Previously covered	ssa	See section 4.2.8
Distance Calliper Accuracy	acceptance	Previously covered	ssa	See section 4.2.9
Mammography Unit Assembly Evaluation	annual	ssa	ssa	See section 4.3.1 Note Additionally ensure x-ray tube angular locations positively locked; image receptor and compression plate/ biopsy window free of wobble; Vernier drive and needle guide rigid and wobble free, localisation system zeros; biopsy device properly immobilised and AEC chart displayed – see text
Collimation Assessment*	annual	ssa	ssa	FOV defined by biopsy window and is aligned centrally with digital image receptor, with tolerances of ± 5 mm – see text.
System Resolution	annual	Previously covered	ssa	See section 4.3.3
AEC / SDNR	annual	Previously covered	ssa	See section 4.3.4 Note: technique charts should be consulted for correct factor settings. Minimum PMMA thickness of 2 cm used for SDNR see text
Image Uniformity and Artefact Evaluation	annual	Previously covered	ssa	See section 4.3.5 Note – ROIs to be in corners of image, 10 mm from edge.
Image Quality evaluation	annual	Previously covered	ssa	See section 4.3.6 Note may use ACR 'mini' digital stereotactic phantom – see text for revised scoring
Ghost image evaluation	annual	Previously covered	ssa	See section 4.3.7
System Linearity & Noise Analysis	annual	Previously covered	Previously covered	See section 4.3.8
kVp performance	Annual	Previously covered	Previously covered	See section 4.3.9
HVL	annual	Previously covered	Previously covered	See section 4.3.10
Mean Glandular Dose	annual	ssa	ssa	See section 4.3.11– Note; see technique chart for factors used in dose calculations.
Exposure time	annual	Previously covered	Previously covered	See section 4.3.12
Viewbox and room luminance	annual	ssa	ssa	See section 4.3.13
Monitor Performance	annual	Previously covered	ssa	See section 4.3.14
Printer (Hardcopy)	annual	Previously covered	ssa	See section 4.3.15
Localisation accuracy test	annual	ssa	ssa	

[p] test previously completed as part of mammography tests
[q] See stand alone biopsy units

Appendix 6 Summary of criteria in terms of CR exposure indicators

A number of companies currently manufacture CR units for use in mammography and they have developed unique exposure indicators. Reviews of these indicators, with a comparison between the different manufacturers, have been reported in the literature[9,41] The table below can be used to indicate the test criteria that should be applied in terms of the current CR exposure indicators.

		Tolerance in terms of CR exposure indicator		
Test	*Test criteria*	*Fuji, Philips & Konica*	*Kodak (Carestream)*	*Agfa*[r]
3.2.7. Image quality evaluation	Air kerma (dose) to the plate must not change by greater than ±10%	±10% in S# of baseline	± 40 units in EI of baseline	±5% in SAL or ±430 in SAL log or ±580 in PVL log16 of baseline
3.2.14. AEC Calibration Test	Air kerma (dose) to the plate for each of the three thicknesses of PMMA be within ±10% of the baseline value for each thickness	±10% in S# of baseline for each thickness	± 40 units in EI of baseline for each thickness	±5% in the SAL , or ±430 in SAL log or ±580 in PVI log16 of baseline for each thickness
3.2.17. Cassette Image Plate Condition & Interplate Sensitivity Variation (also 4.3.5)	Air kerma (dose) to individual plate must differ from mean for that size by less than ±5% Difference in mean air kerma (dose) to plates of different sizes <20%	S# for individual plates must be within ±5% of mean for same size S# difference for two different plate sizes <20%	EI for individual plate must be within ±20 units of mean for same size EI difference for two different plate sizes <100 units	SAL for individual plates must be within ±2.5% or SAL log must be within ±220 or PVI log16 must be within ±290 of mean for same size SAL difference <10% or SAL log difference < 1000, or PVI log16 < 1300 for two different plate sizes
4.3.8. System Linearity & Noise Analysis	R^2 value of appropriate plot of exposure indicator versus ESAK must be >0.99	Plot S# versus reciprocal of ESAK	Plot EI versus log (ESAK)	Plot SAL versus SQRT(ESAK) or SAL log versus log(ESAK) or PVI log 16 versus log(ESAK)
4.3.16 Exposure Indicator Calibration & Image Fading	Under specified conditions (see Table 4) Exposure Indicator must meet criteria outlined in columns to right	S# = 120 ± 20	EI = 2300 ± 100	SAL = 1130 ± 100 SAL log = 21600 ± 1000 PVI log 16 = 41100 ± 1300

[r] Agfa have indicated that the preferred exposure indices to use with mammography plates are SAL log (sometimes called PVI log15) or PVI log16, the actual choice being dictated by software version and plate type. SAL may be used in some old software versions and LgM should not be used.

Appendix 7 Summary of Recommendations for Facility QC for DBT units

Procedure	Recommended Control-Limits/Requirements	Minimum Frequency	Key Procedure Elements	Recommendations for Record Keeping[s]
Full Field Artefact Evaluation	mAs = baseline ± 10% There must be no evidence of: • Clinically significant structures that are more conspicuous than the objects in the phantom used for weekly testing. • Blotches or regions of altered noise appearance. • Observable grid lines or breast support structures. • Bright or dark pixels. • Dust artefacts mimicking calcifications • Significant stitching or registration artefacts	Daily	1. Expose a uniform thickness of PMMA using clinically relevant technique factors under AEC. 2. Central projection image and central reconstructed image should be inspected closely for potential artefacts 3. View images on acquisition monitor using zoom and roam to check for possible detector faults. The magnification should be sufficient to achieve at least 1:1 resolution.	Records showing: • Date test was performed. • Person performing test. • Test results • kVp, target/filter & mAs
Image Quality Evaluation	mAs = baseline ± 10% The ability to clearly visualise 4 fibres, 3 speck groups & 3 masses in an image of an ACR accreditation phantom OR The ability to clearly visualise 2 fibres, 1 speck group & 2 masses in an image of an ACR DM phantom The position of the reconstructed slice used for scoring the phantom must not change by more than ± 1 mm.	Weekly	Obtaining the phantom image: 1. Use an ACR accreditation phantom or the new ACR DM phantom. 2. Light contact between the compression paddle and the phantom surface. 3. Consistent positioning of the phantom. 4. Consistent selection of clinically relevant kVp and target/filter combinations. Evaluating the phantom image: 1. Scroll through the reconstructed images until the slice displaying the speck details most clearly is reached. Use zoom and modest adjustment of window/level functions to score fibres and specks. 2. Use of consistent viewing conditions that reflect those used to read actual mammograms. 3. Image quality scoring by the same person, if possible. 4. Use of a control chart to record results.	Record radiographic settings (kVp, target/filter combination, mAs values) and image quality scores, position of slice used for scoring Control chart showing: • Plots of mAs, image quality scores, slice position • ≥ 25 results. • Clearly marked control limits. • Baseline values • Remarks e.g. corrective action. Phantom images identifying: • Date • The x-ray system • The technique factors
Detector Calibration – Flat Field Test	Pass or Fail	Weekly or as per manufacturer's requirements	Follow manufacturer's specific procedure	Checklist/logbook entry showing: • Date performed • Person performing task

[s] All written/electronic QC records should be retained for one year unless otherwise indicated by local Regulatory requirements. Images used to assess image quality with the ACR Accreditation or ACR DM phantom should be retained for a minimum of one month.

Procedure	Recommended Control-Limits/Requirements	Minimum Frequency	Key Procedure Elements	Recommendations for Record Keeping[s]
AEC Calibration Test	mAs = baseline ± 10% for same target/filter combination for each thickness of PMMA	Quarterly	1. Use PMMA thicknesses of 2 cm, 4 cm and 6 cm covering complete image receptor 2. Use clinical AEC settings (kVp, target/filter and mode)	Records showing: • Date test was performed. • Person performing test. • x-ray system identification. • kVp, target/filter, AEC mode and mAs.
Compressed breast thickness	For units using special Bucky's for DBT indicated breast thickness accurate to ±5 mm	Monthly	Confirm accuracy of thickness indication under conditions as indicated by the manufacturer	Checklist/logbook entry showing: • Date performed • Inspection results • Person performing task

Appendix 8 Summary of Recommendations for Medical Physics Testing for DBT units

Procedure	Performance Requirements / Guidelines	Routine Testing Guidelines	Acceptance & Additional Tests
Collimation & Alignment Assessment			
• *x-ray field / Image receptor alignment*	The x-ray field shall irradiate the image receptor fully but not extend beyond breast support on the chest wall edge of the image receptor by more than 2 mm or beyond the Bucky support on the other three margins.	Assess alignment for each target/geometry combination. Note: When a special Bucky is used for DBT that may also be used to acquire normal 2D projection images the requirements outlined in section 4.3.2 must be met.	As per routine tests.
• *Paddle / Image alignment*	The chest wall edge of the compression paddle shall be aligned just beyond the chest wall edge of the image receptor such that it does not appear in the image. In addition, the compression paddle shall not extend beyond the chest wall edge of the image by more than 1% of the SID.		As per routine tests.
Compressed breast thickness	For units using special Bucky's for DBT, indicated breast thickness accurate to ±5 mm	Confirm accuracy of thickness indication under conditions as indicated by the manufacturer	As per routine tests
Missed tissue	The missing tissue must be ≤ 5 mm Full thickness of breast tissue must be imaged	Confirm in DBT mode of acquisition even if previously confirmed in projection imaging mode.	As per routine tests
Distance Calliper Accuracy	Measured dimensions of object within reconstructed image plane must be within 2% of true dimensions	1. Use the ACR accreditation (or ACR DM) phantom as per image quality test below 2. Select the reconstructed slice which best displays the speck details for image scoring and perform in plane distance measurements The outside location of the detail insert is useful for this purpose. 3. Compare with actual dimensions	Confirm accuracy of measurements at reporting workstation if possible and also confirm accuracy in more than one slice.
AEC System Performance Assessment	mAs = baseline ± 10% for same target/filter combination for each thickness of PMMA	1. Use PMMA thicknesses of 2 cm, 4 cm and 6 cm covering complete image receptor 2. Use clinical AEC settings (kVp, target/filter and mode)	As per routine tests.
Image Uniformity & Artefact Evaluation	mAs = baseline ± 10% There must be no evidence of: • Clinically significant structures that are more conspicuous than the objects in the phantom used for weekly testing. • Blotches or regions of altered noise appearance. • Observable grid lines or breast support structures. • Bright or dark pixels. • Dust artefacts mimicking calcifications • Significant stitching or registration artefacts	1. Assess for 40 mm PMMA covering complete detector using clinically relevant technique factors under AEC. 2. Central projection image and central reconstructed image should be inspected closely for potential artefacts 3. View images on acquisition monitor using zoom and roam to check for possible detector faults. The magnification should be sufficient to achieve at least 1:1 resolution.	Assess all projection and reconstructed images in the acquisition for all available target/filter combinations.

Procedure	Performance Requirements / Guidelines	Routine Testing Guidelines	Acceptance & Additional Tests
Image Quality Evaluation	mAs = baseline ± 10% for same target/filter combination Slice used for scoring should be 37±2 mm (ACR accreditation phantom) or 34±2 mm (ACR DM phantom) above breast support and must not change by more than ± 1 mm from previous measurement. The ability to clearly visualise 4 fibres, 3 speck groups & 3 masses in an image of an ACR accreditation phantom or the ability to clearly visualise 2 fibres, 1 speck group & 2 masses in an image of the ACR DM phantom	1. Use typical clinical acquisition parameters selected under AEC. Note that the acquisition may be combined with FFDM mode using "Combo mode". 2. Select the reconstructed slice which best displays the speck details for image scoring. This is typically 37±2 mm or 34±2 mm above the breast support with the ACR accreditation phantom and ACR DM phantom, respectively.	As per routine testing
Beam Quality	(kVp/100) + 0.03 ≤HVL< (kVp/100) +C where C = 0.12 mm Al for Mo/Mo = 0.19 mm Al for Mo/Rh = 0.22 mm Al for Rh/Rh = 0.23mm Al for Rh/Ag = 0.30 mm Al for W/Rh = 0.32 mm Al for W/Ag = 0.31 mm Al for W/Al	Measure the HVL required for Mean Glandular Dose calculations.	As per routine tests
Mean Glandular Dose	• ≤2.0 mGy for a 4.2 cm 50% adipose, 50% glandular breast (i.e. ACR accreditation phantom or ACR DM phantom). • <1.2 mGy for 2.0 cm PMMA (2.3 cm 50% adipose, 50% glandular breast) • < 4.5 mGy for 6.0 cm PMMA, (6.5 cm 50% adipose, 50% glandular breast) • Displayed MGD values must agree with calculated values within ±25%.	Assess for an AEC controlled exposure using typical clinical settings using ACR phantom (or ACR DM phantom) and also for 20 mm and 60 mm PMMA. Confirm displayed and calculated MGDs agree to ±25%	As per routine tests.

11 References

[1] Craig, A.R., Heggie, J.C.P., mclean, D., Coakley, K.S. and Nicoll, J.J., *Recommendations for a mammography quality assurance program*, Australasian Physical & Engineering Sciences in Medicine, 24: 1-27, 2001.

[2] RANZCR, Mammographic Quality Control Manual Royal Australian and New Zealand College of Radiologists, 2002.

[3] Australian Government, Department of Health, breastscreen Australia, *National Accreditation Standards*, 2015.

[4] Digital Mammography Quality Control Manual American College of Radiology, 2016.

[5] Bloomquist, A.K., Yaffe, M.J., Pisano, E.T., Hendrick, R.E., Mawdsley, G.E., Bright, S., Shen, S.Z., Mahadevappa, M. *Et al.*, *Quality control for digital mammography in the ACRIN DMIST trial: Part I*, Medical Physics, 33: 719-736, 2006.

[6] Pisano, E.T., Gatsonis, C., Hendrick, R.E., Yaffe, M.J., Baum, J.K., Acharyya, S., Conant, E.F., Fajardo, L.L. *et al.*, *Diagnostic Performance of Digital versus Film Mammography for Breast-Cancer Screening*, The New England Journal of Medicine: 353, 2005.

[7] Yaffe, M.J., Bloomquist, A.K., Mawdsley, G.E., Pisano, E.T., Hendrick, R.E., Fajardo, L.L., Boone, J.M., Kanal, K. *Et al.*, *Quality control for digital mammography: Part II recommendations from the ACRIN DMIST trial*, Medical Physics, 33: 737-752, 2006.

[8] EUREF, *Addendum on Digital Mammography: European Guidelines for Quality Assurance in Mammography Screening.* European Reference Organisation for Quality Report No., 2003.

[9] EUREF, *European Protocol for the Quality Control of the Physical and Technical Aspects of Mammography Screening* as published in *European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth edition, Supplements*, 2013.

[10] Pisano, E.T. and Yaffe, M.J., *Digital Mammography*, Radiology, 234: 353-362, 2005.

[11] American Association of Physicists in Medicine, *Acceptance Testing and Quality Control of Photostimulable Storage Phosphor Imaging Systems* AAPM, Task Group 10 Report No. TG10, 1998.

[12] Monnin, P., Gutierrez, D., Bulling, S., Guntem, D. And Verdun, F.R., *A comparison of the performance of digital mammography systems*, Medical Physics, 34: 906-914, 2007.

[13] NHSBSP, *Routine control tests for full field digital mammography systems* National Breast Screening Programme Report No. NHSBSP Equipment Report 0702, 2007.

[14] Young, K. (private communication)

[15] Aslund, M., Cederstrom, B., Lundqvist, M. And Danielsson, M., *Physical characterization of a scanning photon counting digital mammography system based on Si-strip detectors*, Med Phys, 34: 1918-25, 2007.

[16] AAPM, *Assessment of Display Performance for Medical Imaging Systems* American Association of Physicists in Medicine, Task Group 18 Report No. TG18, 2005.

[17] Samei, E., Badano, A., Chakraborty, D., Cornelius, C., Flynn, M.J., Hemminger, B., Hangiandreou, N., Johnson, J. *Et al.*, *Assessment of display performance for medical imaging systems: Executive summary of AAPM TG18 report*, Medical Physics, 32: 1205-1225, 2005.

[18] Aslund, M., Cederstrom, B., Lundqvist, M. And Danielsson, M., *Optimized AEC for scanning digital mammography based on local variation of scan velocity*, Proceedings of the SPIE, 5745: 468-477, 2005.

[19] Elbakri, I.A., Lakshminarayanan, A.V. and Tesic, M.M., *Automatic exposure control for a slot scanning full field digital mammographic system.*, Medical Physics, 32: 2763-2770, 2005.

[20] International Electrotechnical Commission, *Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests - Imaging performance of dental X-ray equipment* International Electrotechnical Commission Report No. IEC 61223-3-4, 2000.

[21] International Electrotechnical Commission, *X-ray tube assemblies for medical diagnosis - Characteristics of focal spots.* International Electrotechnical Commission Report No. 60336, 4th Edition 2005.

[22] Gunn, C., *Radiographic Imaging. A Practical Approach*, 3rd ed. Churchill Livingstone, 2002.

[23] Marshall, N.W., *Retrospective analysis of a detector fault for a full field digital mammography system*, Physics in Medicine and Biology, 51: 5655-5673, 2006.

[24] *dicomworks*. Http://dicom.online.fr/

[25] *imagej*. Http://rsb.info.nih.gov/ij/

[26] See NHSBSP technical reports available at: https://www.gov.uk/government/collections/breast-screening-professional-guidance

[27] Standards Australia & Standards New Zealand, *Approval and test specification - Medical electrical equipment - General requirements for safety - Collateral Standard: Requirements for radiation protection in diagnostic X-ray equipment*. AS/NZS IEC Report No. 60601.1.3:2015.

[28] Strauss, K.J. and Rossi, R.P., *Specification, acceptance testing, and quality control of mammography imaging equipment*. In *A categorical course in physics - technical aspects of breast imaging*, edited by A.G. Haus and M.J. Yaffe (RSNA, Oak Brook, IL, 1994), pp. 219-246.

[29] Rossmann, K., *Point Spread-Function, Line Spread-Function and Modulation Transfer Function*, Radiology, 93: 257-272, 1969.

[30] Coltman, J.W., *The Specification of Imaging Properties by Response to a Sine Wave Input*, Journal of the Optical Society of America, 44: 468-471, 1954.

[31] Droege, R.T. and Morin, R.L., *A practical method to measure the MTF of CT scanners*, Medical Physics, 9: 758-761, 1982.

[32] International Electrotechnical Commission, *Evaluation and routine testing in medical imaging departments - Part 3-2: Acceptance testing - imaging performance of mammographic x-ray equipment* International Electrotechnical Commission Report No. 61223-3-2 Ed. 2.0, 2007.

[33] Maidment, A. And Albert, M., *Conditioning data for calculation of the modulation transfer function*, Medical Physics, 30: 248-252, 2003.

[34] Carton, A.-K., Vandenbroucke, D., Struye, L., Maidment, A., Kao, Y.-H., Albert, M., Bosmans, H. And Marchal, G., *Validation of MTF measurement for digital mammography quality control*, Medical Physics, 32: 1684-1695, 2005.

[35]International Electrotechnical Commission, *Medical Electrical Characteristics of Digital X-ray imaging devices - Part 1-2: Determination of the quantum detection efficiency - Detectors used in mammography*, International Electrotechnical Commission Report No. 62220-1-2, 2007.
[36]Hoeschen, C., Tischenko, O., Buhr, E. And Illers, H., *Comparison of technical and anatomical noise in digital thorax x-ray images*, Radiaiton Protection Dosimetry, 114: 75-80, 2005.
[37]Tischenko, O., Hoeschen, C., Dance, D.R., Hunt, R.A., Maidment, A. And Bakic, P.R., *Evaluation of a novel method of noise reduction using computer-simulated mammographs*, Radiaiton Protection Dosimetry, 1-3, 2005.
[38]Fletcher-Heath, L. And Van Metter, R., *Quantifying the performance of human and software CDMAM phantom image observers for the qualification of digital mammography systems*, 2006.
[39]Van Metter, R. And Fletcher-Heath, L., *Applying the "European protocol for the quality of the physical and technical aspects of mammography screening" threshold contrast visibility assessment to digital systems*, 2006.
[40]ACR, *Mammography quality control manual* American College of Radiology, Merrifield, VA, 1992.
[41]AAPM, *Acceptance Testing and Quality Control of Photostimulable Storage Phosphor Imaging Systems* American Association of Physicists in Medicine, Task Group 10 Report No. TG10, 1998.
[42]Samei, E., Seibert, J.A., Willis, C.E., Flynn, M.J., Mah, E. And Junck, K.L., *Performance evaluation of computed radiography systems*, Medical Physics, 28: 361-371, 2001.
[43]NHSBSP, *Commissioning and routine testing of full field digital mammography systems* NHSBSP Equipment report 0604 (Version 3), 2009.
[44]Robson, K.J., *A parametric method for determining mammographic X-ray tube output and half value layer*, British J Radiology, 74: 335-340, 2001.
[45]International Commission on Radiation Units and Measurements, *Patient Dosimetry for X Ray Used in Medical Imaging* ICRU Report No. Report 74, 2006.
[46]Eklund, S., Thilander, A. And Leitz, W., *The impact of anatomic variations on absorbed radiation doses in mammography*, Radiation Protection & Dosimetry, 49: 167-170, 1993.
[47]Cross, P., *Doses in mammography: From the phantom to the patient*, Australasian Radiology, 38: 20-23, 1994.
[48]Geise, R.J. and Palchevsky, A., *Composition of Mammographic Phantom Materials*, Radiology, 198: 347-350, 1996.
[49]Heggie, J.C.P., *Survey of Doses in Screening Mammography*, Australasian Physical & Engineering Sciences in Medicine, 19: 207-216, 1996.
[50]Klein, R., Aichinger, H., Dieker, J., Jansen, J.T.M., Joite-Barfu, S., Sabel, M., Schulz-Wendland, R. And Zoetelief, J., *Determination of average glandular dose with modern mammography units for two large groups of patients*, Physics in Medicine and Biology, 42: 651-671, 1997.
[51]Young, K.C., Ramsdale, M.L. and Bignall, F., *Review of dosimetric methods for mammography in the UK breast screening programme*, Radiation Protection Dosimetry, 80: 183-186, 1998.
[52]Beckett, J. And Kotre, C.J., *Dosimetric implications of age related glandular changes in screening mammography*, Physics in Medicine and Biology, 45: 801-813, 2000.
[53]Dance, D.R., Skinner, C.L., Young, K.C., Beckett, J. And Kotre, C.J., *Additional factors for the estimation of mean glandular breast dose using the UK mammographic dosimetry protocol*, Physics in Medicine and Biology, 45: 3225-3240, 2000.
[54]Dance, D.R., *Monte Carlo calculations of conversion factors for the estimation of mean glandular breast dose*, Physics in Medicine and Biology, 35: 1211-1219, 1990.
[55]Wu, X., Barnes, G.T. and Tucker, D.M., *Spectral dependance of glandular tissue dose in screen-film mammography*, Radiology, 179: 143-148, 1991.
[56]Wu, X., Gingold, E.L., Barnes, G.T. and Tucker, D.M., *Normalised average glandular tissue dose in molybdenum target - rhodium filter and rhodium and rhodiuim -target rhodium filter mammography*, Radiology, 193: 83-89, 1994.
[57]Sobol, W.T. and Wu, X., *Parametrization of mammography normalized average glandular dose tables*, Medical Physics, 24: 547, 1997.
[58]Dance, D.R.(private communication)
[59]Liu, B., Goodsitt, M. And Chan, H.-P., *Normalised average glandular dose in magnification mammography*, Radiology, 197: 27-32, 1995.
[60]ACR, *Stereotactic breast biopsy quality control manual* American College of Radiology, Reston, VA, 1999.
[61]RANZCR, *Mammographic Quality Assurance Program, Guidelines for Quality Control Testing for Digital (CR & DR) Mammography, Version 3.0*, Royal Australian and New Zealand College of Radiologists, 2012.
[62]IAEA, *Quality Assurance Programme for Digital Mammography*, IAEA Human Health Series No 17, Vienna, 2011.
[63]NHSBSP, *Technical evaluation of the Konica Minolta Regius 190 CR Mammography System and Three Types of Image Plate*, NHSBSP Equipment Report 0806, 2008.
[64]NHSBSP, *Technical Evaluation of Agfa DX-M Mammography CR Reader with HM5.0 Needle Image Plate*, NHSBSP Equipment Report 0905, 2009.
[65]*Sante Dicom Viewer Free* http://www.santesoft.com/dicom_viewer_free.html.
[66]Paquelet, J.R. and Hendrick, R.E., *Lesion Size Inaccuracies in Digital Mammography*, American Journal of Roentgenology, 194: W115-W118, 2010.
[67]Sechopoulos, I., Suryanarayanan, S., Vedantham, S., D'Orsi, C., Karellas, A., *Computation of the glandular radiation dose in digital tomosynthesis of the breast*, Medical Physics, 34: 221-232, 2007.
[68]Sechopoulos, I. And D'Orsi, C.J., *Glandular Radiation Dose in Tomosynthesis of the Breast using Tungsten Targets*. Journal Applied Clinical Medical Physics, 9: 161-171, 2008.
[69]Dance, D.R., Young, K.C. and van Engen, R.E., *Estimation of mean glandular dose for breast tomosynthesis: factors for use with the UK, European and IAEA breast dosimetry protocols*, Physics in Medicine and Biology, 56: 453-471, 2011.
[70]Jacobs, A., Cockmartin, L., Dance, D.R. and Bosmans, H., *Digital Breast Tomosynthesis: comparison of different methods to calculate patient doses*. Proceedings

of Standards, Applications and Quality Assurance in Medical Radiation Dosimetry (IDOS); 2010 9-12 November 2010; Vienna: IAEA. Http://www-pub.iaea.org/MTCD/Publications/PDF/supplementarymaterials/P1514/Pub1514_vol2_web.pdf.

[71]Feng, S.S. and Sechopoulos, I., *Clinical digital breast tomosynthesis system: dosimetric characterization*. Radiology, 263: 35-42, 2012.

[72]http://www.euref.org/downloads/software-physico-technical-protocol/cdmam-readout#CDMAM_Analyser

[73] NHSBSP, *Commissioning and routine testing of full field digital mammography systems.* NHSBSP Equipment report 0604 (Version 3), 2009. Appendix 4 includes appropriate spreadsheets for testing monitor and printer response.

[74]Monnin, P., Marshall, N. W., Bosmans, H., Bochud, F. O. And Verdun, F. R., *Image quality assessment in digital mammography: Part II. NPWE as a validated alternative for contrast detail analysis.* Physics in Medicine and Biology, 56: 4221-4238, 2011.

[75]Yaffe, M.J., Boone, J.M., Packard, N., Alonzo-Proulx, Huang, S.Y. et al, *The myth of the 50-50 breast.* Medical Physics, 36: 5437-5443, 2009.

[76]Vedantham S, Shi L, Karellas A and O'Connell A. M., *Dedicated breast CT: fibroglandular volume measurements in a diagnostic population*. Medical Physics, 39: 7317-7328, 2012.

[77]Dance, D.R., Young, K.C. and van Engen, R.E, *Further factors for the estimation of mean glandular dose using the United Kingdom, European and IAEA breast dosimetry protocols.* Physics in Medicine and Biology, 54: 4361–4372, 2009.

[78]Standards Australia & Standards New Zealand, *Approval and test specification - Medical electrical equipment - General requirements for safety - Collateral Standard: Requirements for radiation protection in diagnostic X-ray equipment*. AS/NZS IEC Report No. 60601.2.45, 2015.

[79]Sechopoulos, I., Sabol, J.M., Berglund, J., Bolch, W.E., Brateman, L. et al, *Radiation dosimetry in digital breast tomosynthesis: Report of AAPM Tomosynthesis Subcommittee Task Group 223*. Medical Physics, 41: 091501, 2014.

[80]Ciatto, S., Houssami, N., Bernardi, D., Caumo, F., Pellegrini, M. Et al. *Integration of 3D digital mammography with tomosynthesis for population breast-cancer screening (STORM): a prospective comparison study*. Lancet Oncol, 14: 583–589, 2013.

[81]Skanne, P., Bandos, A.I., Gullien, R., Eben, E.B., Ekseth, U., Haakenaasen, U. Et al. *Comparison of digital mammography alone and digital mammography plus tomosynthesis in a population-based screening program*. Radiology, 267: 47–56, 2013.

[82]Friedewald, S.M., Rafferty, E.A., Rose, S.L., Durand, M.A., Plecha, D.M., Greenberg, J.S. et al. *Breast cancer screening using tomosynthesis in combination with digital mammography*. JAMA, 311: 2499–2507, 2014.

[83]Mccarthy, A.M., Kontos, D., Synnestvedt, M., Tan, K.S., Heitjan, D.F., Schnall, M. Et al. *Screening outcomes following implementation of digital breast tomosynthesis in a general-population screening program*. J National Cancer Institute, 106: dju316, 2014.

[84]Rafferty, E.A., Durand, M., Conant, E.F., Somers Copit, D., Friedewald, S.M., Plecha, D.M., Miller, D.P., *Breast cancer screening using tomosynthesis and digital mammography in dense and nondense breasts*. JAMA, 315: 1784–1786, 2016.

[85]Mertelmeier, T, Speitel, J. And Frumento C., *3D breast tomosynthesis – intelligent technology for clear clinical benefits*. White Paper, Siemens Medical Solutions, 2012.

[86]Smith, A., *Design considerations in optimising a breast tomosynthesis system*. Hologic White Paper WP-00046.

[87]Skaane, P, Bandos, A.I., Eben, E.B., Jebsen, I.N., Krager, M. Et al, *Two View Digital Breast Tomosynthesis screening with synthetically reconstructed projection images: comparison with digital breast tomosynthesis with full-field digital mammographic images*. Radiology, 271: 655-663, 2014.

[88]Zuley, M.L., Guo, B., Catullo, V.J., Chough, D.M., Kelly, A.E. et al, *Comparison of two-dimensional synthesized mammograms versus original digital mammograms alone and in combination with tomosynthesis images*. Radiology, 271: 664-671, 2014.

[89]EUREF, *Protocol for the Quality Control of the Physical and Technical Aspects of Digital Breast Tomosynthesis Systems.* Version 1.01 June 2016.

[90]Royal Australian and New Zealand College of Radiologists, *Standards of Practice for Diagnostic and Interventional Radiology*. Version 10.2 (2017).

[91]Reiser, I and Sechopoulos, I., *Review of Digital Breast Tomosynthesis.* Medical Physics International J., 2: 57-66: 2014.

[92]See https://medphys.royalsurrey.nhs.uk/nccpm/?s=mgd which provides access to the relevant Dance dosimetry papers and relevant tables.

[93]Norweck, J.T., Seibert, J.A., Andriole, K.P., Clunie, D.A., Curran, B.H. et al, *ACR–AAPM–SIIM Technical Standard for Electronic Practice of Medical Imaging*. J. Digital Imaging, 26: 38-52, 2013. A more recent and slightly amended version of this document is available from https://www.acr.org/News-Publications/Publications.

[94]IAEA, *Dosimetry in Diagnostic Radiology: An International Code of Practice*, TRS 457, Vienna (2007). Document available from http://www-pub.iaea.org/MTCD/publications/PDF/TRS457_web.pdf.