

# IAEA HUMAN HEALTH SERIES

No. 17

## Quality Assurance Programme for Digital Mammography



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International Atomic Energy Agency

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QUALITY ASSURANCE PROGRAMME  
FOR DIGITAL MAMMOGRAPHY

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IAEA HUMAN HEALTH SERIES No. 17

QUALITY ASSURANCE PROGRAMME  
FOR DIGITAL MAMMOGRAPHY

INTERNATIONAL ATOMIC ENERGY AGENCY  
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# FOREWORD

The application of radiation for the diagnosis and treatment of disease is an important component of the work of the IAEA. In the area of diagnostic radiology, this work is focused on quality assurance (QA) methods to promote the effective use of radiation for diagnostic outcome through achieving and maintaining appropriate image quality, and on dose determination to allow the monitoring and reduction of dose to the patient.

The role of mammography in the timely detection of breast cancer is well established. Recent technological developments have seen extensive application of digital techniques to mammography in many Member States. This technology allows remote diagnosis, thus improving patient outcomes in remote or under-resourced settings. The need for QA of and technical information on digital mammography is critical, as many of the implications of a transition to digital technology are not well understood.

Currently there is a small number of QA protocols in digital mammography that apply to limited national and regional settings. Many Member States, therefore, have requested guidance in this area. In responding to these requests, the current publication was written with the aim of presenting an internationally harmonized approach to QA in the field. This approach will allow Member States to implement QA of mammography in a standardized way. This is needed to improve the effectiveness of national programmes that underpin population screening in the fight against breast cancer.

This publication on QA of digital mammography was developed as a companion to the recently published Quality Assurance Programme for Screen Film Mammography (IAEA Human Health Series No. 2) and follows the same format and style. Since 2007, the IAEA has convened three consultants meetings to prepare the present publication. Additional work undertaken by this group includes the field testing of a number of new phantoms and test equipment developed for the digital environment, and the compilation of performance standards; this work is ongoing and is accessible on the IAEA web site (<http://humanhealth.iaea.org>). A draft of this report was circulated for comment among members of the international mammography community, and their suggestions have been incorporated.

The IAEA acknowledges the contribution of the drafting committee, chaired by M. Yaffe (Canada), with M. Chevalier (Spain), J.C. Heggie (Australia), P. Mora (Costa Rica) and K. Young (United Kingdom). The IAEA officer responsible for this document was I.D. McLean of the Division of Human Health.

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# 1. INTRODUCTION

## 1.1. WHY IS HIGH QUALITY NECESSARY IN MAMMOGRAPHY?

Breast cancer is the most common cancer among women worldwide and is a leading cause of cancer mortality in women. Breast cancer incidence increased 30–40% from the 1970s to the 1990s in most countries, with the most marked increases among women aged 50 years and older, although the incidence in women under 50 is also increasing. Overall, North American and northern European countries have the highest incidence rates of breast cancer; intermediate levels have been reported in western Europe, Oceania, Scandinavia and Israel; the lowest levels are observed in eastern Europe, Central and South America, and Asia. Breast cancer incidence and mortality rates vary fourfold by geographic location between those countries with the highest rates and those with the lowest.

Mammography is an X ray examination of the breast. Its principal purpose is to facilitate the detection of breast cancer at a point earlier in its natural history than is possible by clinical examination. It has been demonstrated that routine screening with high quality mammography is effective in reducing mortality from breast cancer in women aged 40–69 [1, 2]. In countries with mammography screening programmes, there has been a marked decrease in breast cancer mortality over the past two decades [1]. Mammography is also useful in refining the diagnosis of breast cancer (assessment or workup) after a suspicious area in the breast has been detected and for localizing a lesion for therapy.

The radiological signs of breast cancer include mass densities that are typically slightly more attenuating of X rays than the surrounding normal tissue, small microcalcifications, asymmetry between the two breasts and architectural distortion of tissue patterns. To detect breast cancer accurately and at the earliest possible stage, the image must have excellent contrast to reveal mass densities and spiculated fibrous structures radiating from them, which are characteristic of cancer. In addition, the spatial resolution must be excellent to reveal the calcifications, their number and their shape. The imaging system must have adequate latitude to provide this contrast and resolution over the entire breast effectively. The geometrical characteristics of the X ray unit and the positioning of the breast by the radiographer must be such that as much breast tissue as possible is included in the mammogram. Finally, the noise (signal fluctuation) of the image must be sufficiently low to reveal the subtle structures in a reliable manner, and the X ray dose must be as low as is reasonably achievable while being compatible with these image quality requirements.

In digital mammography, the screen film combination used as the image receptor in conventional mammography is replaced by a detector that samples a finite number of locations and produces an electronic signal for each location. The magnitude of each signal is related to the transmission of X rays through the breast, and is digitized and stored in computer memory.

Recent publications indicate that digital mammography provides accuracy equal or superior to that of screen film mammography [3]. Digital mammography also has the potential to increase efficiency in image archiving and retrieval, and to avoid the costs, complexity and waste disposal problems associated with chemical processing of film. These factors have stimulated interest in the acquisition of digital systems. This presents both opportunities and challenges to those involved in delivering mammography services. One of the important challenges is to have in place, in a timely fashion, an appropriate framework of quality assurance (QA) for digital mammography systems.

## 1.2. PURPOSE

It has been well established that to achieve high quality mammography, the following elements are essential:

- (1) Well trained and experienced personnel (radiologist, radiographer, medical physicist);
- (2) Modern, well designed equipment;
- (3) Equipment in good working order;
- (4) Proper positioning and technical factors for exposure;
- (5) Appropriate image viewing conditions.

An effective QA programme is necessary to ensure that all these elements remain in place over time. This is especially the case with the added technical complexity of digital imaging. The part of this programme that is concerned with technical aspects is referred to as quality control (QC).

This publication is intended to provide a full review of QA issues for those Member States that are now using digital mammography or that are assessing the implications of using digital mammography. Importantly, it contains a standardized framework for QC for digital mammography that can be used in Member States. It is intended to provide practical tests to help ensure high quality digital mammography. To be feasible in areas where resources may be limited, the tests are designed to be carried out with the simplest test equipment possible.

This publication is current as of 2011, but there will be many improvements and changes in equipment in the future. As the frequencies of tests and tolerance ranges will probably also change as more experience is gained, it would always be prudent to check the latest versions of specific tables and charts in this publication, which will be posted on the IAEA web site at: <http://humanhealth.iaea.org>. Other supporting documentation and tutorial materials will also be posted on the site.

### 1.3. PHILOSOPHY

Several well established QC programmes for screen film mammography currently exist in different jurisdictions [4–7], and recently programmes have been developed for digital mammography [8–13]. These programmes are comprehensive and reflect the resources available in those countries. The IAEA recognizes the different resources and needs of Member States, and has developed specific programmes for individual areas. The present publication attempts to incorporate the most important components of the existing digital QA programmes in a harmonized manner [14] to be useful to a broad range of Member States. It has been developed with the philosophy that if digital mammography is to be performed, it must be of high quality to allow the earliest detection of cancers. In some areas, resources, both technological and human, are limited; therefore, this publication has also been developed with practicality in mind.

## 2. CONSIDERATIONS FOR THE TRANSITION TO DIGITAL MAMMOGRAPHY

### 2.1. CURRENT STATUS OF DIGITAL MAMMOGRAPHY

Screen film mammography has been well established as a tool for detection and radiological diagnosis of breast cancer. Used in routine screening of asymptomatic women, it has been shown to contribute to reduced mortality. It is still the most widely used imaging technique for detecting breast cancer and has the advantages of being relatively inexpensive and accessible.

Recently, however, digital mammography has been developed to overcome certain technical limitations of screen film mammography. These include: (a) the limited exposure latitude of film; (b) the deterioration of film response at both low and high exposures; (c) inflexibility in adjusting image brightness and contrast, and rigid linkage of these to X ray exposure level; (d) the lack of efficiency in utilizing the incident radiation dose; (e) noise associated with film granularity and screen structure; (f) the inefficiency of methods for rejection of scattered radiation; (g) limitations in optimizing imaging; (h) inconvenience in storage and retrieval of images; and (i) environmental issues regarding disposal of processing chemistry.

Unlike many medical imaging procedures, digital mammography has undergone quite extensive evaluation, both technical and clinical, including comparisons between digital and screen film mammography for screening [15, 16]. The Digital Mammographic Imaging Screening Trial (DMIST) [3] demonstrated an advantage of digital mammography in terms of sensitivity in women with dense breasts, women under 50 years of age and premenopausal women.<sup>1</sup> In these women, digital mammography was seen to be more sensitive in detecting cancer, with no increase in the false positive rate compared with film. For older women, performance was comparable, although for women over age 65 with fatty breasts, film showed a tendency (non-significant) to be more accurate.

There is currently considerable enthusiasm regarding digital mammography, and many facilities are interested in purchasing such systems. This publication considers some of the factors affecting the performance of digital mammography and those technical elements that distinguish the performance of one system from that of another. It must also be recognized that while digital mammography will almost certainly eventually supplant screen film mammography, it is still a new technology with very high capital costs. In addition, there are other important considerations regarding the purchase of a digital system, including the costs of preparing the installation (electrical supply, cooling, etc.), computer information system requirements, service costs, the costs of maintaining the system at the state of the art, and training of personnel. Moreover, with this new technology, there may be differences in efficiency (both positive and negative) in producing and interpreting mammograms.

Potential advantages of digital mammography include:

- Improved accuracy of diagnosis in the dense breast;
- Higher throughput of image acquisition;
- Reduced patient dose;
- The ability to disseminate images for viewing at multiple locations;
- The elimination of problems associated with chemical processing (i.e. environmental and occupational health issues, and costs related to film and processing chemistry);
- Improved archival and retrieval capabilities;
- The possibility of introducing new techniques (computer assisted detection (CAD), telemammography, tomosynthesis, contrast enhanced digital mammography);
- The ease of providing images to be used as teaching tools.

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<sup>1</sup> Note that these groups overlap, and that breast density is thought to be the major responsible factor.

Potential challenges or disadvantages associated with digital mammography include:

- Higher capital costs.
- The increased time required for image interpretation coupled with a need for radiologists to adjust to new image attributes.
- The need for radiologists, radiographers, clerks, etc., to adjust to new technology.
- Possible increased patient dose.<sup>2</sup>
- Difficulties in comparing digital images with film mammograms.
- Poorer technical performance characteristics of some digital systems compared with screen film, as expressed by their modulation transfer function (MTF), detective quantum efficiency (DQE) and signal difference to noise ratio (SDNR).
- Incompatibility between different digital systems.
- Difficulty in providing images to nondigital facilities (e.g. referring physicians).
- The increased complexity of technology leading to increased service costs.
- The need to interface the operation of several computer systems (image viewing, patient worklist, reporting), often provided by different vendors.
- Availability of suitably trained service personnel.
- Equipment reliability problems (e.g. detector failures due to abnormal temperatures).
- More demanding environmental requirements (e.g. properly conditioned electrical power, dust control and lighting conditions, Internet connections, ventilation and air conditioning). For example, many digital units require air conditioning to be provided 24 hours a day, 7 days a week to prevent damage to the detector.

All these factors should be taken into account when any facility contemplates making the transition from screen film to digital mammography. In particular, the capital and maintenance costs of digital mammography equipment are considerably higher than those of screen film systems, although there are some offsetting cost savings (no film, processing chemistry, processor maintenance or film library). This factor, combined with uncertainty concerning the clinical and other advantages of digital mammography and concerns about buying a system that might quickly become obsolete (although the technology has now begun to stabilize), has resulted in relatively slow uptake of this technology. Balancing these factors may mean that, in many facilities, mammography is the last analogue (film) technology holdout, although there is a strong incentive to become completely digital and to eliminate the costs and inefficiencies associated with chemical processing and archiving of films.

## 2.2. FACTORS TO CONSIDER IN CHOOSING A DIGITAL MAMMOGRAPHY SYSTEM

In some countries, the sale of digital mammography equipment is heavily regulated and the manufacturer has to demonstrate that performance meets certain standards. In others, standards are far less demanding. Whether or not rigorous standards exist in a given Member State, when considering the purchase of a digital system, it is valuable to examine whether that system has been approved in countries that do enforce such standards. It may therefore be useful to refer to the web sites of national or regional agencies such as the European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services (EUREF) ([www.euref.org](http://www.euref.org)), the United Kingdom's National Health Service Breast Screening Programme ([www.cancerscreening.nhs.uk/breastscreen/](http://www.cancerscreening.nhs.uk/breastscreen/)), the United States Food and Drug Administration (FDA) (<http://www.fda.gov/cdrh/mammography>) or other national sites where lists of acceptable models or assessment reports of performance are available.

The digital mammography system is a complex chain that includes the X ray unit and detector, software, display workstations, the picture archiving and communications system (PACS) and, possibly, printers. For the system to be effective and to provide improved performance over film mammography, all these components must be of high quality and must work effectively together. An example of the sort of problems that can occur when components do not work together is given in Ref. [17].

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<sup>2</sup> It should be noted that depending on the system design, the choice of technique factors and attention to QC, doses in digital mammography can be either lower or higher than those in screen film mammography.



The Integrating the Healthcare Enterprise (IHE) mammography handbook is useful for those who prepare request for proposal (RFP) documents for digital mammography ([http://www.ihe.net/Resources/upload/IHE\\_Mammo\\_Handbook\\_rev1.pdf](http://www.ihe.net/Resources/upload/IHE_Mammo_Handbook_rev1.pdf)). To help the reader to understand the concepts and language of the IHE standard, selected sections of the IHE manuals pertinent to digital mammography have been abstracted; a link to the extracted material is provided in Annex III. By specifying how systems interact, the standard attempts to ensure that images from different brands of mammography machines will be displayed in a consistent manner on all brands of review workstations.

At the very minimum, an RFP should include the requirements shown in the box below:

#### **For the Image Acquisition Workstation**

The IHE mammography image integration profile is supported as an acquisition modality actor.

The IHE scheduled workflow profile (SWF) integration profile is supported as an acquisition modality actor.

The IHE portable data for imaging (PDI) integration profile is supported as a media creator actor.

#### **For the Image Display Workstation**

The IHE mammography image integration profile is supported as a display modality actor.

The IHE mammography image integration profile is supported as a print composer actor.

The IHE PDI integration profile is supported as a media creator actor.

There is likely to be a supply of used systems available over the next few years. The donation and receipt of used equipment is problematic and should be carefully considered [18]. Such equipment must be examined very carefully to determine whether its performance can and does meet current standards. For example, the detectors on some older models may not be large enough to accommodate the full range of breast sizes. The cost of bringing a used system into compliance must be carefully considered.

A wide range of costs are associated with the different technologies available for digital mammography. Because of differences in design, there are substantial differences in imaging performance in terms of dose and image quality. Purchasers of digital mammography systems are strongly advised that the use of equipment having marginal performance can compromise clinical outcome and result in higher overall cost due to reduced throughput and the potential for medicolegal issues.

### **2.2.1. Analysis of requirements**

In the light of the current status of digital mammography and the factors to be considered in choosing a digital mammography system, the following points of analysis should be considered:

- Decide if the system is to be used for screening mammography, diagnostic mammography or both. If the system is to be used for diagnostic imaging, it should normally be equipped with a small focal spot and magnification capability. This is not necessary for machines used exclusively for screening mammography.
- Ensure that the system is capable of supporting the required imaging volume. Screening facilities frequently have a much higher daily workload (e.g. up to 100 women per day) than do diagnostic units. This imposes requirements on the heat loading capability of the X ray tube, the minimum time between exposures required by the image receptor and the throughput of a photostimulable phosphor (PSP) plate reader (if one is used).
- Establish whether there will be a requirement to integrate stereotactic biopsy systems with the digital X ray system, as could be the case for some diagnostic facilities.

- Choose a system that can be adequately serviced and supported at that location. Acceptable performance of a digital system can only be realized consistently if the system is maintained properly and software is kept current by timely updates.
- Consider whether the image interpretation will be performed on a vendor specific display workstation or whether a PACS workstation with suitable mammographic software and hardware provides an adequate solution. Ideally, all systems should meet the specifications set out in the IHE mammography display profile [19].
- Ensure compatibility of any new digital mammography system with existing digital mammography systems and information systems (e.g. PACS, radiology information system (RIS), hospital information system (HIS)). Worklist capability at the acquisition workstation generated by the RIS/PACS is a key feature of this compatibility. Adequate archival storage must be available for the large datasets encountered in mammography (see Table 1).
- Consider how images may be made available to other facilities and referring physicians. This may require printing capabilities (see next item in list) or the ability to produce DVDs.
- Decide whether the images will be reported from a monitor (soft copy) or from printed film. To fully realize the benefits of digital mammography in terms of flexibility of display and to avoid the disadvantages of using film, soft copy reporting is preferable. However, there may well be circumstances where film printing is justified. If film printing is undertaken, the printer should have specifications appropriate to mammographic image printing (e.g. the pixel size on the printer must closely match that of the acquired images). The size of the film available with the printer should be compatible with the film viewing device and should result in nearly life-size images, with the chest wall located at the edge of the film.
- It is important to ensure that means are available to view previous examinations. This is a challenging problem, as it always involves compromise. One possibility is to include a film viewer in the reading room. If this is done, it is essential that the area be designed so that light from the viewbox causes minimal interference with viewing of digital images on the monitor. Some facilities may instead choose to digitize prior images so that they can be viewed on the monitor alongside the current digital images [20, 21].

### 2.2.2. Purchase specifications

The following should be considered when purchasing a digital mammography system:

- Ensure that all digital systems as well as displays and printers meet the relevant Digital Imaging and Communications in Medicine (DICOM) standards [22] as well as the IHE mammography display profile.
- Ensure that the digital mammography system has in place a mechanism that provides automated transfer of the image acquisition parameters (kilovolts (kV), milliampere-seconds (mAs), target and filter material, breast thickness, compression force) for each exposure into the DICOM header. It should be noted that although this is a very important feature, at the time of writing not all digital mammography systems have this capability. Separate interfaces [23] to accomplish this transfer automatically are available commercially.
- In addition, it is useful to include in the DICOM header information such as the estimated mean glandular dose (MGD) and entrance air kerma.

TABLE 1. DAILY DATA VOLUMES FROM UNCOMPRESSED DIGITAL MAMMOGRAPHY IMAGES (MEGABYTES)<sup>a</sup>

Examinations per day	Images per day	Image field (cm × cm)	Detector element (del) size (μm)			
			50	70	85	100
20	80	18 × 24	2 765	1 411	957	691
20	80	24 × 30	4 608	2 351	1 594	1 152
100	400	18 × 24	13 824	7 053	4 783	3 456
100	400	24 × 30	23 040	11 755	7 972	5 760

<sup>a</sup> It is assumed that 2 bytes are required per pixel.

- Ensure that the system has the capability to export unprocessed (DICOM ‘for processing’) images for QC purposes. If images have been compressed, software should be provided to allow restoration of these images to their full size without loss of information.
- Ensure that the system has the capability to import DICOM test images for QC of the soft copy display and/or printer.
- Make sure that the acquisition workstation has at least rudimentary image analysis tools available (e.g. mean, standard deviation, a region of interest (ROI) tool with adjustable size and shape).
- Consider the required communication speed (bandwidth) of the network used to transmit images from the digital mammography system to the PACS archive for storage. The number of images produced per hour and the individual image size will determine the communication speed required.
- Consider also the speed of image retrieval from the archive to the reporting workstations. This will be dictated by the image size and how quickly the radiologist requires the images at the workstation (e.g. can the images be transmitted overnight?). For communication between one facility and another, consider the slowest link in the communication chain, as this will dictate the transfer speed.

It must be recognized that over the past several years the technology and software for digital mammography have evolved considerably. Therefore, great care should be taken before purchasing a digital mammography system (new or used), to ensure that the system provides all the features discussed above.

### 2.3. DESCRIPTION OF DIGITAL MAMMOGRAPHY TECHNOLOGIES

A summary of the digital systems commercially available at the time of writing is given in Table 2.

#### 2.3.1. X ray source

Normally, the limiting factor governing spatial resolution in digital mammography is the detector. The X ray source should have a focal spot that does not significantly degrade spatial resolution at the top surface of the breast beyond that determined by the detector. The heat loading capability of the source should be sufficient to support the required maximum daily throughput of the facility. This may be greater than that using screen film mammography and may vary depending on whether diagnostic or screening mammography is being carried out. Typically, scanning systems impose a higher heat loading on the X ray tube than do the ‘snapshot’ systems discussed in Section 2.3.2.

#### 2.3.2. Imaging geometry

There are two major acquisition geometries, ‘snapshot’ and scanning systems. Snapshot systems acquire the image using a full area detector (i.e. with dimensions equal to those of the projected imaged area) and a single, brief X ray exposure. Because of the single acquisition, no stitching operation is necessary, thereby eliminating the possibility of registration artefacts. Additionally, the rate at which multiple images may be produced can be important for screening mammography where the volume of examinations is high, and may be important for future procedures that involve a rapid series of images.

Scanning systems use detectors that move across the breast in synchrony with one or more slit- or slot-shaped X ray beams. While these systems typically take many seconds to acquire an image, they do not require an anti-scatter grid, and this generally provides a dose reduction advantage compared with the snapshot systems. Motion artefact with these systems is not evident as a blur, because any given area is imaged with a very short exposure time and high X ray intensity. The need to scan the detector results in higher heat loading on the tube than for a snapshot image.

Other key geometric considerations are the detector size(s), thickness of the detector assembly and ability to image close to the chest wall. For smaller detectors, it may frequently be necessary to make several exposures to cover a single large breast. If exposed regions overlap, the breast dose will increase. In addition, the radiologist will be faced with manipulating and interpreting more images. If the detector assembly is too large or too thick, it may be more difficult to position the breast and obtain optimal imaging of some women. It is always important to ensure

TABLE 2. CHARACTERISTICS OF DIGITAL MAMMOGRAPHY SYSTEMS

Manufacturer	Model	Detector element (del) size ( $\mu\text{m}$ )	Detector dimensions ( $\text{cm} \times \text{cm}$ )	Image matrix size	Bit depth	Technology	Grid
<i>Flat panel detectors</i>							
GE	Senographe 2000 D	100	$19 \times 23$	$1914 \times 2294$	14	CsI on a-Si	Y
GE	Senographe DS	100	$19 \times 23$	$1914 \times 2294$	14	CsI on a-Si	Y
GE	Senographe Essential	100	$24 \times 31$	$2394 \times 3062$	14	CsI on a-Si	Y
Lorad/Hologic	Selenia	70	$24 \times 29$	$3328 \times 4096$	14	a-Se	Y
Siemens	Mammomat Novation	70	$24 \times 29$	$3328 \times 4084$	14	a-Se	Y
Siemens	Inspiration	85	$24 \times 30$	$2812 \times 3580$	13	a-Se	Y
Planmed Oy	Nuance	85	$17 \times 24$ $24 \times 30$	$2016 \times 2816$ $2816 \times 3584$	13	a-Se	Y
IMS	Giotto	85	$24 \times 30$	$2816 \times 3584$	13	a-Se	Y
Fujifilm	AMULET	50	$18 \times 24$ $24 \times 30$	$3540 \times 4740$ $4728 \times 5928$	14	a-Se with DOS technology	Y
<i>Scanning systems</i>							
Sectra	MDM L30	50	$24 \times 26$	$4915 \times 5355$	16	Si quantum counter	N
XCounter		50	$24 \times 30$	$4800 \times 6000$	16	Pressurized gas	N
<i>PSP systems</i>							
Fuji	Profect (all models)	50	$18 \times 24$ $24 \times 30$	$3540 \times 4740$ $4728 \times 5928$	12	BaF(BrI):Eu	Y
Carestream	DirectView CR950/975	50	$18 \times 23$ $23 \times 29$	$3584 \times 4784$ $4800 \times 6000$	12	BaFBr:Eu	Y
Agfa <sup>a</sup>	DX-M or CR 85/35X with MM3.0R	50	$18 \times 24$ $24 \times 30$	$3510 \times 4644$ $4710 \times 5844$	12	BaSrFBrI:Eu	Y
Konica	Pureview	43.8	$35 \times 43$	$\sim 8000 \times 9800$	12	BaFI:Eu	Y
Konica <sup>b</sup>	Regius 190	43.8	$18 \times 24$ $24 \times 30$	$\sim 4360 \times 5726$ $\sim 5760 \times 7096$	12	BaFI:Eu	Y
Philips <sup>c</sup>	Cosima X Eleva	50	$18 \times 24$ $24 \times 30$	$3540 \times 4740$ $4728 \times 5928$	12	BaF(BrI):Eu	Y

<sup>a</sup> DX-M can also use an HM5.0 CsBr:Eu needle phosphor plate.

<sup>b</sup> The Konica Regius 190 can use any of the three possible plate types. Types RP-6M and RP-7M are based on BaFI:Eu, whereas type CP-1M uses a CsBr needle phosphor.

<sup>c</sup> The Philips CR unit uses the same plates as the Fuji CR unit.

that the detector has minimal 'dead area' on the edge proximal to the patient's chest wall, so that as little tissue as possible is excluded from the mammogram.

### 2.3.3. Types of digital mammography system

There are two generic types of detector system for digital mammography. One incorporates a photostimulable phosphor plate held in a cassette during exposure. It is frequently referred to as computed radiography (CR)

technology. Systems containing other types of detector, normally integrated into the system rather than enclosed in separate cassettes, are often referred to as digital radiography (DR, or DX) systems.

### 2.3.3.1. Type 1: Photostimulable phosphor system (CR)

This system employs an X ray photostimulable phosphor material, typically BaFBr [24, 25]. It is similar in operation to the detectors that have been used for several years for CR in general radiography. In response to absorption of X rays, energetic photoelectrons are liberated in the crystal. These lose some of their energy by interacting with and exciting loosely bound electrons in the crystal lattice. Some of these electronic charges become ‘trapped’ in the crystalline material of the phosphor, where they remain stable for some time. The number of trapped electrons is proportional to the amount of radiation incident on the phosphor. After exposure, the phosphor plate is placed in a reading device where it is scanned with a fine laser beam (Fig. 1). The light from the laser ‘discharges’ the traps, causing the electrons to return to their ground state. In doing so, the electrons make transitions between energy states created by specific dopant elements incorporated into the crystal lattice. This causes energy to be released in the form of light photons whose wavelength is determined by the choice of dopant. Typically, this wavelength is different from that of the stimulating laser light. This emitted light is collected from the top and/or bottom surfaces of the plate and measured with a photoelectronic detector. The resulting signal is digitized to form the image [26, 27]. In CR systems, a non-linear transformation (normally logarithmic) is applied to the signal during digitization.

In the CR systems used for mammography, the X ray sensitive phosphor plates are held in cassettes that must be inserted in the X ray unit for exposure and then moved to a separate image reading unit. This represents both a strength and a weakness. On the one hand, it allows digital mammography to be performed in an essentially conventional X ray mammography unit, and multiple units can share a single reader, which reduces the capital costs significantly. At the same time, the need to handle cassettes is labour intensive and generally reduces the productivity of the radiographer. Manual data entry is susceptible to errors in labelling of the images. Dust artefacts are also more likely to occur in a cassette based system, and most CR systems do not provide a means for flat fielding to correct for non-uniformity of plate sensitivity or variations in the X ray field. CR readers are usually designed such that the image sampling can be switched between a high resolution mode for mammography and a lower resolution mode for general radiographic applications.

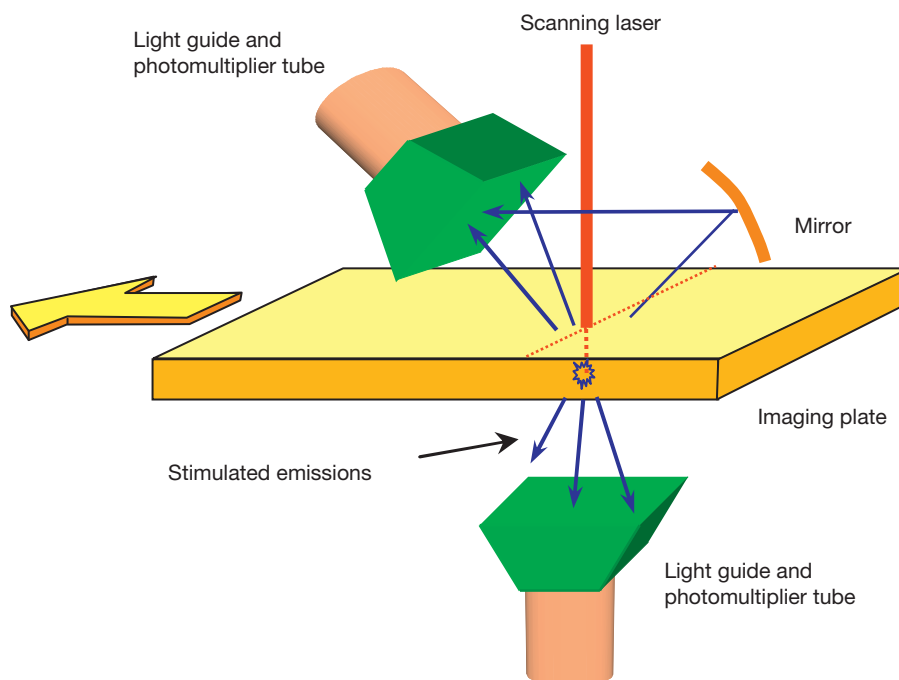


FIG. 1. Schematic diagram of a dual sided reading CR unit. Some CR units may read the stored signal only from one side of the phosphor plate.

### 2.3.3.2. Type 2: Flat plate CsI with photodiode array

In these systems, a CsI(Tl) phosphor layer is deposited directly onto a large area matrix of photodiodes formed on a flat plate amorphous silicon (a-Si, or  $\alpha$ -Si) substrate (Fig. 2). Each light sensitive diode element is connected by a thin film transistor (TFT) switch to a series of control lines and data lines such that the charge produced on the diode in response to light emission from the phosphor is read out and can be digitized. In such systems, the initial signal forming the DICOM ‘for processing’ image is linear with the amount of energy absorbed by the phosphor (subsequent non-linear transformations are usually performed on the images; see Section 2.3.7).

### 2.3.3.3. Type 3: Flat plate amorphous selenium with electrode array

This system does not employ a phosphor. Instead, X rays are absorbed in a layer of amorphous selenium (a-Se, or  $\alpha$ -Se), which is deposited on an array of electrodes formed on a large area a-Si substrate (Fig. 3). An electric field is imposed across the plate to collect the electron-hole pairs liberated upon X ray absorption. The charges drift to the electrode pads and are collected there. During the readout procedure, TFT switches on each detector element (del) are sequentially activated, one row at a time via control lines, and the charge is collected along data lines (running between columns of dels) connecting each del to readout electronics similar to those in a Type 2 system [28]. An extension of this a-Se detector technology is a recent development using optical switching technology rather than TFT to read the image signal.

### 2.3.3.4. Type 4: Slot scanning photon counting detector

In this system, the energy of absorbed X rays is converted to charge in a set of many single-line detectors based on depleted crystalline silicon or on high pressure gas ionization strips. The charge arising from the absorption of an individual X ray photon is collected to form a pulse, which is counted to register that X ray. Individual linear detector arrays are arranged adjacently or spaced apart, and the assembly is scanned in a direction orthogonal to the detector lines to acquire the image (Fig. 4).

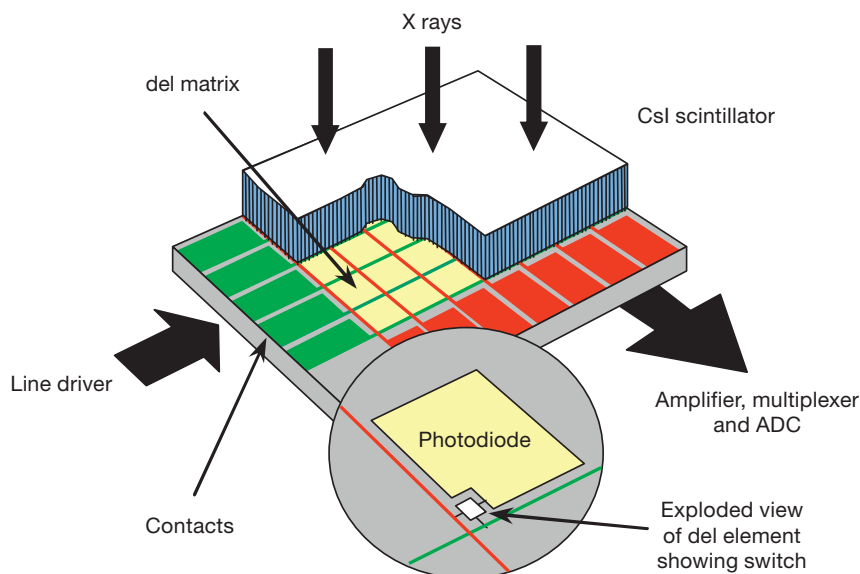


FIG. 2. Indirect flat plate detector based on a CsI scintillator with amorphous silicon (a-Si) switching diodes or thin film transistor readout. The X rays absorbed in the CsI layer are first converted to light, which is then converted to a charge signal by the photodiodes and ultimately digitized. ADC — analogue to digital converter.

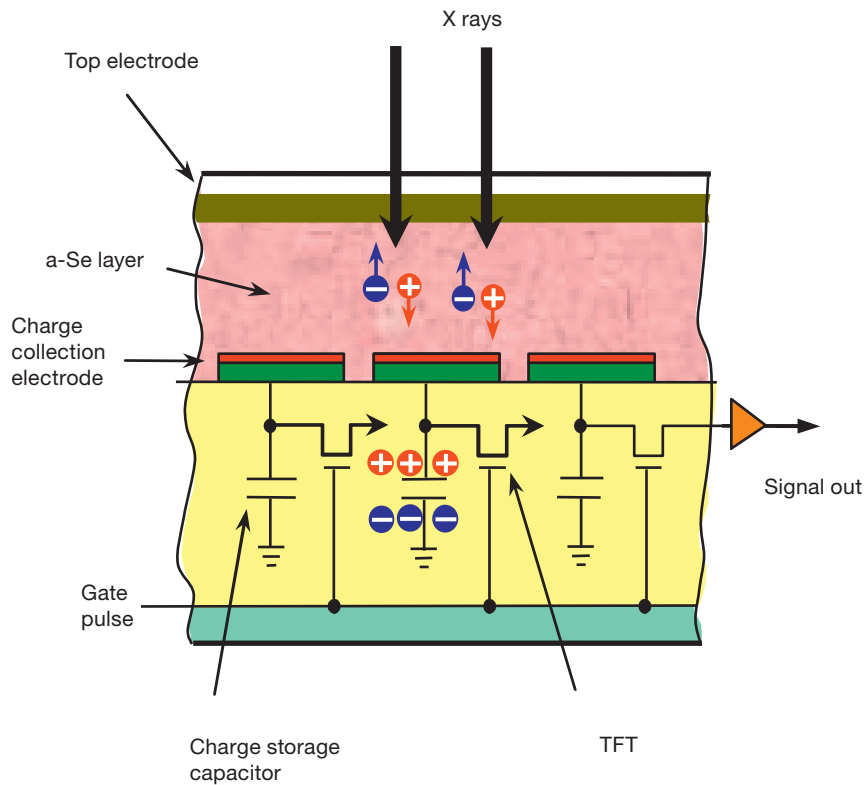


FIG. 3. Direct flat plate detector utilizing amorphous selenium (a-Se) as the X ray absorber. When a voltage is applied across the a-Se layer, the charges produced are collected by the electrodes and digitized.

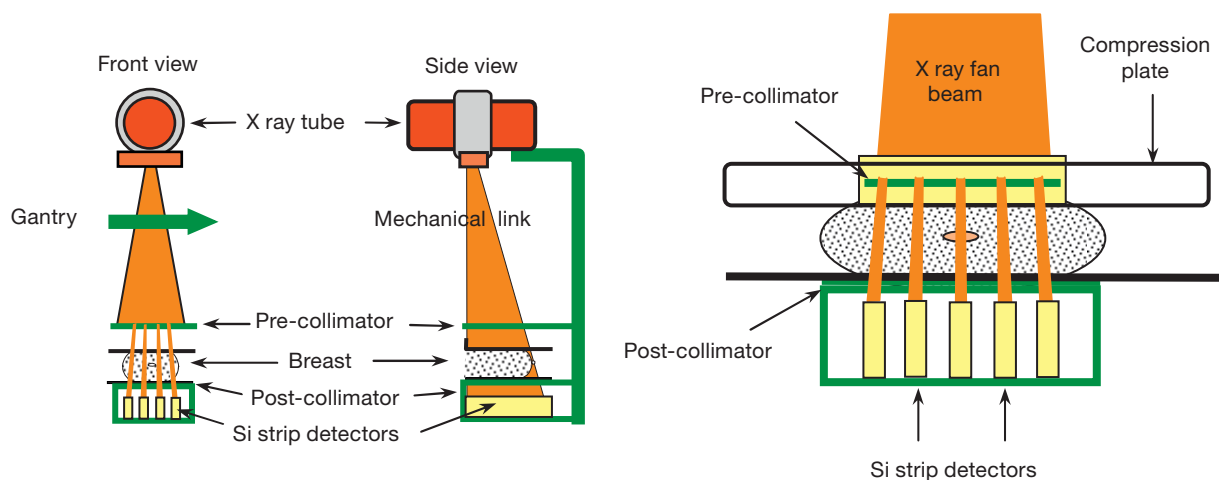


FIG. 4. Sectra MicroDose multi-slit scanning unit. Narrow slit collimators define fan beams that image part of the breast. Post-collimators further reduce the impact of scatter. The multi-slit device moves across the breast, ensuring that all breast tissue is imaged. The crystal-Si detector elements are also unique in that they collect and record the energy from individual X ray quanta.

### 2.3.3.5. General comments about the equipment types

One important consideration when purchasing equipment is the rate at which images can be acquired. Some systems may require an extensive detector preparation cycle between images. The required interval is likely to change as technology evolves, so it is important, especially in high volume facilities, to establish from the vendor what the inter-image time is.

System performance, in terms of spatial resolution, starts with the effective size of the del and the spacing between del, or 'pitch'. The effective size or aperture can be smaller than the pitch if part of the del is insensitive

to X rays. In the case of flat panel detectors, this is the area occupied by the switches and the readout lines, resulting in a reduced 'fill factor' and directly influencing the efficiency of use of the incoming X rays. A smaller aperture causes the image to be sharper but can cause a reduction in detector sensitivity and can result in information being missed. When the aperture is smaller than the pitch, undersampling occurs and a phenomenon called 'signal aliasing' is more likely to be observed. Aliasing causes information to be incorrectly rendered in the image, both suppressing some spatial frequencies and giving the impression of signal information that does not actually exist. Noise aliasing is a similar process that causes an increase in the apparent image noise. In most current digital mammography systems, signal aliasing is not clinically apparent, while noise aliasing may be measurable.

The effective aperture can also be larger than the pitch. This can be due to blurring by spread of light in a CsI phosphor, or in the case of CR systems, scattering of the readout laser light in the screen. In this case the image may be less sharp; however, one possible benefit of this blurring is the reduction of aliasing. This phenomenon may be important in considering differences in performance between direct conversion and phosphor based systems. In the former the effective del aperture is more likely to be close to the pitch, giving rise to an inherently sharper image with more aliasing, whereas in the latter the larger effective aperture caused by slight blurring may result in less aliasing, so there may be a trade-off between sharpness and noise.

#### **2.3.4. Data representation and exposure index values**

Most captive detector digital mammography units provide data in a linear format. The 'for processing' images for these devices are normally flat field corrected to remove stationary effects such as detector gain non-uniformities (individual dels or lines of dels) and beam non-uniformities (filter, heel artefact). The linear values may or may not have a zero offset. Some manufacturers add a constant offset of either 50 or 200 to the data values, which are normally 12 bits (4096), 13 bits (8129) or 14 bits (16 384).

Typically, CR systems compress the signal during image acquisition by applying a logarithmic (or logarithmic like) transformation. Each vendor has a system for defining the relationship between detector exposure and signal in their 'for processing' images. These are variously known as S# value and L# value, exposure index (EI), scan average level (SAL) or log median exposure level (lgM). Annex IV discusses these parameters and other DICOM tags used in digital mammography for the purposes of exposure and dose estimation.

The 'for presentation' images normally cannot be used to accurately estimate local exposure to the detector because most vendors apply a non-reversible, non-stationary transformation of the data, which may include locally adaptive frequency enhancement and peripheral equalization (see Section 2.3.7).

#### **2.3.5. Automatic exposure control on digital mammography systems**

The design of the automatic exposure control (AEC) in digital mammography units differs from that in analogue mammography X ray units. First, the dose to the detector no longer must be constrained to the relatively narrow range suitable for screen film. Thus, doses can be lower or higher, and can be widely varied as required according to the breast thickness. This extra freedom also extends to the choice of technique factors such as kV, and target and filter material. Generally, digital systems will select X ray spectra that are more penetrating than would be the case with screen film systems. This is possible because the loss of subject contrast may be compensated for by enhancement of displayed contrast during image viewing as well as by additional computer image processing. Moreover, greater detector dose can be used, if desired, leading to better image noise characteristics.

It is important to understand that once the dose is increased beyond a noise limited image, the image provides very little subjective indication that the dose is excessive, and 'dose creep' may well result in long term increases beyond optimal levels.

Most DX systems use a measurement of the compressed breast thickness (produced by a sensor in the compression mechanism) to choose some of the technique factors (e.g. kV, target, filter) to be employed in the exposure. Furthermore, some DX units use a trial exposure to determine the transmission through the breast. The image from this trial exposure may or may not be incorporated into the resultant image formation and/or included in the specified post-exposure mAs. In a further refinement of this approach to determining the exposure factors, some DX systems utilize sophisticated AECs that identify the area of greatest attenuation within a defined area of the detector during this trial exposure. This is then used to select an appropriate kV and filtration, and sufficient exposure to achieve a predetermined pixel value, contrast or detector dose set by the manufacturer. As a result, the



dose received by inhomogeneous real breasts and the image quality may not be easily predicted from measurements of such physical quantities as the SDNR and MGD obtained using uniform blocks of polymethyl methacrylate (PMMA).

### 2.3.6. Standard image formats

To facilitate intercompatibility of digital images, the DICOM Committee has created a standard for digital medical images. This standard has specific provisions, known as DICOM MG, for digital mammograms. DICOM conforming images contain a header that provides general information describing the characteristics of each image, followed by the image data. Some CR products use the CR DICOM header, which may or may not include all the information required for proper workflow on IHE compliant mammographic workstations.

Two types of DICOM image format have been defined for mammography (Fig. 5). The DICOM ‘for processing’ image is the image initially provided by the detector. Some basic corrections for detector non-uniformity and possibly detector blurring have been applied to these images. These images can then be processed to create DICOM ‘for presentation’ images, which are suitable for display on a monitor or for printing.

### 2.3.7. Image processing

Image processing is an important feature of all digital mammography systems, and processing operations may be applied at several stages of image formation (see Fig. 5).

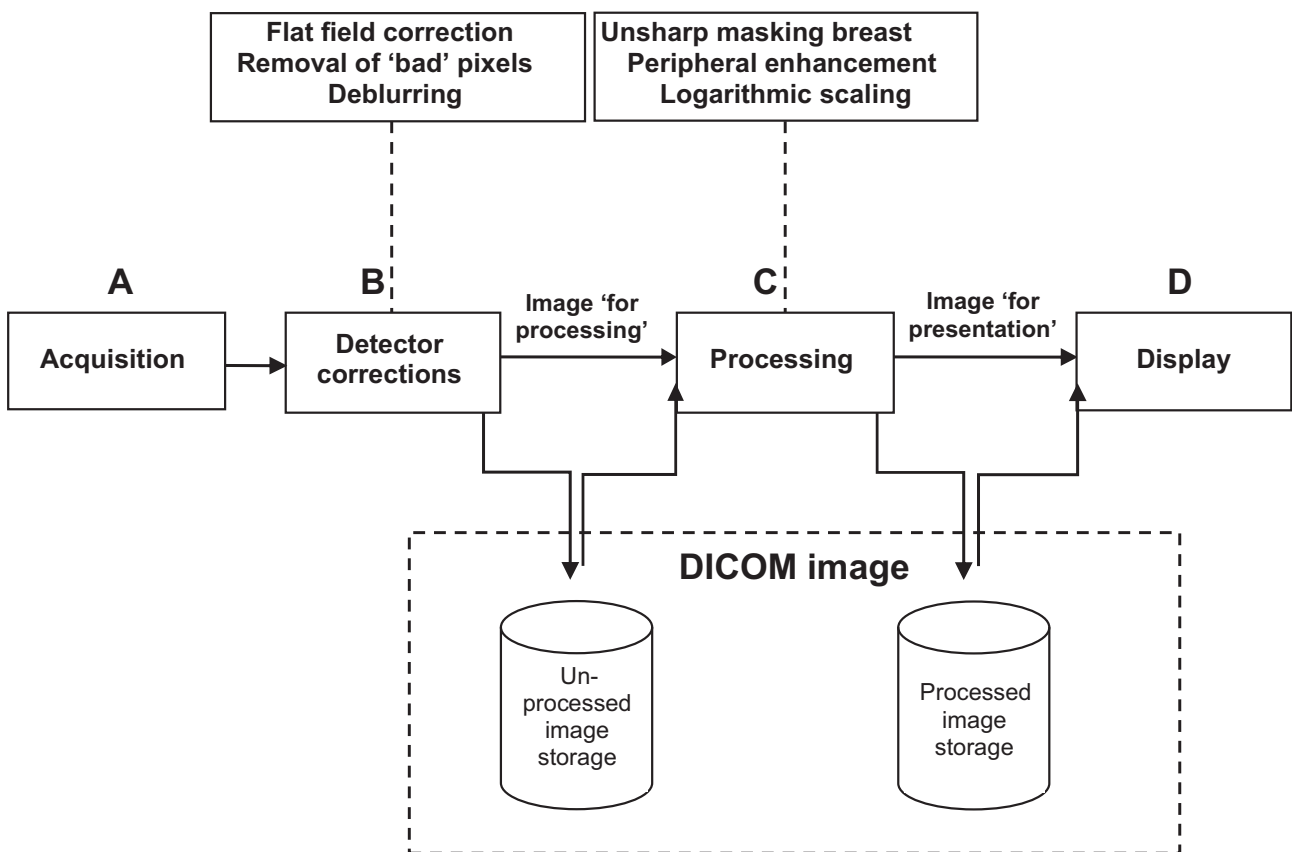


FIG. 5. Concept of the DICOM ‘for processing’ and ‘for presentation’ formats.

### 2.3.7.1. DICOM 'for processing' image

The initial operations that take place in creating the 'for processing' image generally include a flat field or gain correction, where spatial non-uniformity in the detector sensitivity can be corrected by imaging a uniformly attenuating object and creating a gain map that can be used to correct all subsequently acquired images. For flat panel systems and scanning systems, this transformation also corrects for non-uniformities in the X ray field (e.g. the heel effect). For current CR systems, the correction is applied only to the laser readout system and not to the individual phosphor plates or to the X ray field. Therefore, residual artefacts may occasionally be observed. The presence of the uncorrected heel effect in digital images can affect the results of image noise measurements in QC [29]. Other corrections that can occur at this stage include:

- Partial correction for detector blurring through image processing by deconvolving the blurring function of the detector. This procedure can be very effective, but if overdone it will also enhance image noise. It is therefore important that the inherent detector resolution be adequate and that the image noise level be acceptable. The latter is accomplished in part through careful design of low noise detectors and also through appropriate design and use of AEC and/or automatic technique control.
- Removal of 'bad' pixels. If a single detector element is defective, its signal can be replaced by some weighted combination of signals from adjacent dels. This is acceptable if the defective dels are isolated and few in number but is of greater concern if signals from entire patches or lines of the detector are absent or incorrect. Manufacturers specify the number and type of such defects that are acceptable.

### 2.3.7.2. DICOM 'for presentation' image

Additional processing is generally carried out to adapt the image for display and interpretation by the radiologist. Processing operations differ among manufacturers, but may include:

- Peripheral compensation to flatten the signal level at the edge of the breast. This essentially suppresses the effect of thickness reduction near the edge and reduces the dynamic range of image signal that the display system must accommodate, allowing higher contrast settings to be used in image display. When such software is used, it is important that it does not unduly distort the contour of the breast.
- Inversion of the greyscale (black represents high X ray transmission) and non-linear transformation (logarithm, square root, etc.) of the image.
- Background suppression and masking.
- Other image enhancements, for example, histogram equalization. These are also employed to attempt to optimize contrast throughout the image of the breast and to best utilize the limited dynamic range of the display system.

Image enhancement techniques are proprietary to each vendor and frequently can be applied (or not) at the user's discretion. The best way to evaluate these algorithms is to observe the rendition of key structures (spiculations, microcalcifications, and margins of benign and malignant lesions), with and without the enhancement activated, in a series of sample cases including images of both dense and fatty breasts. It is also important to know whether the results of image processing are only available locally at the viewing workstation or are preserved so that the enhanced image can be viewed elsewhere.

## 2.3.8. Display system

The display system plays a major role in influencing overall performance of the digital mammography unit in terms of both the ease of image interpretation and the image quality presented to the radiologist [30]. While some radiologists use hard copy systems (laser printed films) for interpretation, in the long term the benefits and cost effectiveness of digital mammography will only be fully realized if soft copy display is used.

### 2.3.8.1. *Soft copy display*

Flat panel liquid crystal displays (LCDs) are more compact and produce far less heat than do conventional cathode ray tubes (CRTs); however, they have a more limited viewing angle than do CRTs. The display must have a suitable number of high quality monitors (normally two 5 megapixel (MP) monitors are recommended) [31] to allow viewing of as much of the mammogram as possible at the required resolution level. A 5 MP monitor is capable of displaying only a single mammogram with 100  $\mu\text{m}$  delts at full resolution. If multiple images or images with smaller delts are displayed simultaneously, as is normally the case in mammography, they will have to be viewed at a reduced resolution and the images panned and zoomed to inspect structures of interest at full resolution.

The monitor on the acquisition workstation is often overlooked. Generally, a single 3 MP monitor is recommended. The quality must be high enough to allow the radiographer to assess the adequacy of the acquired image without having to walk to the radiologist workstation, which may be located a considerable distance away. If needle localizations are to be performed on the system, the image quality of the acquisition monitor and associated image manipulation operations must be adequate to provide the required image quality.

Display software varies greatly between system types and is a major factor determining user satisfaction with the digital mammography system, where there is a natural tension between the intellectual property interests of manufacturers and the need for seamless integration between different systems. Some important questions when considering monitor software include:

- How convenient are basic image manipulation operations, especially those that will be used with every image?
- What is the flexibility of image hanging protocols?
- Can the system handle images acquired on another vendor's system and display them at an acceptable level of quality?

These issues, particularly the last, have taken on greater significance as digital mammography has become more widely accepted, with facilities increasingly purchasing multiple acquisition units. To address these issues, the IHE [19] is developing guidelines and standards in the form of an integration profile for image display and intersystem compatibility for mammography. Future purchases should comply with this profile. Ongoing activity in this rapidly developing area can be seen at the IHE web site (<http://www.ihe.net>). In a screening situation, automatic fetching and display of prior images is highly desirable and increases efficiency. Image annotation (patient name, etc.) must be displayed such that it does not obscure the breast image.

### 2.3.8.2. *Hard copy display*

Hard copy display systems produce a printout of the digital image on radiographic transparent film. The radiographer usually adjusts the image brightness and contrast before printing out the image, making use of the controls provided at the acquisition workstation. Hard copy image displays have the disadvantage of not allowing the radiologist to control image processing operations during viewing. Therefore, it is strongly recommended that images be displayed for interpretation on a high quality soft copy device. Nevertheless, some facilities will choose to perform hard copy interpretation. In other cases, it may still be necessary to provide hard copy printed images to referring physicians. In this respect, several studies that compared the interpretation of digital mammograms using both hard and soft copy formats did not find significant differences in diagnostic accuracy [32, 33].

Both wet and dry laser imagers are available and produce breast images of similar quality. However, wet laser printers require chemical development, which is expensive, contributes to environmental pollution and requires careful QC to maintain consistent image quality. In addition, dry laser printers are preferred due to their stability. Most manufacturers have discontinued the production of wet laser printers.

The spatial sampling (resolution) of laser imagers should at least match the del size, thus the printing device should not be the limiting factor [19]. Using too low a resolution for printing results in pixelation; that is, printed film with large, coarse looking pixels and an image that is magnified to an unrealistic size. Using too high a resolution (pixels smaller than the mammography system can produce) increases the file size and slows printing of the image. Most of the commercially available printers for digital mammography have two pixel sizes, 100  $\mu\text{m}$  and 50  $\mu\text{m}$  or smaller (around 600 dots per inch) with a pixel bit depth of 12 or 14 bits.

Laser printers used in mammography can print one or more images on a sheet of transparent film (typically, 18 cm × 24 cm or 24 cm × 30 cm). These films are placed on a viewbox in a darkened room for viewing. A viewing system and reading room designed for film mammography are normally suitable for interpretation of hard copy digital mammograms.

Typically, transparent laser films do not have the same maximum optical density capability as mammography films. The dynamic range of laser films is from an optical density of approximately 0.20 up to around 3.2, depending on the film type. It is recommended that the laser imager characteristic curve be in conformity with the DICOM Grayscale Standard Display Function (GSDF).

QC procedures are based on printing out test patterns to check a series of parameters (density uniformity, greyscale response function, spatial resolution, geometrical distortion, image quality). Testing by the radiographer is described in Section 7.4 and testing by the physicist, in Section 8.11.

To test laser printers, it is recommended that test images in the same format as the digital mammograms be sent to the printer from the digital mammography system. In this way, the lookup table (LUT) and any other image processing that will be applied to clinical images will also be applied to the test images. In some cases, this is not possible and test images are sent from the printer itself. One must be aware that in some facilities, the same printer is used to print out images from different types of examination (e.g. breast, chest, bones, ultrasound, computed tomography (CT), magnetic resonance imaging (MRI)). Each examination type or modality has a defined LUT. Therefore, the correct LUT has to be selected before mammograms or the different test patterns are printed. The LUT has to be established in agreement with the mammography system manufacturer. For this reason, it is also important to check which LUT is automatically selected by the printer when the images are sent to print from the mammography system.

As with conventional radiographic films, laser films have to be stored in appropriate conditions before and after processing. As heat processed film is damaged by strong sunlight and high temperatures, exposing it to direct sunlight or leaving it on a viewing screen for a long time should be avoided.

## 3. ELEMENTS OF HIGH QUALITY MAMMOGRAPHY

### 3.1. PERSONNEL

There are many elements that contribute to the mammography process. The experience of personnel directly and indirectly involved in the process is crucial to the final outcome. In this respect it is essential that:

- The mammography images are acquired by experienced radiographers trained specifically in mammography.
- The images are interpreted by an appropriately trained and experienced radiologist.
- A medical physicist is available as a consultant to the facility. This may be on a full time or part time basis, according to the QA and radiation protection needs of the facility. (See Section 4.2.4 and appendix I of Ref. [34] for the specific requirements that a medical physicist should meet.)
- Well trained and experienced personnel service and maintain the mammography equipment.
- There is training on the specific mammographic unit, usually provided by the manufacturer as part of the purchase package.

Access to staff with training in information technology is highly desirable [35].

### 3.2. EQUIPMENT

#### 3.2.1. Digital mammography X ray unit

The digital mammography X ray unit must be specifically designed for mammography and include the following key features:

- An X ray tube with a nominal focal spot of 0.3 mm [36].
- A magnification stand and a second, smaller focal spot of nominal size ( $\leq 0.15$  mm), if magnification mammography is performed (this capability should be present on systems that are used for diagnostic mammography and not exclusively for screening).
- A beryllium exit window.
- Appropriate X ray target material and beam filter(s) for the X ray target. (For examples of target-filter combinations in use at the time of writing, see Table 3; the latest version of this table will be posted on the IAEA web site at: <http://humanhealth.iaea.org>.)
- A motorized compression device.
- Readout of compression thickness and force.
- AEC.
- Scatter rejection capability.
- A focus image distance greater than 60 cm.
- A detector with dimensions large enough to image most compressed breasts without the need for multiple exposures. Typically, this may mean larger than 24 cm  $\times$  26 cm, although there may be geographic variations in this requirement.
- An acquisition workstation with a monitor of sufficient resolution (3 MP is recommended) to allow the radiographer to ensure the quality of the mammography images. This is particularly important when hard copy images are used for clinical diagnoses.

The room in which the digital mammography unit is sited should have stable temperature and humidity for satisfactory operation. This will require appropriate air conditioning. More complete details on siting a mammography unit are provided in Appendix I.

TABLE 3. TYPICAL TARGET–FILTER COMBINATIONS FOR DIGITAL MAMMOGRAPHY

Target	Filter	Thickness, in mm
Mo	Mo	0.03 (GE, Planmed, Fujifilm, Siemens, Giotto)
Mo	Rh	0.025 (GE, Planmed, Fujifilm, Siemens, Giotto)
Rh	Rh	0.025 (GE)
W	Al	0.3 (Sectra D40), 0.43 (Sectra L30)
W	Rh	0.06 (Hologic, Planmed) 0.05 (Fujifilm, Siemens)
W	Ag	0.06 (Hologic) 0.075 (Planmed) 0.05 (Giotto)

### 3.2.2. Viewing conditions

In digital mammography, images are generally viewed on a display monitor. Unlike film, the electronic display can be adjusted; to facilitate the ability to detect subtle lesions or anatomic features, the display must be properly calibrated to match the performance of the human visual system. Therefore, it is helpful to have some understanding of psychophysical factors of vision [30, 37, 38]. The ability of a human viewer to detect a change in brightness,  $\Delta L$ , is dependent on the average brightness,  $L$ , of the area surrounding the image. The smallest visibly detectable change in brightness,  $\Delta L_{\min}$ , is referred to as the ‘just noticeable difference’, or jnd. The size of a jnd tends to be constant for luminance levels above 100 candelas per square metre ( $\text{cd}/\text{m}^2$ ); at lower luminance levels, the jnd increases rapidly (i.e. greater changes in brightness are required to evoke a visual response that there is a difference).

The approach to calibration of a display for digital imaging is to apply ‘perceptual linearization’ to the image data that are to be displayed, such that each step in the image signal sent to the display represents an equal increment of perceived contrast; that is, a constant number of jnds regardless of  $L$ . In other words, to achieve a linear range of perceived contrast steps, an unequal spacing of luminance levels is applied, depending on the luminance.

Perceptual linearization is based on the relationship between the jnd and  $L$ , and is the basis of the DICOM GSDF, which aims to enforce consistency of medical images across various display devices. While there is little concern for constant rendition of jnd with film display devices owing to the typical luminance levels involved, this is not the case with soft copy displays. In this case, contrast enhancement at low luminance levels can be achieved by GSDF calibration.

#### 3.2.2.1. Soft copy

Viewing conditions are very important for image interpretation from a monitor, especially given the low luminance of the monitors [24–26]. There should be no glare reflected from the screen, and the walls behind the screen should be about the same colour and intensity as a mid-grey background on the screen, with the background room illumination at around 30 lux (lx). There should be no distracting icons on the image screens, and radiologists should be positioned such that they are at the distance where they have maximum acuity.

#### 3.2.2.2. Hard copy

If hard copy digital mammograms and mammography films from prior studies are to be viewed, the following conditions should be met:

- A viewbox designed for mammography with a luminance of greater than  $3000 \text{ cd}/\text{m}^2$ ;
- Lamps in the viewbox matched for brightness and colour;

- The ability to mask edges of mammograms;
- Low ambient light in room.

As film designed for laser printing has a lower maximum optical density than does mammography film, lower viewbox luminance is required. Therefore, a viewbox with adjustable luminance should be available.

### **3.2.3. Quality assurance**

To ensure high quality, all of the above conditions must be met; however, in addition, it is essential that a comprehensive QA programme be in place. It is also imperative that time be allocated to allow the tests to be performed regularly, that results be carefully recorded and that corrective action be taken promptly when indicated. The basic elements of a QA programme for digital mammography are outlined in Section 4.

### **3.2.4. Regular maintenance**

In addition to regular QA, it is also essential that all digital mammographic units and associated equipment be subjected to regular maintenance consistent with best practice or with the recommendations of the manufacturer.





## 4. BASIC PRINCIPLES OF QUALITY ASSURANCE IN MAMMOGRAPHY

### 4.1. QUALITY ASSURANCE ACTIVITIES

A QA programme for diagnostic radiology, as defined by the World Health Organization (WHO) [39], is an organized effort by the staff operating a facility to ensure that the diagnostic images produced are of a sufficiently high quality to reliably provide adequate diagnostic information at the lowest possible cost and with the least possible exposure of the patient to radiation consistent with the requisite level of image quality. This requires the establishment of a comprehensive QA programme for medical diagnosis, whose technical aspects are under the supervision of an appropriate medical physicist.

QA programmes for medical exposures should include:

- (1) Measurements of the physical parameters of the radiation generators and imaging devices at the time of commissioning and periodically thereafter.
- (2) Verification of the appropriate physical and clinical factors used in patient diagnosis.
- (3) Written records of relevant procedures and results. This includes a manual that defines clear lines of responsibility, outlines the individual QC tests performed, gives the test frequencies, is useful for staff training, facilitates audit of a service and helps to keep a record of information within the facility.
- (4) Verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment.
- (5) Optimization of clinical protocols and equipment operation to achieve the QA aims as stated above.
- (6) Regular and independent quality audit reviews of the QA programme.

QA programmes are designed to ensure that the radiology equipment and staff procedures can yield the desired information. They include:

- (1) Administrative procedures or management actions designed to verify that:
  - The QC tests are performed properly and according to a planned timetable.
  - Results of these tests are evaluated promptly and accurately.
  - The necessary corrective measures are taken in response to these results.
  - Responsibility for QA actions is appropriately assigned.
  - Quality standards for equipment in the facility are established.
  - Adequate training is provided.
  - Appropriate equipment is selected for each examination, including the writing of adequate equipment specifications.
- (2) Acceptance and commissioning testing (Fig. 6):
  - Acceptance tests are those tests performed to verify that the vendor has met the purchase specifications. Preferably the tests will be performed independently by the medical physicist, but they are often performed by the company installing the equipment under the supervision of the medical physicist [40].
  - In addition, if a digital PSP image receptor is installed to be used with an older X ray system and gantry, the acceptance tests should be conducted on the entire system to assess whether the performance is acceptable.
  - Commissioning tests are those tests performed by the medical physicist at the time the equipment is put into service that are used to establish baseline levels of performance. These tests include all the tests that are required to be performed annually.
  - To a large extent, acceptance and commissioning tests overlap. This publication primarily describes tests that form a comprehensive, ongoing QC programme for mammography, but it is recognized that it is necessary to ensure that the equipment as delivered conforms to specified standards, and that appropriate initial baseline values are established and used to ensure proper maintenance for the quality of the equipment throughout its service life. During acceptance testing, a qualified person should check the electrical and mechanical safety of any new installation.

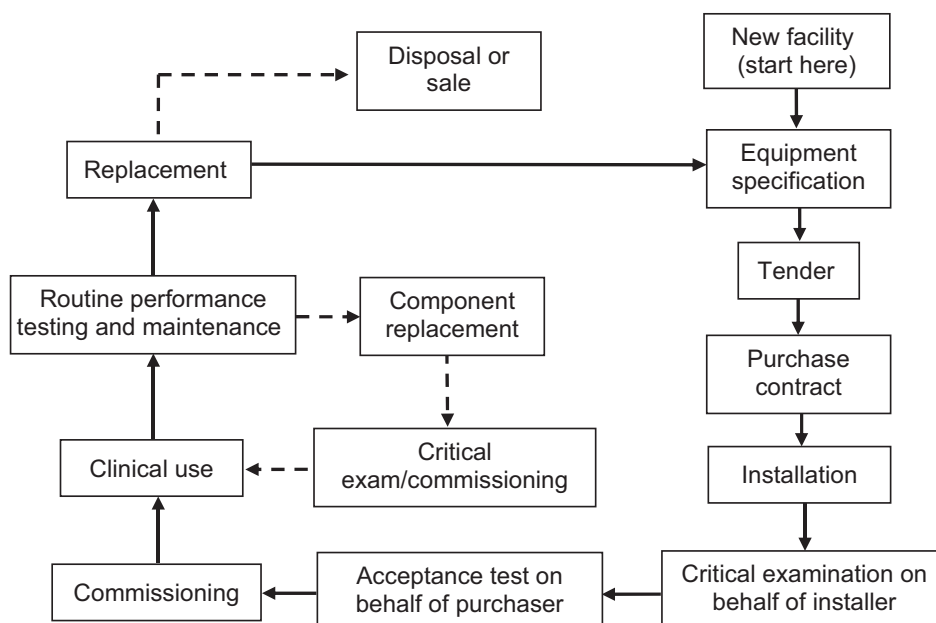


FIG. 6. Life cycle of a piece of equipment.

- (3) QC tests (also classified as either constancy or status tests by the International Electrotechnical Commission (IEC)), used to test the components of the radiological system and to verify that the equipment is operating satisfactorily.
- (4) Verification of proper calibration and operation of QC equipment and availability of all testing material.
- (5) Follow-up of any corrective actions proposed:
  - It is important that routine QC testing be properly performed in the mammography facility and that results be documented thoroughly and carefully. It is equally important that problems and potential problems be clearly documented and communicated to the facility in a timely manner, and that the medical physicist be assured that the receiving party has received and understood the supplied information. This is especially the case when safety concerns are raised.
  - The reporting structure in the facility should be understood by the medical physicist, who ideally will report problems to an individual who is empowered to call in service personnel and who, if necessary, can ensure that the equipment is not used until the problems are corrected. The medical physicist may be asked to explain the problems to service personnel and to share test results with them. The medical physicist and the representative from the facility should work together to ensure that the problems have been appropriately corrected.
- (6) Education and training of staff, including the radiologist, radiographer and medical physicist, each of whom must meet a minimum level of education and training.
- (7) Continuing education: All team members must undertake sufficient continuing education to ensure that they are up to date on new techniques and that they have refreshed their basic knowledge (e.g. radiation safety).
- (8) Experience: To ensure proficiency, on an annual basis the radiologist must read a sufficient number of cases, the radiographer must do a minimum number of cases, and the medical physicist must perform a sufficient number of acceptance and commissioning tests and carry out routine QC testing on a sufficient number of mammography units.

## 4.2. ROLES AND RESPONSIBILITIES

### 4.2.1. Licensee or registrant

The licensee or registrant has specific responsibilities to ensure that all regulatory and/or licensing requirements are met. Furthermore, the licensee or registrant must ensure that all radiologists, radiographers, medical physicists and other personnel who work at the facility are appropriately qualified and trained, and meet all continuing education and experience requirements.

It is the responsibility of the licensee or registrant to ensure that an effective QA programme is in place encompassing all aspects of the digital mammography imaging process. The specific tasks within that programme may be delegated to appropriate staff having more expertise to carry out those tasks. Notwithstanding such delegation, it remains the ultimate responsibility of the licensee or registrant to ensure that the elements of the QA programme are fulfilled and that adequate resources are utilized to implement the training and QA requirements of the programme, and especially to ensure that the problems identified by the QC procedures are corrected in a timely manner.

A lead interpreting physician, usually a mammography radiologist, should be identified by the mammography facility as having the specific responsibility of ensuring that all required QA activities are performed.

### 4.2.2. Radiologist

Although it is recognized that the radiologist will delegate many of the following tasks, he or she still has the responsibilities of:

- (1) Ensuring that the technical personnel and/or radiographers have adequate training and continuous education courses in mammography, including digital mammography;
- (2) Motivating, supervising and managing all aspects related to the QC programme in the area of digital mammography;
- (3) Providing an orientation programme for radiographers based on a carefully established procedures manual;
- (4) Selecting a single radiographer to be the primary QC radiographer to perform the prescribed QC tests and to oversee those tests that have been delegated to other individuals;
- (5) Ensuring the availability of the equipment and necessary materials for implementation of the QC tests;
- (6) Arranging staffing and scheduling so that adequate time is available to carry out the QC tests and to record and interpret the results;
- (7) Ensuring that a medical physicist is available to oversee the equipment related QC programme and to perform the medical physicist's tests;
- (8) Reviewing the radiographer's test results at least every three months, or more frequently if consistency has not yet been achieved, and reviewing the medical physicist's test results annually, or more frequently when needed;
- (9) Overseeing or designating an individual to oversee the radiation protection programme for employees, patients and other individuals in the surrounding area;
- (10) Ensuring that records concerning employee qualifications, mammography technique and procedures, infection control procedures, QC, safety, and protection are properly maintained and updated in the mammography QC procedures manual;
- (11) Continually providing feedback, both positive and negative, to the technical personnel and/or radiographers on the image quality and the QC procedures;
- (12) Verifying the percentage of rejected images performed by the radiographers and ensuring that appropriate corrective action is implemented if this percentage exceeds the specified limit.

#### **4.2.3. Radiographer (mammography technologist)**

The responsibilities of the radiographer include:

- (1) Ensuring that the QC tests are performed, interpreted and recorded appropriately. This is best achieved when one radiographer assumes overall responsibility for QC matters and is able to train others to assist in QC activities.
- (2) Recording imaging problems.
- (3) Undertaking additional continuous education courses in mammography, including digital mammography.

#### **4.2.4. Medical physicist**

The medical physicist is a person trained in medical physics and certified as a medical physicist according to the applicable programme in the Member State, if such a programme exists. Guidelines for the training of a medical physicist are given in appendix I of Ref. [34].

The minimum requirements for an individual delegated to carry out the annual medical physicist's QC tests described in this publication are:

- (1) Training in radiation safety;
- (2) Training in the physics of mammography, in particular digital mammography;
- (3) Practical training in testing digital mammography equipment.

The responsibilities of the medical physicist include:

- (1) Advising the facility on the safe and effective use of X rays for mammography. This includes image quality and radiation protection of the patient and personnel.
- (2) Advising the facility on equipment for digital mammography including the PACS. In some circumstances, the physicist may work as a liaison between the facility and a specialist in PACS.
- (3) Conducting tests to ensure the safety and proper performance of equipment used in mammography. These include acceptance, commissioning and routine QC tests.
- (4) Providing oversight and advice to the radiographer who carries out the radiographer's component of the QC programme.

## **5. CLINICAL CONSIDERATIONS FOR DIGITAL MAMMOGRAPHY**

### **5.1. INTRODUCTION**

The transition from film to digital mammography is progressing rapidly. The DMIST [3] demonstrated the improved accuracy of digital over film for asymptomatic women under 50 years of age, pre- and peri-menopausal women and those women having at least 50% dense fibroglandular breast tissue.

There are both advantages and limitations to digital mammography versus screen film mammography.

#### **5.1.1. Main clinical implications of digital mammography**

Digital mammography can provide high quality images as well as the ability to adjust the presentation so that clinical interpretation may be improved in dense breasts. The time required by the radiographer to conduct an examination is generally decreased, allowing greater patient throughput. There is, however, an increase in the time required for image interpretation, but this is becoming less significant. The elimination of film processing removes cost, hazard, film processing artefacts and losses due to films becoming stuck in the processor.

The images can be centrally stored on a PACS and accessed from many locations. An RIS in conjunction with an HIS in the facility can be used to schedule patients, upload demographic information to the acquisition workstation and track the patient workflow.

### **5.2. IMAGE ACQUISITION**

#### **5.2.1. Differences in patient positioning and radiographic exposure**

While positioning of the breast is similar to that in screen film mammography, with DX systems it may be more difficult for radiographers, especially initially, as the breast support is often thicker and may extend a few centimetres beyond the image sensor, and in some cases a large detector has to be used for smaller patients. Nonetheless, overall patient throughput can potentially increase with digital acquisition, allowing a facility to revise its workload and workflow.

Generally, there is the possibility of decreasing the dose to the breast, although this does not necessarily extend to CR systems. First, digital detectors have increased exposure latitude compared with screen film systems, which means that there are fewer repeat exposures. Second, the use of a higher energy beam technique and an increased DQE will lead to lower absorbed breast dose, but a balance must be maintained between reduction of dose and image quality because insufficient radiation dose to the image receptor results in noisy images, making identification of microcalcifications more difficult. An excessively high dose might not be noticed because it probably would not cause image quality problems, unlike with screen film, where the image overexposure would be obvious. Third, digital detectors have lower limiting spatial resolution compared with screen film, which may limit the ability of the radiologist to characterize the morphology of calcifications; however, increased DQE and image processing may compensate for this somewhat.

As with screen film mammography, it is possible for the quality obtained with digital mammography to be poor if the system is poorly designed, not set up properly, or not serviced or cleaned appropriately.

Individual exposure factors and other technical details can be more readily assessed and analysed for DX units via records of technique factors. It is more difficult to extend this to CR units, where special software and hardware (e.g. a Livingston CR Protocol Bridge ([www.livingstonproducts.com/mammo/CRBridge.html](http://www.livingstonproducts.com/mammo/CRBridge.html))) may be required.

### **5.2.2. Electronic versus geometric zoom**

Electronic zoom has replaced the magnifying lens. The number of pixels that can be displayed on a monitor is usually less than the number contained in a digital mammogram (and certainly less than that number when multiple images are displayed on the same monitor). Therefore, zooming is often necessary to see the image at full resolution with 1:1 pixel display and is always required for full resolution in systems with a pixel size of less than 100  $\mu\text{m}$ . When an image is displayed at other than 1:1 (or 2:1) resolution, the pixels are 'interpolated' into the display image matrix. This means that information may be smoothed across a number of pixels or may be dropped out completely. Often there is aliasing (see Section 2.3.3.5), but unless tested with an appropriate test pattern, this cannot be discerned. While the display zoom may eliminate the need for some spot magnification techniques, it does not replace the need for geometric magnification, which provides more detail and information with a higher signal to noise ratio (SNR) in most instances. Display zoom makes the appearance of the object larger (making it easier for the radiologist to see structures if they are resolved), but it does not improve the spatial resolution of the image. Using these and other tools such as coning and annotating increases the time required to review and report a digital mammogram.

## **5.3. IMAGE INTERPRETATION**

### **5.3.1. Soft copy reading**

A functional radiologist workstation requires three monitors: two 5 MP image monitors and one lower resolution monitor for RIS display. Workstation ergonomics (height of table, angle of monitors, etc.) is more important for digital mammography than for screen film mammography, and it is difficult to find generalized conditions to suit all radiologists. Room lighting is critical, and care must be taken to eliminate glare from other monitors and viewboxes, for example.

With soft copy reading, hanging protocols should be customized for different radiologists, allowing display of protocols for a full range of frequently used mammography options (e.g. routine 4 views, views plus 1, 2 or 3, etc., extra views, prosthesis views, large breast format, mastectomy format) so as to avoid the need to frequently 'drag and drop' images onto the monitor. Different clinical scenarios should be incorporated, including screening, diagnosis, recalls and short term follow-up. Automatic fetching and display of prior images would be needed for breast screening applications. It is preferable for all acquired images to be displayed to the reader automatically. This does not always happen with PACS workstations, so a special effort must be made to ensure that no images are missed. There should also be features to indicate when the displayed image is not completely demonstrated or is not being displayed at full resolution. Image annotation (patient name, etc.) must be displayed such that it does not obscure the breast image. Moreover, it should be noted that soft copy display protocols will not hang properly and will not be synchronized for zoom, etc., unless care is taken with image labelling/tagging.

Soft copy review of digital mammograms (i.e. on the monitor) has the advantage of window and level adjustment. This reduces the problems of over- and underexposed images seen with screen film mammography, and therefore fewer repeats are required for poorly exposed images. This can be particularly useful with the augmented breast. There are multiple tools to aid in the review and comparison of images, such as magnification, quadrant zoom, windowing, panning and marking areas of interest on the image. These tools should be set up on a dedicated radiologist keypad for easy use.

### **5.3.2. Reporting speed issues**

As working with soft copy requires time to display a case and to move through a display protocol, it takes longer to report digital mammograms, regardless of the radiologist's familiarity with the system or the speed of the network. There is also the additional opportunity for the radiologist to adjust the image display, such as window width and window level, and to zoom in on and roam across the image. All these operations necessitate additional reporting time.

### 5.3.3. Differences in image evaluation

Image interpretation in digital mammography is no different from that in screen film mammography, although it may take a little while to get used to the different ‘look’ of the digital images. The radiologist still looks for masses, asymmetric densities, architectural change and calcifications. However, digital mammography provides the opportunity for excellent mammography image quality with superior low contrast resolution at acceptable spatial resolution for easier detection of microcalcifications. This improves image interpretation and level of confidence. In addition, image processing software (specifically window and levelling) can be utilized to adjust for tissue ‘thickness’, allowing visualization of skin and subcutaneous tissues at the breast periphery and making image interpretation easier in the thinner parts of the breast. Historically, this part of the breast would have been regarded as ‘overexposed’. Image processing may also improve visualization of specific suspicious features such as calcifications and enhance subject contrast, thus also reducing the risk of missing abnormalities.

### 5.3.4. Use of computer aided detection

CAD algorithms are more efficiently applied to digital images than to films, as the time and expense of digitization is eliminated. Studies have shown that CAD can increase cancer detection by a single reader to a level comparable with that achieved by double reading of the same study by two different radiologists [41–43]. There is certainly the potential for CAD systems to be developed that not only will contribute to the detection of suspicious abnormalities in the mammogram, but will also indicate the probability of malignancy with a particular appearance. However, it is the radiologist who must ultimately decide if the areas marked are significant, as with current CAD systems more false positives than true lesions are marked.

## 5.4. IMAGE STORAGE AND COMMUNICATION

### 5.4.1. PACS and RIS considerations

Digital mammographic images stored in the PACS can be viewed at multiple locations within a facility, so that reporting, teaching and consultation can occur rapidly. One advantage of this is possible improved access to available radiologists and experts. Another is that it is difficult to lose images, either past or present, if they are stored in the PACS and are labelled correctly. Backup systems are required, as servers can fail.

There are some issues related to the storage of image data, specifically:

- The PACS should be able to interface with mammography systems from different vendors and with different modalities such as ultrasound and MRI. All such images should be able to be displayed equally well at each workstation.
- Some facilities are reluctant to store ‘for processing’ images due to the associated increased cost.
- It may be necessary to manually ‘push’ (i.e. transfer electronically) prior digital mammograms from PACS storage to the dedicated mammography review workstations. However, automatic ‘pulling’ of prior images should be possible, and it is important that facilities press their PACS vendors to provide the safest and most efficient workflow possible.
- Very large data sets may be generated in the future with breast tomosynthesis, and this will further challenge storage capacities.
- Problems can arise when sharing digital mammographic images on computer disks (CD, USB or DVD media) with another facility. CDs often include limited software capability to view and adjust images and may be reviewed by clinicians on ordinary computer monitors rather than on the high resolution 5 MP monitors used by radiologists. It is therefore important that when disks are written, the DICOM images are transferred correctly and the destination site has the facilities to upload the images to a diagnostic workstation. It is clear that at present not all digital mammography images are optimally displayed on all workstations. CD transfer of information may require data encryption or other methods to ensure patient record confidentiality.

To allow full utilization of the digital environment in mammography, especially in a breast screening environment, both a PACS and an integrated RIS or HIS are required. To maximize efficiency, this integration should preferably be seamless to facilitate well planned workflow customized to the facility's needs. There must be synchronization between the RIS and the workstation viewer software to ensure that the patient record and the images on-screen match. In the case of screening, this will then require that the RIS be customized to allow recording of multiple mammography reports, double-blind reading, a third radiologist or consensus opinion and a determination of the final 'outcome' of the reading. Other advantages of the fully integrated RIS include easy access to current patient clinical or referral information with little opportunity for information loss, and easy access to past reports and clinical information. Useful 'other' information (e.g. biopsy reports) can also be scanned into the RIS for increased accessibility.

The use of IHE compliant DICOM data in a PACS environment readily allows analysis of facility quality indicators, such as the time taken for procedures, the time to reporting and actual reporting times, and this has a positive effect on facility quality improvement.

## 5.5. TRAINING AND TRANSITION CONSIDERATIONS

### 5.5.1. Special training requirements

While image reading with digital mammography is not substantially different from that with screen film systems, the process for image review is. Therefore, radiologist training is required in the use of workstation tools and the RIS/PACS. Both radiologist and radiographer training in the use of vendor specific RIS/PACS features, 'new' digital workflow processes, display protocols and use of software tools is essential. It has been estimated that it might take up to 90 days for radiologists to adjust to the new reading environment, which may necessitate changes to patient scheduling during this period. Radiographers may initially find the transition to digital equipment challenging, especially if they are not accustomed to using computers. It is important that they adjust to working with the equipment features, rather than trying to work in the same way they did with screen film. In addition, they must be careful not to repeat images unnecessarily as a result of the increased speed and convenience of DX.

### 5.5.2. Planning for transition from screen film to digital mammography

The transition phase from screen film to digital mammography requires:

- (1) Extensive planning, particularly for changes relating to workflow and display protocols. In some cases, hospitals and radiology practices have engaged specialized teams for long periods prior to the introduction of digital imaging and the PACS, and have included external professionals such as an architect in the transition preparation team.
- (2) A close working arrangement with the suppliers of equipment, to ensure that where there are options in installation configuration the equipment is set up in the way that best suits the facility's needs.
- (3) Time for the radiologist to become familiar with the workstation, software tools, display protocols and RIS use.
- (4) Provisions for making comparisons between current digital mammograms and prior mammogram images. A strategy is needed to manage this, and three possibilities should be considered:
  - Scanning of prior non-digital images into the PACS and display of these images in routine protocols to minimize the use of light boxes for analogue film viewing. While this is the most desirable from a workflow and clinical perspective, the cost can be prohibitive. Apart from the cost of a high quality film scanner, labour costs for the scanning must be fully considered. It should be noted that the film digitization process demands high standards and that training is required for staff. In some cases, this scanning might be outsourced.
  - Scanning of comparison images on an as needed basis. This has the effect of extending the film scanning over a period of as long as 10 years. However, there is the advantage of the cost being spread out over that time, allowing the transition to be manageable.
  - Maintaining the analogue (screen film) images, which are mounted on a viewbox or multiviewer. This is slow and awkward, and viewboxes need to be mounted carefully to avoid reflected light falling on the



monitors. This option increases the report time for a study and has negative impacts on the radiologist's concentration and efficiency, with the possibility of reducing reporting accuracy.

- (5) Consideration of environmental issues to address the heat and light generated by the computers and monitors.
- (6) Consideration of ergonomic improvements of the reporting environment to avoid eye strain and problems with the wrist and shoulders. This includes an analysis of the number of monitors needed to view patient information as well as the increasing number of images from other digital modalities.

## 5.6. COST CONSIDERATIONS

### 5.6.1. Procurement and maintenance costs

While the cost and disposal of chemicals for film processing are eliminated with digital mammography, the cost of acquiring and servicing a dedicated digital mammography system is several times that of a screen film system. The cost of the high resolution monitors used for interpretation is also greater than that of mammography viewboxes and multiviewers. It is, however, less costly to convert to CR systems, as the existing mammography systems can be utilized and both large and small cassettes are available. Nevertheless, DX has been found to be less costly than screen film mammography over the longer term [44].

In addition to the initial and ongoing costs of X ray equipment, procurement and maintenance of a PACS will be required for the efficient use of digital mammography. In this case, the total costs of computer software and hardware, a high speed local network, as required, and a wider area network need to be considered. However, this is less of an issue in a facility that is already, or will be, performing other digital imaging.

During the transition phase from screen film to digital mammography, capital and labour costs of film digitization may be incurred, including the purchase cost of a high quality film digitizer.

### 5.6.2. Improving efficiency and accuracy of practice

Digital technology facilitates telemammography, with improved service to under-resourced areas. Digital systems can be installed on a bus that travels to remote areas, and the digital images produced can be seen immediately by the radiographer so that an image with positioning problems can be repeated before the patient leaves the bus. These screening images may then be sent over a high speed communications network to a site where a radiologist specializing in mammography can review and report the examinations, with a faster turnaround time and less waiting and anxiety for the patient. The images can be sent across the street, across town, or to a regional or national centre to the radiologist, who no longer needs to travel to the remote site to report, or to wait until the images are delivered.

There is improved efficiency for radiographers, who no longer have to process films. However, CR type digital mammography systems still require handling and processing of cassettes in dedicated readers, and therefore the associated risk of musculoskeletal strain is not eliminated. In addition, care must be taken not to decrease appointment time unduly for DX, otherwise the risk of repetitive strain injury will increase and the client's experience of the examination may be compromised. Mammography guided procedures such as pre-operative wire localizations and galactograms can be done more quickly when there is no longer a need for films or cassettes to be processed. This decreases both the time that a breast is in compression during the localization procedure and the time a radiologist spends on the procedure.

## 5.7. ARTEFACTS

While the incidence of artefacts on digital mammographic images<sup>3</sup> is typically less than that with film based mammography, artefacts can be produced on digital systems. This section provides a pictorial catalogue of some of the more common artefacts seen on digital systems, although some are also seen on film screen systems. More complete treatments can be found in the literature [45].

The process of 'flat fielding' is necessary to avoid machine related non-uniformity of the image brightness or 'drop out' from defective pixels (Fig. 7). Other detector related artefacts include electronics failure (Figs 8 and 9), detector crystallization (Fig. 10) and image lag (Fig. 11).

Extreme examples of motion blurring may still occur in digital mammographic images, as exemplified in Fig. 12. If the technologists do not view the images closely or if they fail to use the zooming tool, more subtle motion blurring may be missed, especially if the monitors on the digital acquisition workstation are of a lower spatial resolution than those used by the radiologists (Fig. 13).

Talcum powder may mimic calcification, as illustrated in Fig. 14, and calcifications on the skin may be misinterpreted as being in the body of the breast in some circumstances (Fig. 15).

Although it is not unique to digital mammography and is not strictly an artefact, poor collimation can result in large amounts of tissue being missed, as illustrated in Fig. 16.

Finally, images must be checked before a case is closed in order to avoid a mislabelling of images that cannot be corrected later.

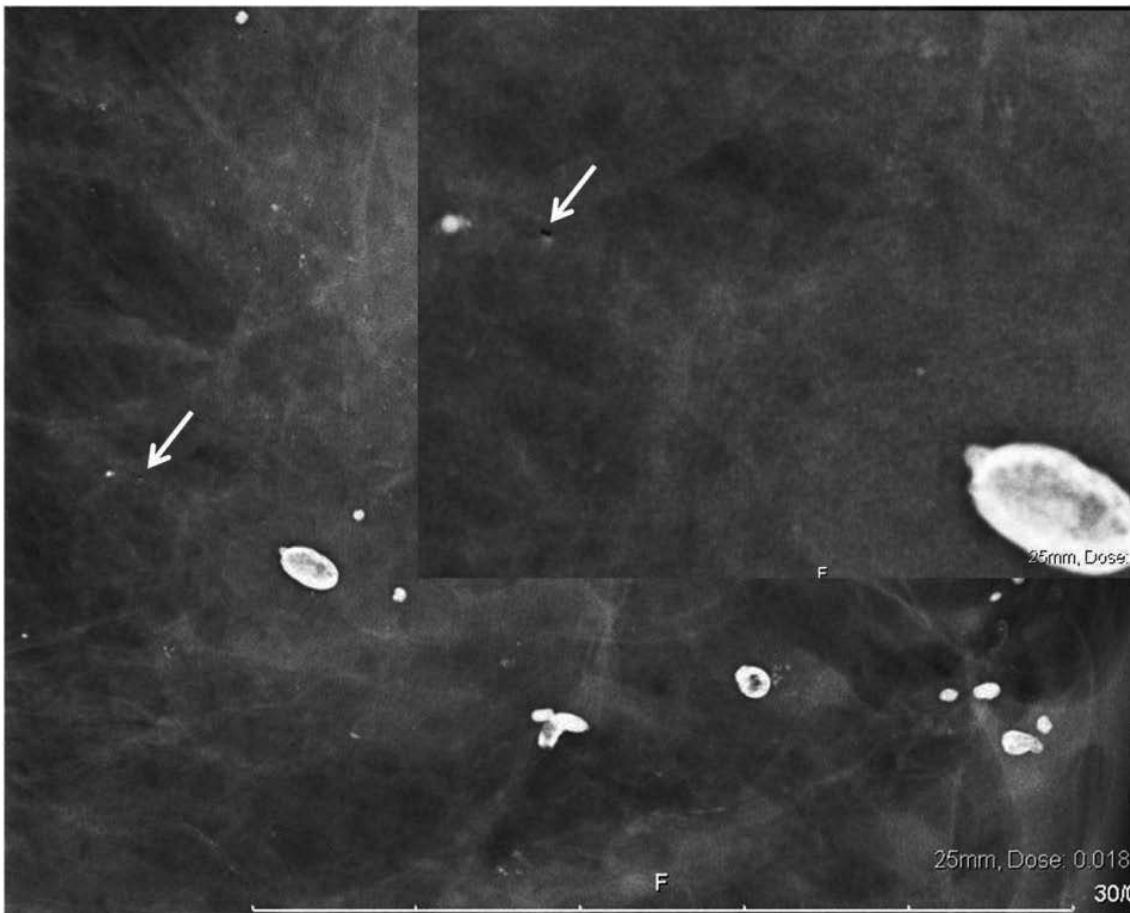


FIG. 7. A cluster of defective pixels (white arrow on the left) is barely discernible in an image of a breast taken using magnification mammography. When electronically zoomed in on, as in the insert, the cluster is clearly evident. Depending on the number of pixels or dels implicated, the detector 'dead del' map should be updated. In more extreme cases, the detector may need to be replaced.

<sup>3</sup> A digital mammography artefact can be defined as any variation in the image pixel values that does not reflect the true attenuation differences in the breast tissue.

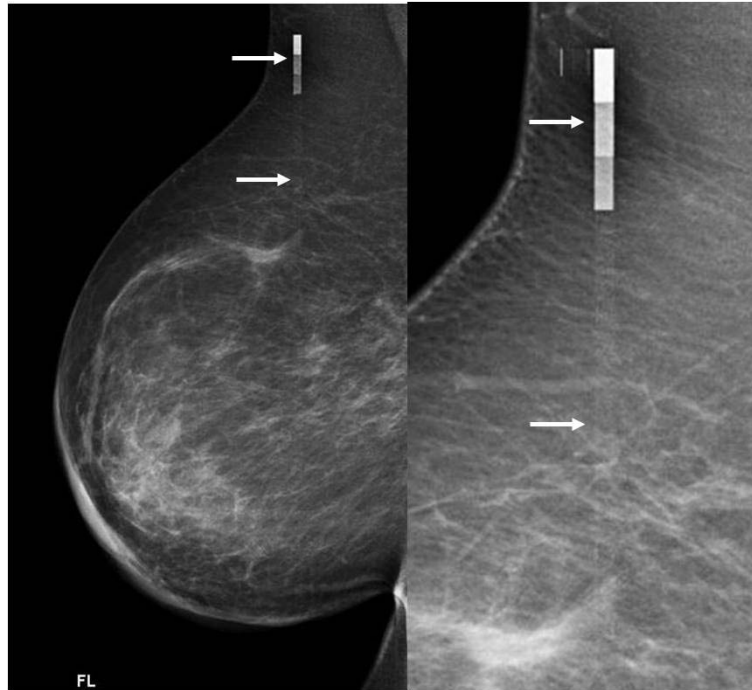


FIG 8. The image on the left demonstrates an odd looking, well defined artefact that, when electronically zoomed in on, looks like a step wedge embedded in the breast. The direct cause of the artefact is a failure of image acquisition electronics. In this case, the fundamental cause was a failure of the room air conditioning, which allowed the temperature at the detector to exceed the allowed tolerance.

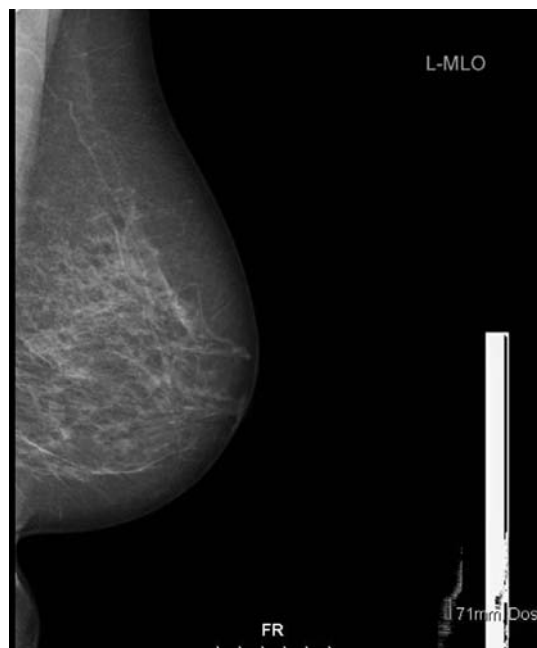


FIG 9. An obvious example of an image acquisition electronics failure in an a-Se detector. Fortunately, in this instance it occurred near the nipple edge and not the chest wall, and thus the images of this patient did not require repeating.

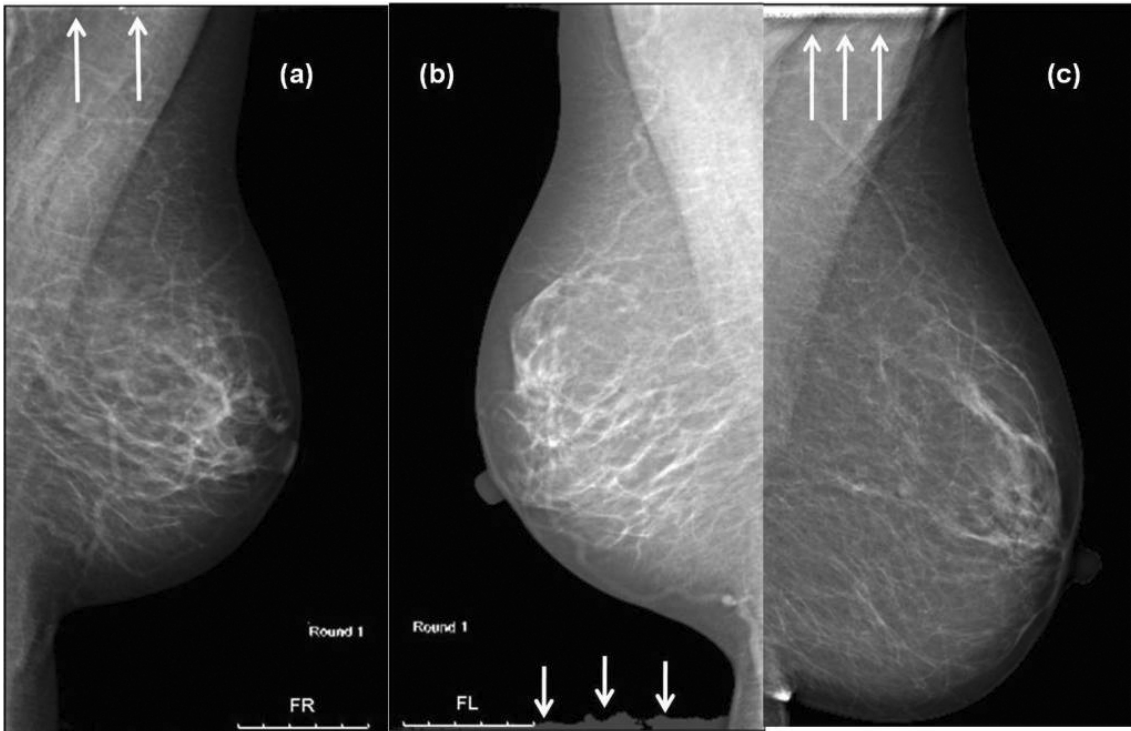


FIG. 10. Detector crystallization. (a) The arrows in the top left-hand corner indicate a subtle artefact in the mediolateral oblique (MLO) view image that appears to mimic calcification. (b) The subsequent MLO view of the other breast indicates that the artefact is in fact caused by the a-Se detector beginning to crystallize. The window width and window level in this image have been adjusted to highlight the problem. (c) A more obvious and serious example of a-Se detector crystallization is apparent in this image (see arrows).

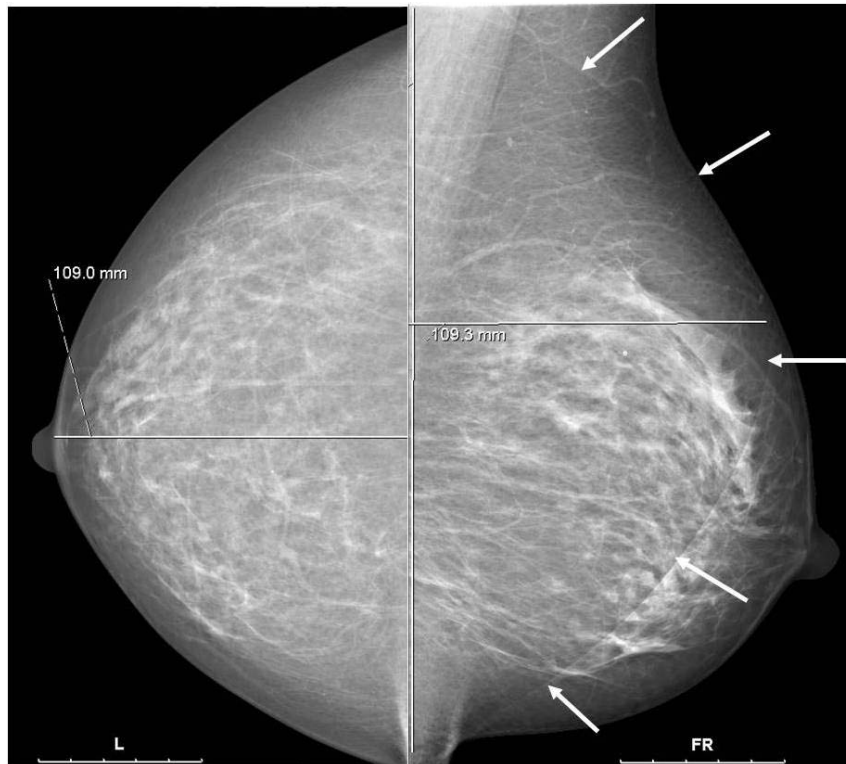
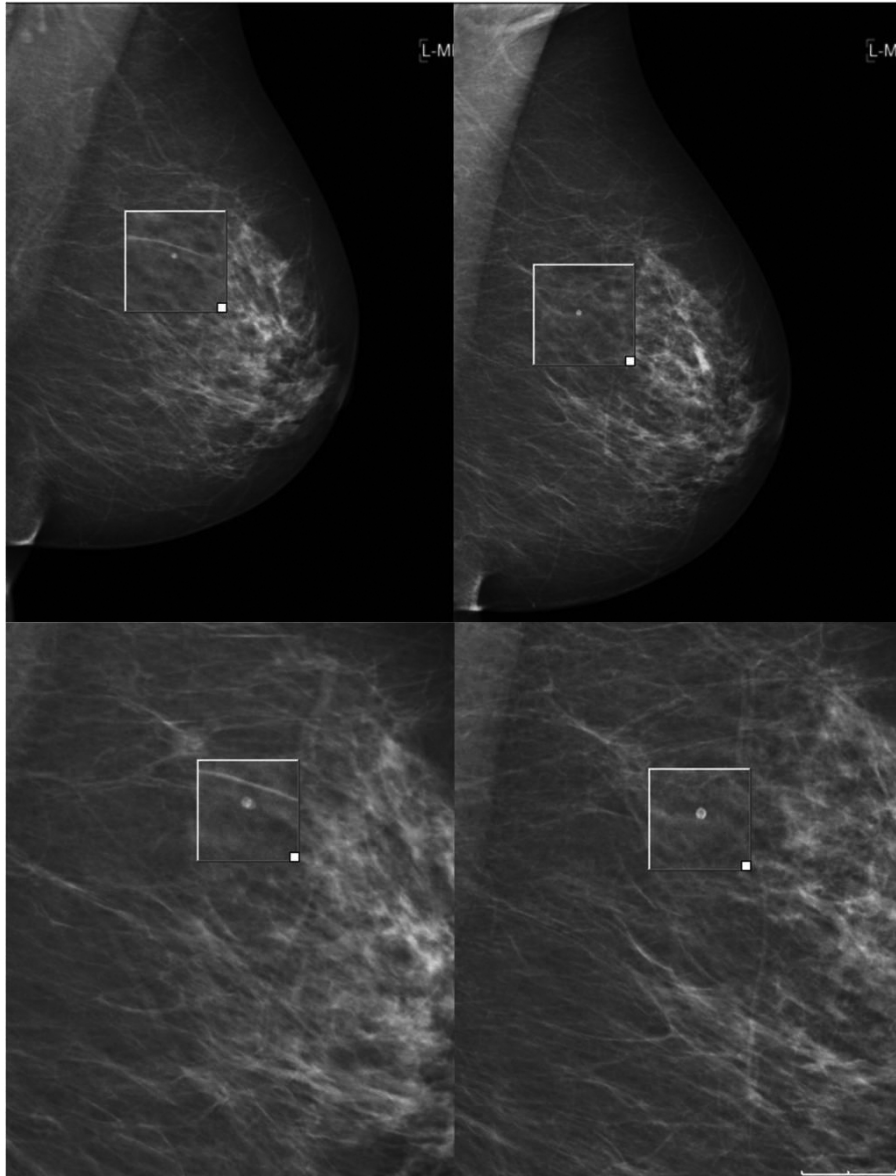


FIG. 11. The image on the left is a standard craniocaudal (CC) view of a breast, and the image on the right is the MLO view acquired immediately afterward. As indicated by the arrows, the CC view is still evident in the latter image. This is a totally unacceptable example of a-Se detector image lag, caused in this instance by the room temperature not being high enough to maintain the detector temperature at the required level.



*FIG. 12. An extreme example of motion artefact, in this instance caused by a CR cassette not being firmly locked in the cassette holder when the MLO view was acquired.*



*FIG. 13. A more subtle example of a motion artefact is shown in the left hand images. The artefact was observed on the radiologist reporting workstation but only became apparent when the electronic zoom was used on the acquisition workstation. The repeated image shown on the right demonstrates the calcification more sharply.*



FIG. 14. An artefact mimicking calcification caused by talcum powder is clearly evident in the left hand image, as indicated by the arrows. The subsequent image on the right, after removal of powder, is devoid of the artefact. Similar artefacts may also arise from zinc powder on the skin.

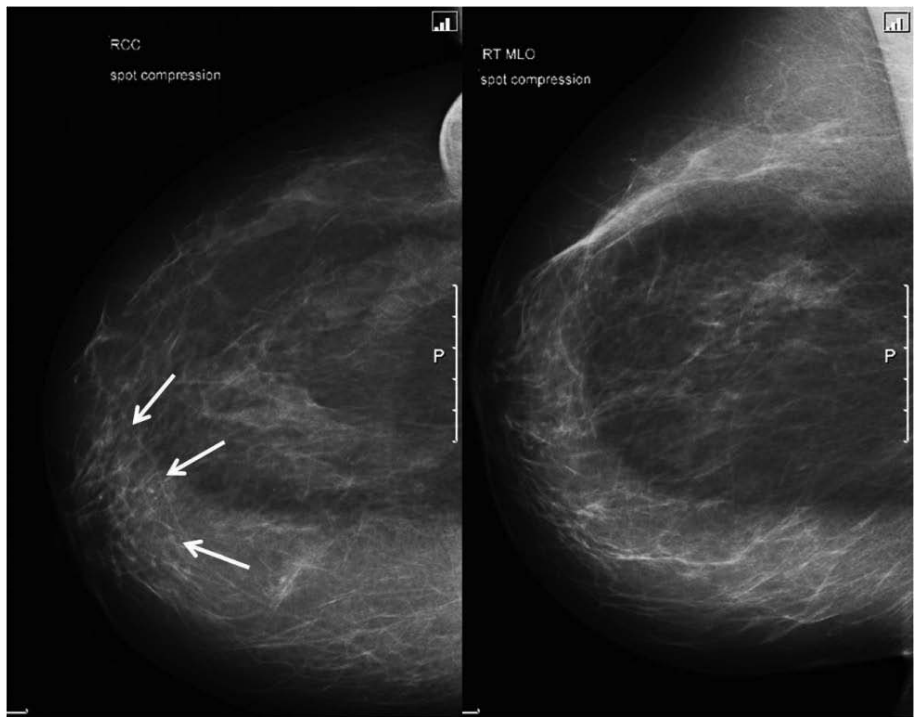
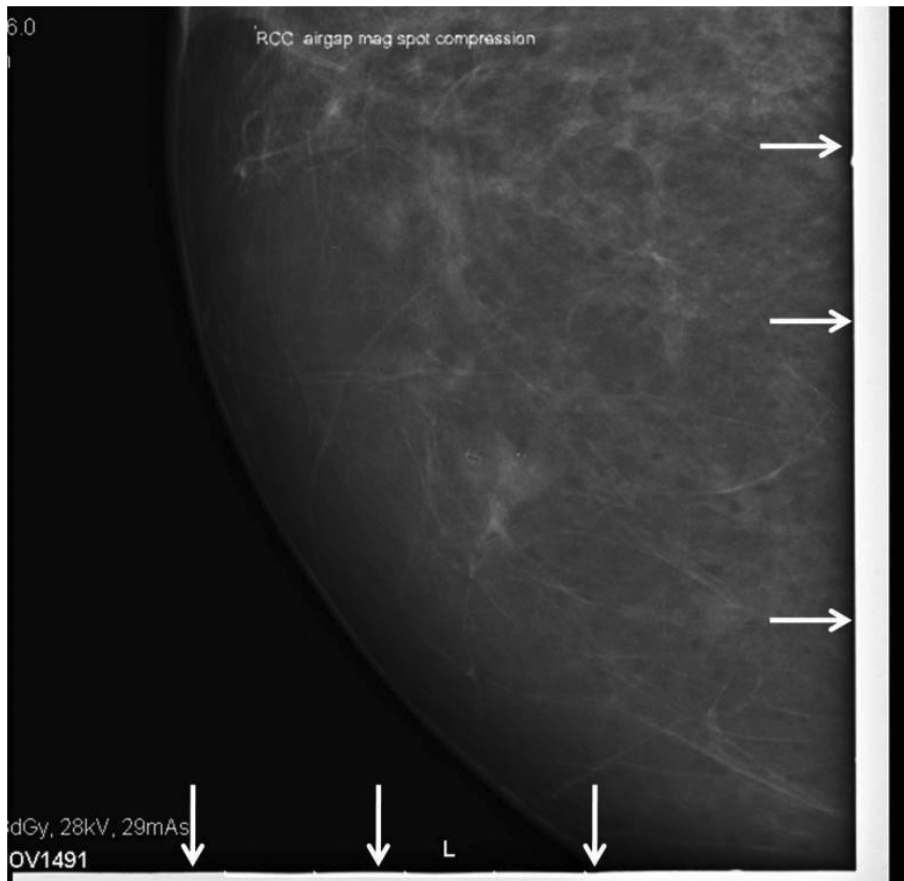


FIG. 15. Right CC image (spot compression view), shown on the left, appears to demonstrate calcification (as indicated by the arrows) in the body of the breast. The right MLO image, shown on the right with the nipple in profile, is apparently devoid of calcifications. The calcifications are in fact located on the skin around the nipple.



*FIG. 16. An example of poor collimator adjustment. In this magnification view, the collimator has not been adjusted by the service organization to allow the entire detector to be irradiated, leaving a marked white border on the bottom and right-hand margins of the image. Apart from being disconcerting for the radiologist interpreting the study, this allows an unacceptable amount of breast tissue to be missed, most seriously on the chest wall.*



## 6. OUTLINE OF QUALITY CONTROL TESTS

QC tests are intended to verify the stability of the operation of the equipment or elements used to acquire the mammogram. The tests have been classified into two types: essential and desirable, with respect to their importance in influencing image quality and dose. The performance of the first category of tests is considered indispensable; however, it is recommended that the tests in the second category also be carried out if adequate human resources and equipment can be made available.

### Test Priority

*Essential* refers to tests that:

- Must be done in a facility; or
- The minimum frequency at which the tests must be performed.

*Desirable* describes:

- The test procedures that should be performed if feasible; or
- The frequency at which the tests should be performed if feasible.

Many of the tests need to be performed very frequently (weekly and daily). Therefore, it is recommended that these tests be performed by local personnel who are present daily in the facility (technical personnel, normally radiographers). In the majority of cases, the lower frequency (and more specialized) tests have been assigned to medical physicists. Tolerance values for the tests are indicated. These, too, are classified into two categories: acceptable and achievable. In some cases, only the acceptable level has been defined.

### Performance Standards

*Acceptable* indicates that performance must be within these tolerances;  
if it is not, the equipment should not be used.

*Achievable* indicates the level of performance that should be attained under favourable circumstances;  
this is the level at which a facility should work if it is feasible.

A facility should strive to ensure that equipment operates at the achievable level of performance, as this will produce the highest image quality and the most appropriate dose performance. It is recognized, however, that limited resources, uncorrectable environmental factors and other factors may occasionally prevent the achievable levels from being obtained. In no case should the facility continue to perform mammography if the equipment does not meet the acceptable standard of operation, because below this level the value of the procedure and/or its safety is considered unacceptable. Each test in the QC programme has a specified tolerance level for achievable and acceptable results, as applicable. Should the results of a test fall outside the specified tolerance, the test should usually be repeated to confirm the result before action is taken.

Suitable minimum specifications for test equipment are provided in Appendix II.

Table 4 in Section 7 of this publication lists all the QC tests to be carried out by the radiographer; those QC tests to be carried out by the medical physicist are listed in Table 10 in Section 8 of this publication. In some cases, either person could perform a particular test, so the tests are listed in both tables. In such cases, a decision must be made as to who will actually perform the test, and that person should consistently carry out the test thereafter.



## 7. RADIOGRAPHER'S QUALITY CONTROL TESTS

The tests provided here form a QC programme for the radiographer and in most cases offer a *replacement* for tests that are in the manufacturer's programme. It is not necessary to perform both sets of tests. This programme does *not* include maintenance or calibration procedures. Maintenance and calibration activities should be performed by the appropriate individual according to the manufacturer's instructions.

A brief description of the methodology to be undertaken when performing the radiographer's QC tests is provided in this section (Table 4). The tests do not necessarily have to be performed in the order in which they appear in this publication. The preferred order will depend on various factors relating to the mammography facility as well as the preferences of the individual performing the testing, always keeping in mind that the results of one test may affect the execution of others. Data collection sheets are found in Annex I and are available in electronic format, along with other information relevant to testing of digital mammography, on the IAEA web site at: <http://humanhealth.iaea.org>

TABLE 4. RADIOGRAPHER'S QUALITY CONTROL TESTS

Test	Priority <sup>a</sup>	Tolerances or recommended levels
<i>Daily tests</i>		
Monitor inspection, cleaning and viewing conditions	D <sup>b</sup>	See Section 7.1.1.4
Digital mammography equipment daily checklist	E	See Section 7.1.2.5
Daily flat field phantom image	D	See Section 7.1.3.5
Visual inspection for artefacts (CR systems only)	E	See Section 7.1.4.4
Laser printer sensitometry	E <sup>c</sup>	See Section 7.1.5.4
Image plate erasure (CR systems only)	E <sup>d</sup>	See Section 7.1.6.3
<i>Weekly tests</i>		
Monitor QC	E	See Section 7.2.1.4
Viewbox cleanliness	E	See Section 7.2.2.4
Weekly QC test object and full field artefacts	E	See Section 7.2.3.4
Image quality with breast mimicking phantom	D	See Section 7.2.4.4
<i>Monthly tests</i>		
Safety and function checks of examination room and equipment	E	See Section 7.3.1.4
Full field artefacts	E	See Section 7.3.2.4
Laser printer artefacts	E <sup>e</sup>	See Section 7.3.3.4
<i>Quarterly tests</i>		
Printed image quality <sup>f</sup>	E	See Section 7.4.1.4
Repeat image analysis	E	See Section 7.4.2.6
Spatial resolution test (CR and scanning systems only)	E	See Section 7.4.3.3

TABLE 4. RADIOGRAPHER'S QUALITY CONTROL TESTS (cont.)

Test	Priority <sup>a</sup>	Tolerances or recommended levels
<i>Semi-annual tests</i>		
CR plate sensitivity matching	E	See Section 7.5.1.4 for CR manufacturer specific requirements
CR plate artefacts	E	See Section 7.5.1.4 Acceptable: No clinically significant artefacts

<sup>a</sup> E — essential, basic requirement; D — desirable.

<sup>b</sup> It is desirable that this test be performed on a daily basis and essential that it be performed weekly.

<sup>c</sup> For wet processors, it is desirable that this test be performed on a daily basis and essential that it be performed on those days that images will be printed for diagnostic purposes. For dry processors, the test is only required monthly.

<sup>d</sup> Secondary erasure should be performed daily and primary erasure weekly or as per the manufacturer's instructions.

<sup>e</sup> It is desirable that checks for laser printer artefacts be performed weekly and essential that they be performed monthly.

<sup>f</sup> If laser film with wet processing is used for hard copy printing, see the relevant section in the report on Quality Assurance Programme for Screen Film Mammography (IAEA Human Health Series No. 2 [34]) for guidance on storage, processing and darkroom issues.

## 7.1. DAILY TESTS

### 7.1.1. Monitor inspection, cleaning and viewing conditions

#### 7.1.1.1. Scope

- Objective: To keep monitor screens free of dust, fingerprints and other marks that might interfere with image interpretation; to confirm that image viewing conditions are acceptable.
- Frequency: Daily.

#### 7.1.1.2. Instrumentation

- (1) Dry, soft, lint free cloth or lens tissue.
- (2) Water or approved monitor cleaning solution (the cleaning solution should be available in the examination and interpretation rooms).

#### 7.1.1.3. Methodology

- (1) Clean all monitor screens gently with the cloth, lightly dampened with water if required. Note that abrasive materials or alcohols should not be used on monitor faces, since the anti-glare surface on the display might be destroyed.
- (2) Record monitor cleaning status on the daily and weekly checklist (Chart 1 in Annex I).
- (3) Check image viewing conditions at the interpretation workstation.
- (4) Record the viewing condition status on the daily and weekly checklist (Chart 1 in Annex I).

#### 7.1.1.4. Recommendations and corrective actions

- (1) Monitor screens must be free of dust, fingerprints and other marks that might interfere with image interpretation. There should be no 'shiny' patches or obvious non-uniformities on the surface.
- (2) The lighting conditions and room configuration must match those described on the medical physicist's worksheet. Sources of bright light must not be present in the room and must not be reflected from any viewboxes and/or monitor surfaces. Any required corrective action must be undertaken before images are interpreted.
- (3) Cleaning personnel should be carefully instructed that during routine cleaning of the room, nothing must be done to the surfaces of the image displays (i.e. no abrasives, chemical cleaners, etc., should be used).

## **7.1.2. Digital mammography equipment daily checklist**

### *7.1.2.1. Scope*

- Objective: To confirm that the digital mammography unit is functioning adequately.
- Frequency: Daily.

### *7.1.2.2. Instrumentation*

Daily and weekly checklist for the digital mammography system.

### *7.1.2.3. Methodology*

- (1) Visually inspect the unit for loose parts, cracks in the compression paddles, compressor and Bucky cleanliness, and overall integrity.
- (2) Check that all hoses and cables are free of breaks, crimps and knots. Hoses and cables should not be located under heavy equipment.
- (3) Ensure that the current technique chart is posted.
- (4) Ensure that the cleaning solution for the breast support plate and compressor is available.
- (5) Perform any additional daily tests or procedures required by the manufacturer's QC programme or by local or national QC protocols.
- (6) Record the status on the daily and weekly checklist (Chart 1 in Annex I).

### *7.1.2.4. Interpretation of results and conclusions*

Confirm that the criteria for the daily checks are met.

### *7.1.2.5. Recommendations and corrective actions*

If the criteria for the recommended daily checks are not met, service support should be called.

### 7.1.3. Daily flat field phantom image

#### 7.1.3.1. Scope

It is important that artefacts that could interfere with clinical interpretation be detected before image quality deteriorates significantly. If an artefact that looks like a dead pixel or group of dead pixels occurs, it is very important to monitor whether it persists in time, and whether its position changes on successive days. Performance of a daily flat field image allows detection and monitoring of such problems.

- Objective: To ensure that clinical images produced are free of artefacts that might interfere with image interpretation.
- Frequency: Daily.

#### 7.1.3.2. Instrumentation

Uniformly thick slab of PMMA. Typically this should be 45 mm thick; however, a slab of another thickness that has been supplied by the manufacturer for flat field correction would also be acceptable. The slab should be free of scratches and other imperfections that would cause artefacts. It should preferably cover the entire area of the image receptor (Fig. 17). The same test object should be used each time. It is acceptable, but not required, to have a contrast disc or other fixed structure in the image.

#### 7.1.3.3. Methodology

- (1) Place the test object on the breast support, centred laterally and extending slightly beyond the chest wall edge of the digital image receptor.

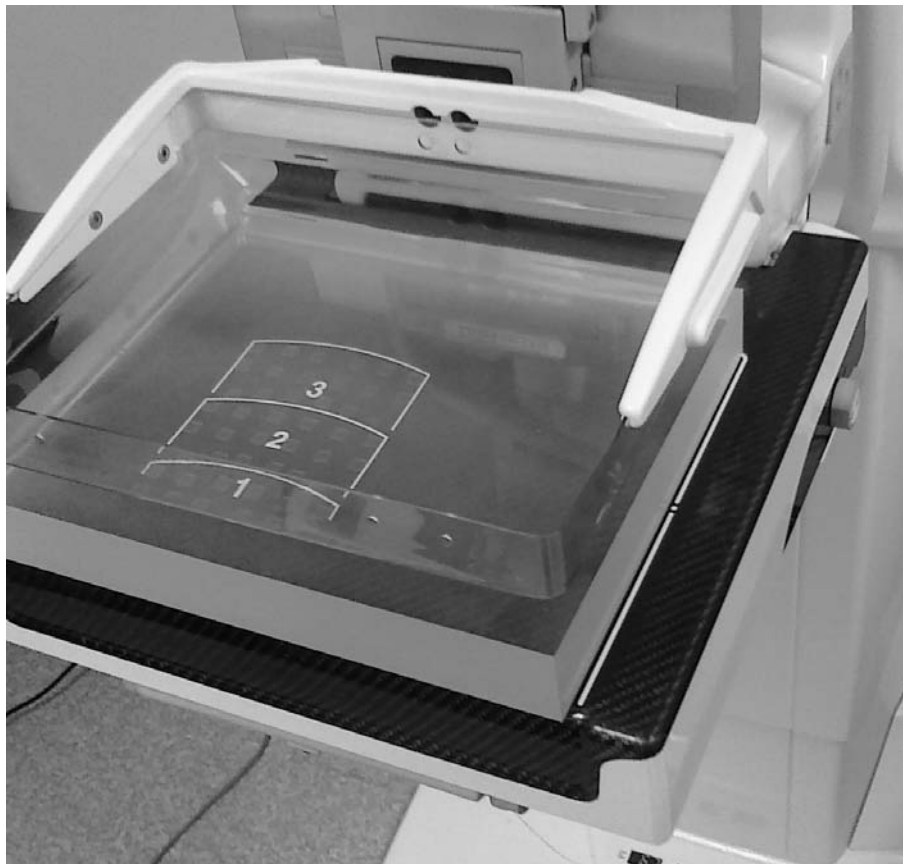


FIG. 17. Photograph of a flat field QC test object.

- (2) Apply the compression force typically used clinically (e.g. 80 N).
- (3) Acquire an image of the test object using standard clinical settings. The DICOM ‘for presentation’ version of the image should be used for this test (see Section 2.3.7.2).
- (4) View the ‘for presentation’ image on the acquisition display workstation. Use the window width and window level recommended by the medical physicist. These settings result in the background of the phantom being displayed as a mid-grey. The same window width and window level settings ( $\pm 10$ ) should be used each time an image is evaluated. An appropriate choice of window width is critical for catching artefacts yet not ‘failing’ clinically acceptable images. Window width choice should be based on what is appropriate or typical for breast images or for a phantom with breast-like features.
- (5) With the same window width and window level as used above, evaluate the entire image for overall appearance and for artefacts. Examine the entire image for both broad area artefacts such as non-uniformities, blotches and streaks, and for detailed artefacts such as black or white pixels, clusters of pixels, lines and specks. Broad area artefacts are typically best seen while observing the phantom image as a whole, not piecewise. Detailed artefacts are typically best seen while observing the phantom image at full spatial resolution, where one pixel on the display corresponds to one pixel in the image, or even in magnified form (with a magnification greater than 1.0). Record the absence or presence of artefacts on the daily flat field phantom image on the data collection sheet (Chart 7 in Annex I).

*Note:* An artefact is considered significant if it may mimic or obscure anatomic features.

#### 7.1.3.4. Interpretation of results and conclusions

- (1) There should be no blotches or regions of altered texture appearance.
- (2) There should be no observable lines or structural artefacts.
- (3) There should be no ‘bright’ or ‘dark’ pixels evident.

#### 7.1.3.5. Recommendations and corrective actions

If any artefacts are visible that might mimic or obscure anatomic information, or if any patterns are seen, a recalibration or flat fielding of the digital detector may be needed for DX systems. The compression plate and all accessible surfaces that are in the imaging field should be cleaned to remove any debris or extraneous material. (For CR systems, see also Section 7.1.4.) After this has been done, repeat the test. If artefacts persist, contact the authorized service representative.

#### 7.1.3.6. Time frame for corrective action

Immediately: If this test fails, do not image patients until corrective action has been taken.



#### 7.1.4. Visual inspection for artefacts (CR systems only)

##### 7.1.4.1. Scope

Dust on CR plates or debris on the breast support plate or the compression plate can create artefacts that mimic microcalcifications (Fig. 18(a)). Scratches or other defects on the plates can interfere with image interpretation, and dust on the optics of the plate reader can cause disturbing linear artefacts on images (Fig. 18(b)).

- Objective: To ensure that clinical images are free of artefacts that might interfere with image interpretation.
- Frequency: Daily, constantly throughout the day.

##### 7.1.4.2. Instrumentation

- (1) Cleaning cloth and solution, as recommended by the CR plate manufacturer.
- (2) Cleaning cloth or wipe approved for use on the breast support plate and compressor plate.

##### 7.1.4.3. Methodology

- (1) Inspect clinical images constantly during the day for excessive artefacts attributable to dust on the imaging plates or in the readout system, defects on the imaging plates, or dirt on the breast support plate or compression paddle. Note that images from all plates in regular use should be inspected.
- (2) If artefacts are detected at a level that could interfere with the diagnostic quality of the images, inspect the plates for dust or defects.
- (3) Record the plate inspection and/or cleaning status on the daily and weekly checklist (Chart 1 in Annex I).

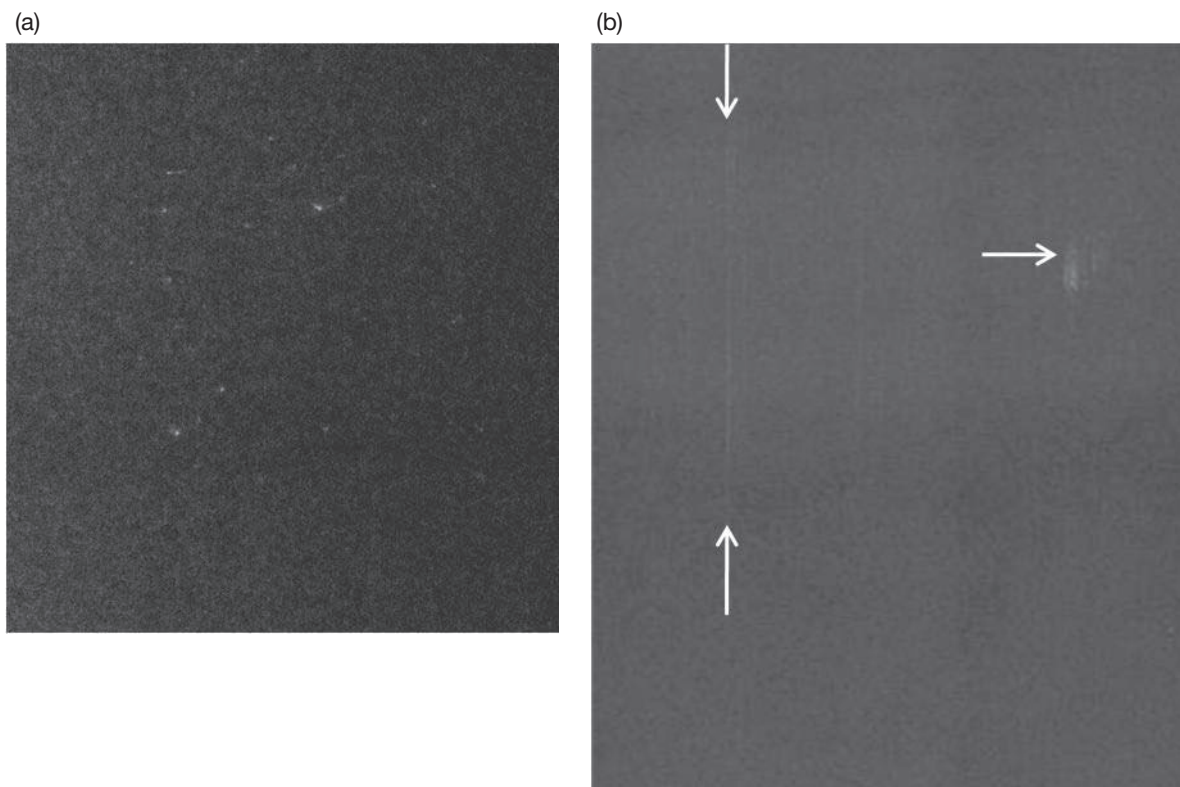


FIG. 18. Artefacts caused by (a) dust on part of an imaging plate, and (b) scrapes (horizontal arrow) and dust in the CR readout system (vertical arrows).

#### 7.1.4.4. Recommendations and corrective actions

- (1) If the CR plates are dusty, clean them according to the manufacturer's protocol. Plates containing significant defects should be replaced.
- (2) If it is found that plates must be cleaned frequently (more than weekly), this may indicate problems with dust in, or the cleanliness of, the imaging environment. If this is the case, attention should be given to ventilation (i.e. the possible need for improved air filtration or humidity control in the room and/or the CR plate reader) and room cleaning protocols.
- (3) If there are point-like dust artefacts (normally from dust on the screens) or lines (possibly caused by dust in the CR light path), appropriate cleaning by the user, using the manufacturer's recommended cleaning procedure, should be performed. If this does not correct the artefacts, service support should be called.

*Note:* Excessive frequency and/or aggressiveness of plate cleaning may lead to premature wear of the plates. See manufacturer's instructions for cleaning and handling plates.

### 7.1.5. Laser printer sensitometry

#### 7.1.5.1. Scope

Laser printer sensitometry is a routine test to be performed by the radiographer. A more complete testing procedure is carried out quarterly. The printer should be set up by the manufacturer and tested before use by the medical physicist to establish baseline performance. These baseline values are called 'reference operating levels' (ROLs). Alternatively, the radiographer can establish the ROL values for sensitometry, as described later in this section.

- Objective: To confirm and verify that the laser film processing system used to print clinical images is working in a manner consistent with baseline performance as established by the medical physicist so that the printed image quality is consistently high.
- Frequency: For systems with *wet* processing, it is desirable that this test be performed daily, and it is essential that it be performed each day before clinical images are to be printed and when changes in sensitometry are suspected. For systems with *dry* processing, the test should be performed *monthly* and when changes in sensitometry are suspected.

#### 7.1.5.2. Instrumentation

- (1) Densitometer.
- (2) Printer produced sensitometry strip (greyscale step wedge) or DICOM test image sent from the acquisition workstation.

#### 7.1.5.3. Methodology

##### (a) Establishing laser printer sensitometry ROLs

- (1) Print and process a greyscale step wedge.
- (2) Repeat step 1 for five days, obtaining five films.
- (3) Read and record the optical densities on the data collection sheet (Chart 3 in Annex I), as follows:
  - Maximum density ( $D_{\max}$ ) — the darkest step;
  - Density difference (DD) — the step closest to an optical density of 2.20 (DD1) minus the step closest to but not less than 0.45 (DD2) (i.e.  $DD = DD1 - DD2$ );
  - Mid-density (MD) — the step closest to but not below an optical density of 1.20 or the working optical density;
  - Base + fog (B + F) — the lightest step.
- (4) Determine the averages for these four values ( $D_{\max}$ , DD, MD and (B + F)) over the first five days. Use these averages as the ROLs on the chart.
- (5) Record the date the ROLs were calculated on the chart.

*Note:* New ROLs should not need to be set, except when major changes are made to equipment. The printer should be recalibrated to meet the expected ROLs when the film or processing chemistry is changed. Consult the medical physicist.

##### (b) Laser printer sensitometry

- (1) Print a greyscale step wedge image.
- (2) Read and record the densities on the step wedge pattern as follows:
  - Maximum density ( $D_{\max}$ ) — the darkest step;
  - Density difference (DD) — the step closest to an optical density of 2.20 (DD1) minus the step closest to but not less than 0.45 (DD2);

- Mid-density (MD) — the step closest to but not below an optical density of 1.20 or the working optical density;
  - Base + fog (B + F) — the lightest step.
- (3) Record and plot these four values ( $D_{\max}$ , DD, MD and (B + F)) on the laser printer sensitometry chart (Chart 4 in Annex I).
  - (4) Record completion of the sensitometry procedure on the daily and weekly checklist (Chart 1 in Annex I).

#### 7.1.5.4. Interpretation of results and conclusions

The tolerances for film sensitometry are given in Table 5.

TABLE 5. TOLERANCES FOR FILM SENSITOMETRY

Parameter	Acceptable tolerance	Achievable tolerance
$D_{\max}$ <sup>a</sup>	$\geq \text{ROL} - 0.15$ or 3.50, whichever is less	$\geq \text{ROL} - 0.10$ or 3.50, whichever is less
DD	$\text{ROL} \pm 0.15$	$\text{ROL} \pm 0.10$
MD	$\text{ROL} \pm 0.15$	$\text{ROL} \pm 0.10$
B + F	$\leq \text{ROL} + 0.03$	—

<sup>a</sup> Note that there is no upper control limit.

#### 7.1.5.5. Recommendations and corrective actions

- (1) If  $D_{\max}$  falls below the acceptable limit of  $\text{ROL} - 0.15$ , or is less than 3.50, or if the DD or MD falls outside the acceptable limit of  $\text{ROL} \pm 0.15$ , the source of the problem must be determined and corrected before digital mammograms are printed. In addition, the data points outside tolerance should be circled and the cause of the problem noted in the 'Remarks' section of the control chart. After correction, the new data point should be plotted on the same date.
- (2) If  $D_{\max}$  falls below its achievable ROL by more than 0.10, or if the DD or MD falls outside of the  $\text{ROL} \pm 0.10$  achievable limit, but these parameters are still within the acceptable limits, the test should be repeated immediately. If the same result is obtained, it is acceptable to print films, but the printer or processor should be monitored closely.
- (3) If the B + F exceeds the control limit of  $\text{ROL} + 0.03$ , the source of the problem must be determined and corrected before digital mammograms are printed.

On wet processors, the most likely sources of change are processing chemistry, replenishment and temperature changes. For example, if few films have been printed for some time, the processing chemistry may have oxidized and may not have been properly replenished. On dry processors, a likely source of change is the drum temperature. On both types of processor, a change in film emulsion batches could lead to a change in film optical densities. If this occurs, an internal recalibration of the printer should be carried out.

## **7.1.6. Image plate erasure (CR systems only)**

### *7.1.6.1. Scope*

CR plates may retain signals from previous exposures (lag). In addition, they are susceptible to artefactual signals arising from both naturally occurring and human-made sources of ionizing radiation. Although the plate reading system automatically erases plates after each readout, it is necessary to perform additional erasure of plates that have been unused for some time. It is recommended that this erasure be repeated before clinical exposures on plates that have not been used for more than eight hours. Some manufacturers provide a mechanism to carry out a more intensive erasure, which should be performed periodically, typically weekly. In both cases, the manufacturer's instructions should be followed.

- Objective: To ensure that all plates remain free of clinically significant artefactual signals arising from naturally occurring and human-made sources.
- Minimum frequency: Daily for standard erasure procedure; weekly for intensive erasure, or as recommended by manufacturer.

### *7.1.6.2. Methodology*

- (1) Perform a daily/weekly erasure of each plate, as recommended by the plate manufacturer.
- (2) Record on the daily and weekly checklist (Chart 1 in Annex I) that the task has been completed.

### *7.1.6.3. Recommendations and corrective actions*

It should be recognized that CR plates have a finite lifetime during which they perform to the specified level. If erasure procedures fail to remove residual artefacts, the plates should be replaced.

## 7.2. WEEKLY TESTS

### 7.2.1. Monitor quality control

#### 7.2.1.1. Scope

The accuracy of the diagnosis and the efficiency of the radiologist are influenced by the conditions under which the mammograms are viewed. Viewing conditions can affect the diagnostic potential of even the best quality mammograms. These conditions are determined by: the luminance and calibration of the monitors used for soft copy interpretation; the luminance of the viewboxes used for hard copy interpretation; the ambient room illumination or the amount of light falling on the monitor and/or viewbox surface; and the quality of the masking of films on the viewbox.

Contrast is extremely important in the mammography image and is degraded by extraneous light. Consequently, monitors and viewboxes should be positioned to avoid incident light from windows, other monitors or viewboxes, and other sources of bright light, either direct or reflected. General lighting in the room should be diffuse and at a low level.

The monitor QC test should be performed on *all* primary medical display devices used to interpret digital mammograms (radiologist workstations), and on all secondary display devices. Secondary display devices include the monitor(s) attached to the acquisition workstation used to verify patient image quality and/or the monitor used to manipulate and print the images (radiographer workstations). If the interpreting physicians provide final interpretations from hard copy *only*, the tests will only apply to the secondary display devices.

A set of tests for evaluating the monitors is provided here. It should be noted that test procedures have also been developed by manufacturers or as part of regional or national QC programmes [46], and these may provide a suitable (and possibly simpler) alternative to these tests.

- Objective: To ensure that images on the acquisition workstation monitor and on the monitor used for interpretation are displayed at adequate contrast and resolution.
- Frequency: Weekly and after any service or maintenance of the workstations.

#### 7.2.1.2. Instrumentation

- (1) Modified TG18-QC (or SMPTE) test pattern with DICOM header to match processed images produced by each acquisition system used at the site. This test pattern may be obtained from the manufacturer of the digital mammography unit or the workstation. The images can be loaded as patient images in the same manner that prior patient images are loaded for reviewing on the system. This could be from the PACS or from a CD provided by the medical physicist, for example. These images should be stored on the system and should not be deleted.
- (2) Patient images.

#### 7.2.1.3. Methodology

##### (a) Evaluating the monitors using test patterns

- (1) Before conducting this test, review the acceptable viewing conditions worksheet (see Chart 15 in Annex II) posted by the medical physicist in the room where the radiologist workstation is located.
- (2) Ensure that the lighting conditions and room configuration match those described on the worksheet. Ensure that no sources of bright light are present in the room or are being reflected from viewboxes and/or monitor surfaces.
- (3) If differences exist between the acceptable configuration and the current configuration, adjust the room appropriately to ensure that viewing conditions are acceptable (i.e. turn off lights that should be off, close curtains, etc.).
- (4) For each primary and secondary display device, view the modified TG18-QC pattern on each monitor used to display digital mammograms. For primary display devices, typically two monitors are used to display digital mammograms (see note below).

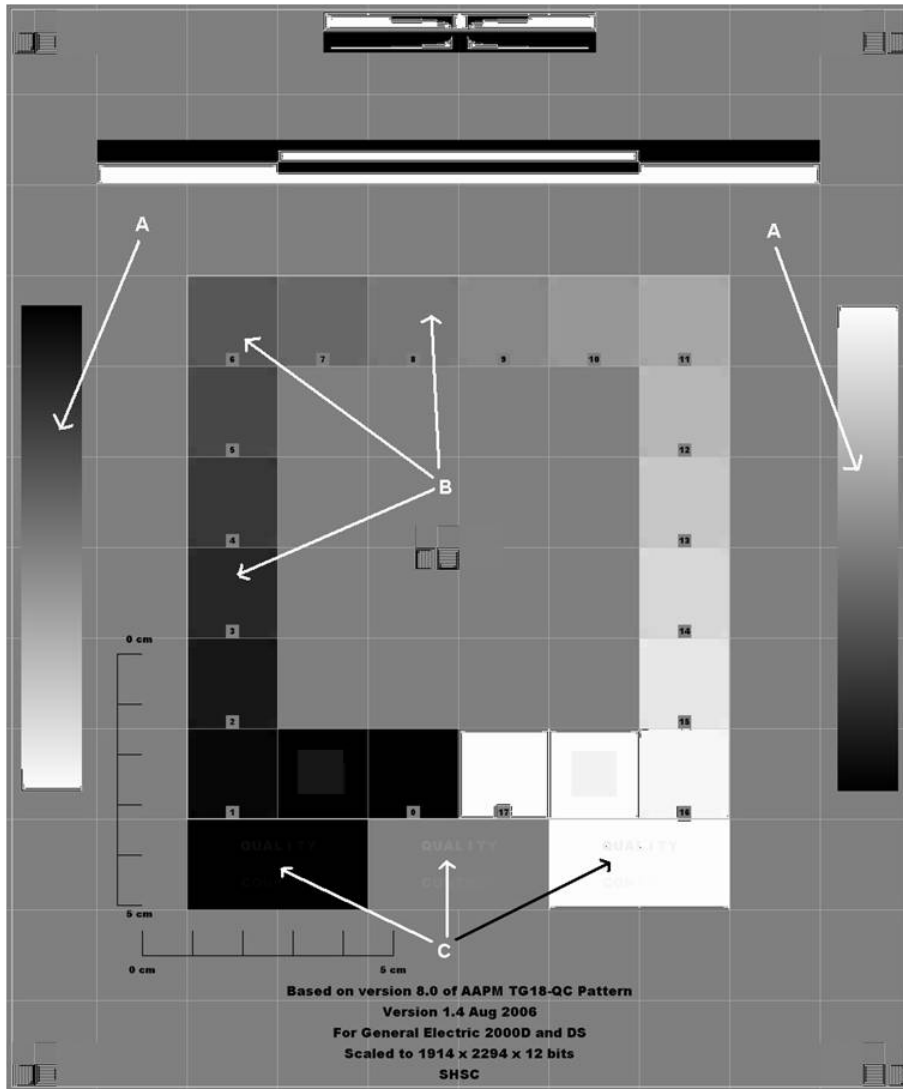


FIG. 19. Modified TG18-QC pattern with vertical greyscale bars (A), luminance patches (B) and lettering (C) indicated.

- (5) Display the test pattern image in the normal manner (as would be done for a clinical image). Ensure that the window width is set to maximum and that the window level is set to half the maximum. Use the same window width and window level settings each time.
- (6) Evaluate subjectively the following aspects of the image (Fig. 19):
  - General image quality;
  - Evidence of smearing;
  - Evidence of other artefacts.
- (7) Confirm that the vertical greyscale ramps that go from black to white along the sides of the pattern (regions marked 'A' in Fig. 19) demonstrate a smooth and continuous variation in brightness.
- (8) Geometric distortion:
  - Check that the lines on the pattern are straight.
  - Check that the image is centred on the screen.
  - Check that the boxes appear square.
- (9) Luminance:
  - The luminance squares frame the central portion of the pattern (regions marked 'B' in Fig. 19). Check that each is a distinct shade of grey, different from all other patches.
  - Examine the 0–5% and the 95–100% contrast squares (Fig. 20) located at the ends of the luminance square frame. Record if the patches are visible on the relevant monitor QC charts for radiologist (primary) and acquisition (secondary) display devices (Charts 5 and 6 in Annex I, respectively), as applicable.

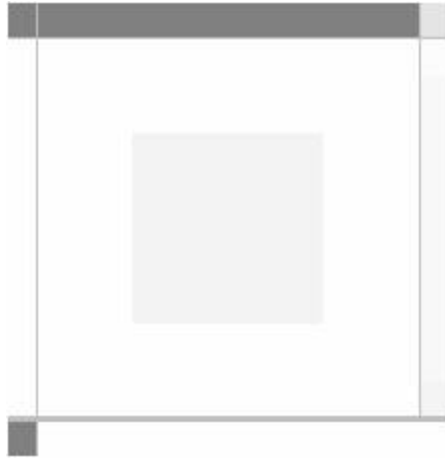


FIG. 20. The 95–100% contrast square from the TG18-QC test pattern.

- (10) Lettering (only required for display devices/radiologist workstations): Examine the text areas below the central region of the pattern (regions marked ‘C’ in Fig. 19). The words ‘QUALITY CONTROL’ are printed in fainter and fainter text over the backgrounds. Record the number of letters visible over the following backgrounds on the relevant monitor QC charts (Charts 5 and 6 in Annex I):
- Dark;
  - Mid-grey;
  - Light.

*Note:* Proprietary test QC tests are an acceptable substitute for this test, provided that they were confirmed by the medical physicist at commissioning to be equivalent to the test described above.

Viewing conditions for the secondary display devices should be as close as possible to those used for interpretation so that a proper assessment of image quality can be made by the radiographer.

Once the window width and window level settings are correctly set, it is often possible to ‘save’ how the image is displayed so that the next time the image is called up, the settings are already correct. (Consult the person responsible for applications training for instructions.)

- (b) Radiologist workstation clinical image check
- (1) From the radiologist workstation used for interpretation, locate a random clinical patient file on the menu and open the file for viewing. Load the same clinical image on all monitors for viewing (Fig. 21). *Do not* change the window width or window level settings.

*Note:* It is not necessary to use the same clinical image each week for this test. Simply choose a random image and place the same image on each monitor.

- (2) Evaluate the following items and record a ‘pass’ or ‘fail’ for each on the chart for primary display evaluation (Chart 5 in Annex I).
- Verify that the background (non-breast) areas appear black and not grey.
  - Verify that the background (non-breast) areas appear to have the same level of blackness on all monitors.
  - Verify that corresponding areas of dense breast tissue appear to have the same brightness on all monitors.
  - Verify that corresponding areas of dense breast tissue appear to have the same contrast on all monitors.



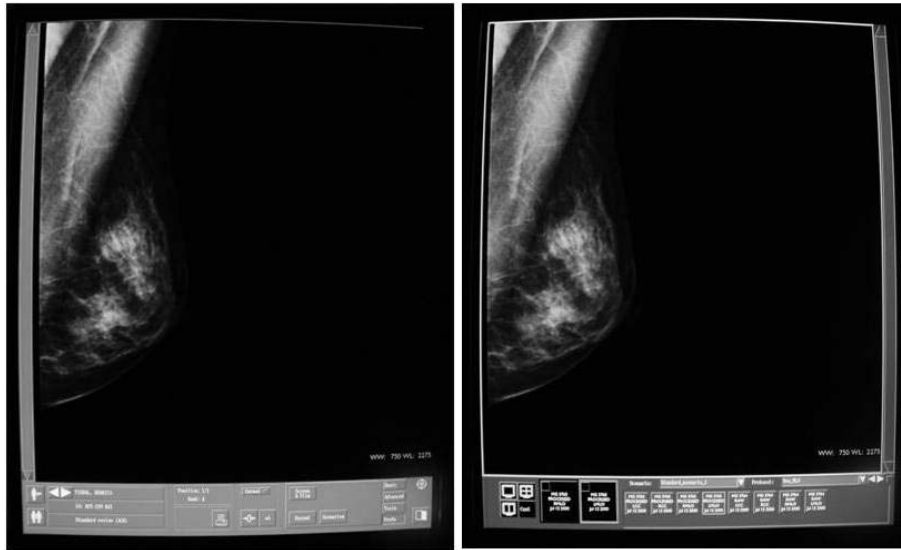


FIG. 21. Radiologist workstation with the same clinical image displayed on both monitors.

#### 7.2.1.4. Interpretation of results and conclusions

- (1) Viewing conditions for the radiologist workstation should be as recommended by the medical physicist.
- (2) There should be no noticeable artefacts in the TG18-QC image. These might include diagonal lines, flickering, blotches, non-uniform greyscale ramps, curved 'straight' lines and bright or dark pixels.
- (3) All 16 luminance patches should be distinct from each other in shade in the TG18-QC image.
- (4) The smaller, 5% contrast squares in the TG18-QC image should be visible in both the dark (0–5%) and light (95–100%) squares.
- (5) The letters 'QUALITY CONT' should be visible in each of the three regions of the TG18-QC image on the radiologist workstations.
- (6) The images on all radiologist workstations should appear to be visually identical (i.e. the same brightness and contrast).
- (7) A clinical image check should establish that the background is black, that image contrast is adequate and that the brightness or contrast settings of the two monitors are well matched.

#### 7.2.1.5. Recommendations and corrective actions

If results are outside of tolerance or are unacceptable, the tests should be repeated. If the results remain unacceptable, it may be appropriate to contact the responsible medical physicist for further advice with regard to implementing the recommendations listed below:

- (1) If viewing conditions appear unacceptable or do not correspond to those indicated by the medical physicist, consider changing the position of workstations.
- (2) If artefacts are evident in the TG18-QC images, contact the monitor service person.
- (3) If not all 16 luminance patches are distinct, it may be necessary to recalibrate the monitors. If recalibration fails to correct the problem, contact the monitor service person.
- (4) If the luminance 5% difference squares are not visible, the monitors may need to be recalibrated. If recalibration fails to correct the problem, contact the monitor service person.
- (5) If any of the letters in 'QUALITY CONT' in any of the three regions on the primary display devices (radiologist workstations) are not visible, the monitors may need to be recalibrated or the room lighting level may need to be changed. If recalibration fails to correct the problem, contact the monitor service person.

- (6) If clinical images do not appear visually identical on the radiologist interpretation workstation, the monitors may need to be recalibrated. If recalibration fails to correct the problem, contact the monitor service person.
- (7) If the clinical image check reveals that the background is not black, that image contrast is inadequate, or that the brightness or contrast settings of the two monitors do not match, the source of the problem must be identified and corrective action must be taken before any clinical examinations are interpreted from the review workstation (see Fig. 22 for an example). A qualified service engineer may be needed to make brightness and contrast adjustments on the radiologist workstation monitors and to recalibrate monitors.
- (8) All corrective actions should be recorded on the relevant monitor QC charts (Charts 5 and 6 in Annex I), as appropriate.

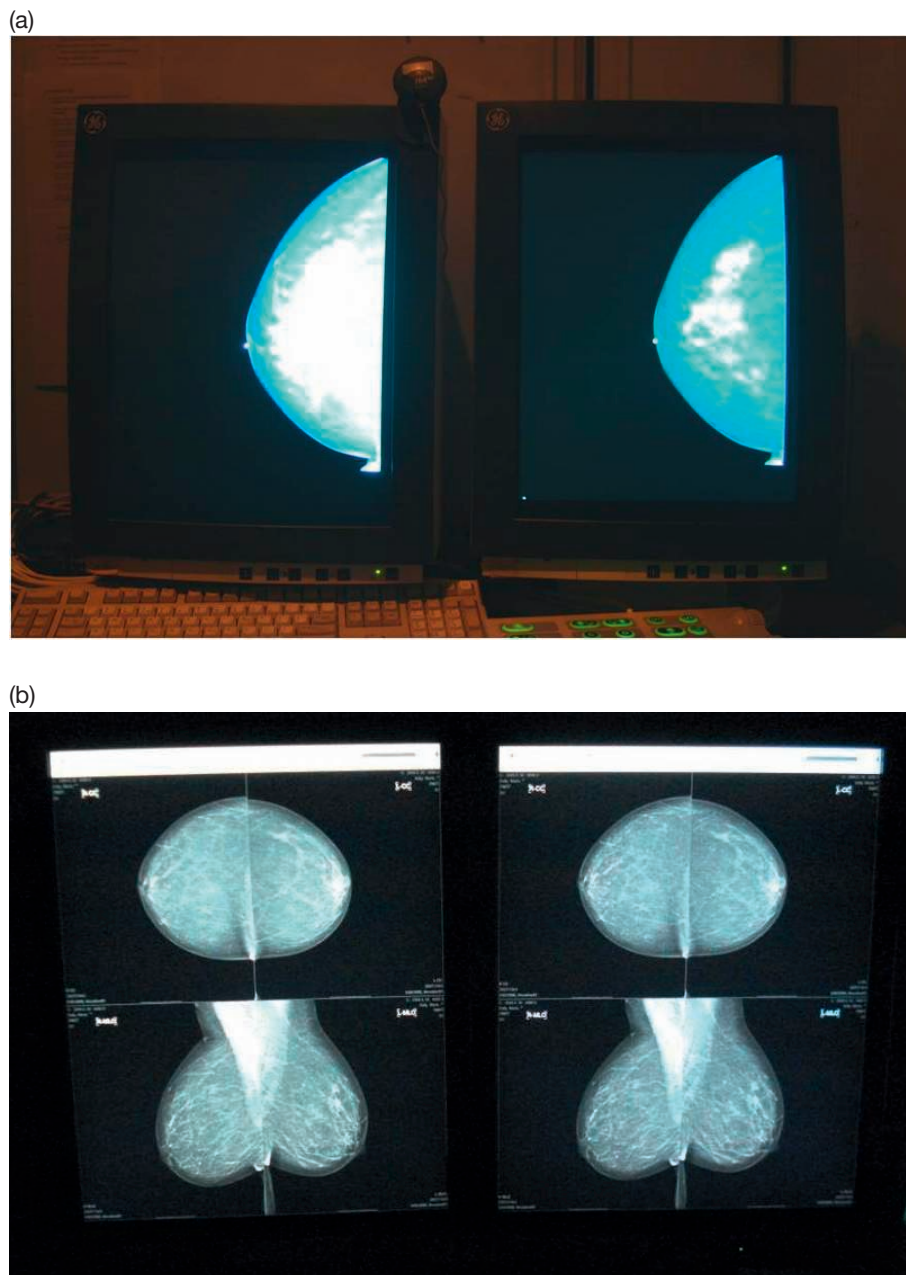


FIG 22. Unacceptable monitors: (a) significant differences are noted in the background blackness, brightness and contrast; (b) the monitor on the left has a maximum luminance 20% greater than that on the right.

#### 7.2.1.6. Time frame for corrective action

Immediately: If the *review workstation* is not performing acceptably, corrective action should be taken before any further patient images are acquired using the acquisition workstation; if the *acquisition workstation* is not performing acceptably, corrective action should be taken before the acquisition workstation is used for patient images.

*Note:* Failure of a radiologist review workstation monitor to pass this test does not mean that patient image acquisition must cease, only that interpretation of patient images using that monitor must cease until the problem is corrected.

Failure of the acquisition workstation monitor requires the cessation of patient imaging, unless the review workstation is located close enough to the acquisition workstation that each image can be checked before the next is taken.

## 7.2.2. Viewbox cleanliness

### 7.2.2.1. Scope

Viewboxes are a vital link in the process of interpreting a mammogram, yet they receive little attention, even after extensive effort has been invested in producing high quality mammograms. Particular attention should be paid to the uniformity of the luminance and the luminance level of the viewbox. Viewboxes used to review prior film mammograms should have luminance levels of at least 3000 cd/m<sup>2</sup>. If hard copy laser printed films are viewed on the same viewbox, a lower luminance may be desirable, in which case a variable brightness control would be useful. It is essential to mask the area around the mammograms to exclude extraneous light, which reduces image contrast and limits the maximum densities that can be seen without 'bright lighting' each film.

Fluorescent tubes decrease in brightness over time, although not rapidly (i.e. about 10% in 2000 hours). It is advisable to replace fluorescent tubes every 18–24 months. All tubes should be replaced at the same time. In addition, all replacement tubes should be of the same type and colour. If it is necessary to replace any fluorescent tubes because of decreased light output or for any other reason (e.g. flickering), all tubes should be replaced at the same time to ensure uniformity of colour and luminance.

- Objective: To ensure that viewboxes are clean and uniform, and that masking is available.
- Minimum frequency: Weekly.

### 7.2.2.2. Instrumentation

- (1) Window cleaner.
- (2) Soft towels.

### 7.2.2.3. Methodology

- (1) Clean viewbox surfaces using window cleaner and soft paper towels.
- (2) Ensure that all marks have been removed.
- (3) Visually inspect the viewboxes for uniformity of luminance.
- (4) Ensure that all viewbox masking equipment is functioning properly and easily.
- (5) Record performance of this task on the daily and weekly checklist (Chart 1 in Annex I).

### 7.2.2.4. Performance criteria and corrective action

- (1) Viewboxes should be free of dirt and marks from grease pencils or markers, etc. Any marks that are not easily removed with window cleaner should be removed with a safe and appropriate cleaner.
- (2) Viewboxes should appear uniformly bright, with the same hue. If viewboxes appear non-uniform, all the fluorescent lamps should be replaced as soon as possible. At the same time as the lamps are replaced, the interior of the viewbox and the rear side of the viewing panel should be cleaned.
- (3) Masking materials should be available and easy to use. If masking materials are missing, they should be replaced. If viewbox masks are difficult to use, appropriate service or modifications should be requested.
- (4) Viewboxes should be located so that they do not produce glare on soft copy reading monitors.

### 7.2.2.5. Time frame for corrective action

Immediately: Corrective action should be taken before any further clinical films are interpreted or reviewed for comparison with current digital images.

### 7.2.3. Weekly quality control test object and full field artefacts

#### 7.2.3.1. Scope

In digital mammography, it is essential to perform routine assessments of the image of a test object to confirm that there have been no substantial changes in imaging performance from the baseline. The recommended method provides both subjective and quantitative measures of performance.

- Objective: To monitor the consistency of imaging performance (e.g. variations in detector performance) in terms of factors that affect dose and image quality. Comparison is made with baseline performance levels using 'for presentation' images as viewed by the radiologist. Quantitative performance indicators are the mean pixel value (MPV), mAs employed for imaging and SDNR.
- Minimum frequency: Weekly.

#### 7.2.3.2. Instrumentation

- (1) Rectangular or D shaped phantom of uniform 45 mm thickness (Fig. 23) should be used. The same test object should be used each time. For this test, it is not essential that the object cover the entire field.
- (2) Contrast object: This could be a 1 mm deep, 25 mm diameter depression in the PMMA slab (the depression must have a smooth, flat bottom); a 1 mm thick, 25 mm diameter PMMA disc; or a 0.2 mm thick square of aluminium, 10 mm on a side.
- (3) Baseline image of this test object obtained in a previous physicist's test.

#### 7.2.3.3. Methodology

- (1) Place the test object on the breast support, centred laterally and aligned with the chest wall edge of the digital image receptor.
- (2) As appropriate, place the contrast object about 40 mm from the chest wall, on the centre line of the image detector.



FIG. 23. The weekly QC test object with disc.

- (3) Apply the compression force typically used clinically (e.g. 80 N)<sup>4</sup>. Record the compression force used and the indicated thickness at the top of the weekly QC test object data recording chart (Chart 7(a) in Annex I).
- (4) If there is a separate AEC sensor, it is desirable that it not be directly under the contrast object. The sensor should be in the same position every time the test is performed.
- (5) Acquire an image of the test object using the settings provided in the radiographer baselines and summary chart (see Annex II). This should have been provided by the medical physicist. If this chart is not available, use the same technique settings that would be used for a clinical exposure of a standard breast. Normally this is achieved by using the automatic exposure mode. Otherwise, select the appropriate target, filter, kV, grid, density control position and operation mode (semiautomatic or automatic). The DICOM ‘for presentation’ version of the image should be used for this test (see Section 2.3.7.2). For all tests of CR systems, the systems should be set to the modes indicated in Table 6. There should be a reasonably consistent delay between exposure and image plate readout to avoid introducing variation in the EI.
- (6) Record the technique used to acquire the image on the weekly QC test object data recording chart (Chart 7(a) in Annex I). The same exposure mode should be used for all subsequent phantom exposures. For systems using AEC, the target material, filtration and kV should not change from one exposure to the next. Plot the mAs on the weekly QC test object chart (Chart 7(b) in Annex I). If the target, filtration or kV changes, or if the mAs value changes by more than the action limits, repeat the image. If there is still a problem, contact either the medical physicist or the service organization.
- (7) If patient images are interpreted in soft copy, view the ‘for presentation’ image of the flat field phantom (see Section 7.1.3) on the radiologist display workstation. Use the window width and window level recommended by the medical physicist. With these settings, the background of the phantom is displayed with a mid-grey. The same window width and window level settings ( $\pm 10$ ) should be used each time an image is evaluated. An appropriate choice of window width is critical for catching artefacts yet not ‘failing’ clinically acceptable images. Window width choice should be based on what is appropriate for typical breast images or a phantom with breast-like features.
- (8) With the same window width and window level as used above, evaluate the entire image for overall appearance and for artefacts. Examine the entire image for both broad area artefacts such as non-uniformities, blotches and streaks, and for detailed artefacts such as black or white pixels, clusters of pixels, lines and specks. Broad area artefacts are typically best seen while observing the phantom image as a whole, not piecewise. Detailed artefacts are typically best seen while observing the phantom image at full spatial resolution, where one pixel on the display corresponds to one pixel in the image, or even in magnified form

TABLE 6. SETTINGS AND EXPOSURE INDICES FOR TESTING CR SYSTEMS

Manufacturer/system	Mode setting	Exposure index
Fuji	QC Test/Sensitivity Semi	S#
Philips	QC Test/Sensitivity Semi	S#
Agfa	Systems diagnostic/flat field mammo	SAL/SALlog/PVIllog <sup>a</sup>
Carestream	Others/pattern	EI
Konica	Mammo/Test	S#

<sup>a</sup> Depending on the workstation, its configuration and the plate digitizer used.

(with a magnification greater than 1.0). Record the absence or presence of artefacts on the weekly QC test object data recording chart (Chart 7(a) in Annex I).

<sup>4</sup> The actual force should be similar to the value typically used clinically, but the *same* value should be used for all testing. Note that in some systems and in some modes of operation, the compressed breast thickness is utilized in an automated algorithm to determine the technique factors; this thickness is, in turn, dependent on the degree of compression applied.

*Note:* It is not necessary to view the image on all available soft copy monitors. This is a test of image acquisition, not display. Monitor performance is assessed separately.

An automated program provided by the manufacturer or QC company [47] may be used to reduce the effort required by the technologist for test steps 8 and 9; however, it is important to also visually inspect a flat field image at regular intervals. It is also important for the automated program to give the results to the technologist immediately, before imaging of patients is performed.

*Note:* An artefact is considered significant if it may mimic or obscure anatomic features.

- (9) If patient images are interpreted on hard copy, print the image using the window width and window level that would be used for a patient image. View the image on a mammographic quality viewbox, preferably the one used by the radiologist. Evaluate the entire phantom image for artefacts, recording the absence or presence of artefacts on the weekly QC test object data recording chart (Chart 7(a) in Annex I). Record whether the phantom image was evaluated on hard copy (H), soft copy (S) or both (B).
- (10) If it is possible, display the unprocessed ('raw' or 'for processing') image of the phantom taken in step 5 of this test on a workstation that provides ROI analysis.
- (11) With the image displayed so that the contrast object is clearly visible (see Fig. 24), place a circular ROI, approximately 80 mm<sup>2</sup> in area (10 mm in diameter), over and entirely contained within the contrast object area. For the aluminium square, an ROI of 45 mm<sup>2</sup> (7.5 mm in diameter) can be used. Use the same size ROI (or as close to it as possible) each time.
- (12) Measure the MPV and label this value *A* (see step 14); record this number on the weekly QC test object data recording chart (Chart 7(a) in Annex I).
- (13) In a region outside, but immediately adjacent to, the contrast object, measure the MPV and standard deviation within an ROI similar in size to that used above as measurements *B* and *C*, and record these values on the data recording chart (Chart 7(a) in Annex I).

*Note:* The ROI placed over the contrast object should not touch or extend beyond the edges of the contrast object. The ROI placed outside the contrast object should be to the left or right of the contrast object (as viewed on the image receptor).

When recording signal mean and standard deviation values, it is not necessary to write down all the digits seen on the screen. Four significant digits (1234) are sufficient for the signal value. Three significant digits are sufficient for the noise (standard deviation) value. For example, if 123.4567 is displayed for the signal, record 123.4; if 9.87654 is displayed for the standard deviation, record 9.88.

- (14) Calculate the SDNR using the values of *A*, *B* and *C* as:  $SDNR = |B - A|/C$

*Note:* An alternative method would be to use software built into the mammography system or workstation to automatically calculate SDNR, if the manufacturer has incorporated this test into the software.

- (15) Record the SDNR and MPV on the data recording chart (Chart 7(a) in Annex I). For CR systems with no access to pixel values, record the EI.

*Note:* Baseline levels should only be recalculated when changes are made to equipment, such as replacement of a tube or the detector, or recalibration of the detector, AEC or generator. If the unit is serviced, new baseline levels may need to be calculated. Almost all these conditions require an equipment evaluation by the medical physicist.

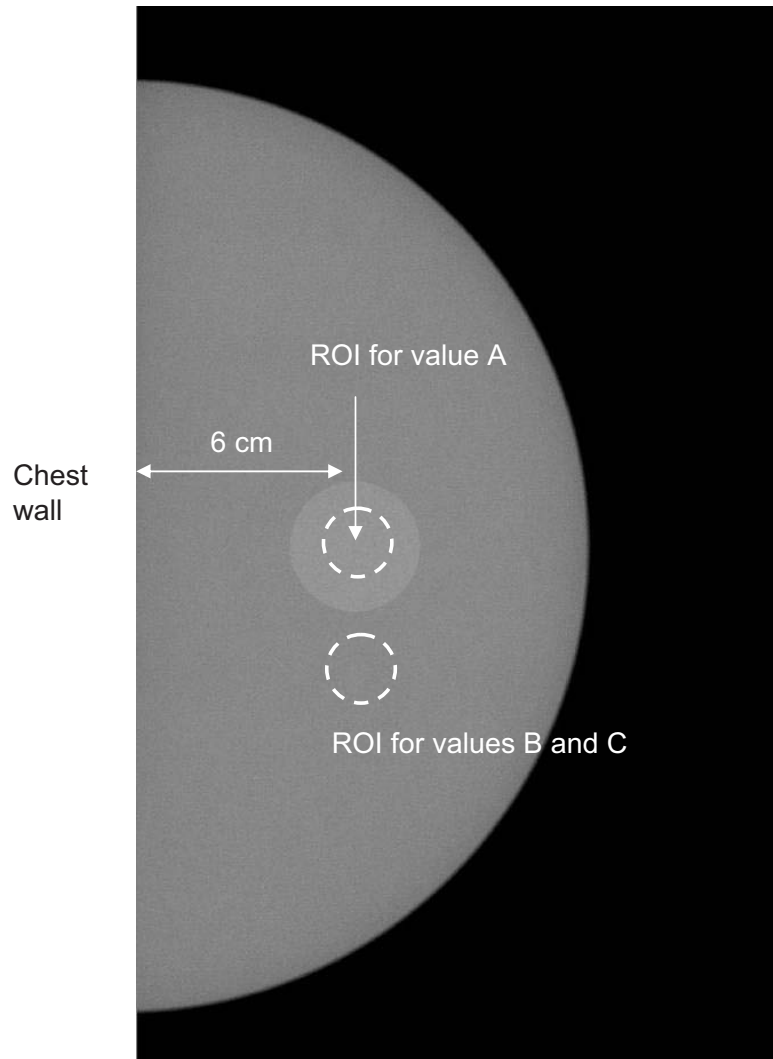


FIG. 24. ROIs in the image of the weekly QC test object used to calculate the SDNR.

(16) Record the outcome of the test on the daily and weekly checklist (Chart 1 in Annex I).

#### 7.2.3.4. Interpretation of results and conclusions

The tolerances for imaging the weekly QC test object are given in Table 7. In addition to the tolerances specified in Table 7:

- (1) There should be no blotches or regions of altered texture appearance.
- (2) There should be no observable lines or structural artefacts.
- (3) There should be no 'bright' or 'dark' pixels evident.



TABLE 7. TOLERANCES FOR IMAGING WEEKLY QC TEST OBJECT

Parameter	Acceptable tolerance with respect to baseline values
mAs	$\pm 10\%$ <sup>a</sup>
Mean pixel value (MPV)	$\pm 10\%$
Signal difference to noise ratio (SDNR)	$\pm 10\%$
CR systems: Exposure index (EI)	
Fuji, Philips and Konica (S#)	$\pm 10\%$
Agfa (SAL/SALlog/PVIllog)	$\pm 5\%/\pm 430/\pm 580$
Carestream (EI)	$\pm 40$ units

<sup>a</sup> Provided that the anode/filter and kV used are identical.

#### 7.2.3.5. Recommendations and corrective actions

If any value of mAs, MPV, SDNR or, in the case of CR systems, EI is outside the tolerances or is unacceptable, the tests should be repeated. If the results remain unacceptable, it may be appropriate to contact the responsible medical physicist for further advice on implementing the recommendations listed below:

- (1) Ensure that the correct image type ('raw' or 'for processing') is used for signal measurements. Also check to see if service adjustment, ambient or detector temperature, recalibration of the detector system or software changes might be responsible for the readings appearing outside the tolerances. If no service adjustment has occurred, and if any of the values are still outside the tolerances on a repeat test, contact the authorized service representative.
- (2) If it is found that during repeated exposures with the same phantom in place (e.g. in step 6 in Section 7.2.3.3) the mAs varies excessively because the kV, target or filter has switched, the system may be operating at a 'switching point'. Under these circumstances, to facilitate consistency testing, the medical physicist may advise adding a thin slab (5–10 mm) of PMMA so that the AEC operates at a different point.
- (3) If any artefacts are visible that might mimic or obscure anatomic information, or if any patterns are seen, a recalibration or flat fielding of the digital detector may be needed for DX systems. The compression plate and all accessible surfaces that are in the imaging field should be cleaned to remove any debris or extraneous material (for CR systems, see also Section 7.1.4). After this has been done, repeat the test. If artefacts persist, contact the authorized service representative.

#### 7.2.3.6. Time frame for corrective action

Immediately: If this test fails, do not image patients until corrective action has been taken.

## 7.2.4. Image quality with breast mimicking phantom

### 7.2.4.1. Scope

This test is provided as an interim measure, to be used as an *alternative* to the tests described in Section 7.2.3 in cases where quantitative analysis tools for QC are not made available to the user. Such tools are considered to be important as part of overall QA, and their absence is considered to be an unacceptable situation for the long term. Generally, a quantitative test is preferable, as it is more objective and reproducible. No particular phantom can be recommended. Instead, a facility could use whatever nationally or internationally recommended phantom is currently used for its screen film programme.

- Objective: To ensure that the overall image quality has not degraded from baseline performance levels and that there are no obvious artefacts.
- Minimum frequency: Weekly.

### 7.2.4.2. Instrumentation

- (1) Breast phantom containing structures mimicking those found in the breast.
- (2) Baseline phantom image (This should have been retained from a previous physics testing, at acceptance or commissioning).
- (3) Magnifying lens (4× to 5× magnification, only for images on hard copy).

### 7.2.4.3. Methodology

- (1) Place the phantom on the breast support, positioned flush with the chest wall and centred laterally.
- (2) Lower the compression paddle to apply a clinically realistic compression force (e.g. 80 N).
- (3) If there is a separate AEC sensor, confirm that it is under the phantom.
- (4) Make an exposure with the technique factors used in the clinical practice for a breast with characteristics equivalent to those of the phantom. Normally this is achieved by using the automatic exposure mode. Otherwise, select the appropriate target, filter, kV, grid, density control position and operation mode (semiautomatic or automatic).
- (5) On the corresponding data collection sheet, record the exposure factors and technique used; for CR systems, record the EI (see Table 6).
- (6) Process the image using the algorithms that would be used clinically.
- (7) View this image in a manner similar to that used clinically. Ideally, this should be done on the radiologist workstation. If this is not possible, it can be done on the acquisition workstation. Images should be evaluated on the viewbox if interpretation is done from printed films.
- (8) Compare this image with the baseline image obtained on this system. Determine if there are artefacts that may be confused with any of the phantom details. With suitable magnification, carefully examine the image for non-uniform areas, the effects of dirt or dust, lines, image processing artefacts or any other type of artefact.
- (9) If desired, evaluate the image according to the evaluation method provided by the manufacturer<sup>5</sup>. Record the data on a data collection sheet (e.g. Chart 8 in Annex I), and record the test outcome on the daily and weekly checklist (Chart 1 in Annex I).
- (10) Investigate the causes of any artefacts.

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<sup>5</sup> A description of how this is done for the American College of Radiology (ACR) accreditation phantom is provided in the report Quality Assurance Programme for Screen Film Mammography (IAEA Human Health Series No. 2 [34]).

#### 7.2.4.4. Interpretation of results and conclusions

Tolerances:

- (1) The mAs used for the phantom exposure should be within  $\pm 10\%$  of the baseline mAs value if the kV and filter have not changed.
- (2) For CR systems, the tolerances for the EI given in Table 7 should not be exceeded.
- (3) There should be no significant degradation of image quality from the baseline image. Note that the image quality assessment of the phantom should yield results that are as good as or better than those expected with high quality screen film mammography as tested with the same phantom.
- (4) There should be no blotches or regions of altered noise appearance.
- (5) There should be no observable lines or structural artefacts.
- (6) There should be no 'bright' or 'dark' pixels evident.

#### 7.2.4.5. Recommendations and corrective actions

If results are outside the tolerances or are unacceptable, the tests should be repeated. If the results remain unacceptable, it may be appropriate to contact the responsible medical physicist for further advice on implementing the recommendations listed below:

- (1) If the image quality deteriorates over time, it will be necessary to carry out other investigations to determine the source of the change<sup>6</sup>. A simple review of whether appropriate settings (e.g. kV, AEC, display, processing algorithms) have been used may reveal the source of the problem. Verify whether there has been a software upgrade of the system that has changed the AEC settings. Otherwise, a more serious underlying problem may require the assistance of the medical physicist.
- (2) If any artefacts are visible that might mimic or obscure anatomic information, or if any patterns are seen, a recalibration or flat fielding of the digital detector is needed. After this has been done, repeat the artefact phantom test. If artefacts persist, contact the authorized service representative.

#### 7.2.4.6. Time frame for corrective action

Immediately: If this test fails, do not image patients until corrective action has been taken.

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<sup>6</sup> Due to the subjectivity associated with the observer, it is recommended that the test always be performed by the same person, using the same criteria and viewing conditions.

## 7.3. MONTHLY TESTS

### 7.3.1. Safety and function checks of examination room and equipment

#### 7.3.1.1. Scope

- Objective: To verify the mechanical and electrical operation of the mammography unit; to ensure that the image acquisition information is correct.
- Frequency: Monthly is desirable; quarterly and after any service, maintenance or software upgrades is essential.

#### 7.3.1.2. Instrumentation

- (1) Thermometer, preferably mounted on the wall of the digital mammography room.
- (2) Safety and function checklist (Chart 9 in Annex I).

#### 7.3.1.3. Methodology

- (1) Measure the temperature in the mammography acquisition room.
- (2) Visually inspect the unit for loose parts, cracks in the compression paddles, Bucky cleanliness and overall integrity.
- (3) Check that all hoses and cables are free of breaks, crimps and knots. Hoses and cables should not be located under heavy equipment.
- (4) Verify that the angulation indicator is working correctly.
- (5) Verify that the interlocks are working correctly.
- (6) Ensure that the gantry moves smoothly.
- (7) Ensure that panel switches, indicator lights and meters are functioning.
- (8) Ensure that the field light is functioning.
- (9) Ensure that the current technique chart is posted.
- (10) On the interpretation workstation, display a recent clinical image and verify that the time and date as well as the facility identification are correct in the image annotation.
- (11) If printed films are produced, ensure that appropriate information appears on the films.
- (12) Check that the breast thickness indicator is accurate to  $\pm 5 \text{ mm}^7$  when using a compression force typically used clinically (e.g. 80 N). Use the method recommended by the medical physicist.
- (13) Confirm that the face guard is present and not damaged.
- (14) Confirm that the automatic compression release and manual compression release will both work in the advent of a power failure.
- (15) Confirm the integrity of the operator shield.
- (16) Ensure that the cleaning solution for the breast support plate and compressor is available.
- (17) Verify any other functions that are specified for monthly monitoring by the equipment manufacturer.
- (18) Record the status of each item on the safety and function checklist (Chart 9 in Annex I) and the final outcome on the monthly, quarterly and semi-annual checklist (Chart 2 in Annex I).

#### 7.3.1.4. Interpretation of results and conclusions

- (1) Room temperature should be in the range recommended by the manufacturer.
- (2) All mechanical and electrical items on the checklist should be in a satisfactory state of repair.
- (3) The time and date as well as the facility identification must be correctly displayed in the image annotation on the interpretation workstation.

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<sup>7</sup> This is particularly important, since some digital mammography units may depend on this measurement to determine the technique factors.

### 7.3.1.5. Recommendations and corrective actions

Many of the items on the checklist are essential for patient safety and for high quality diagnostic images. It may be necessary to add items to the list that are specific to particular equipment or procedures. These should be included on the monthly checklist and confirmed in subsequent evaluations. Time frames for correction of faults are described in Table 8.

- (1) If the room temperature is not in the range recommended by the manufacturer, the air conditioning service personnel should be called.
- (2) Items that are hazardous, inoperative or out of alignment, or that operate improperly, should be repaired by appropriate service personnel before any further patients are imaged.
- (3) Items missing from the room should be replaced immediately. Malfunctioning equipment should be reported to the service engineer for repair or replacement as soon as possible.
- (4) If the time and date and the facility identification are not correctly displayed in the image annotation on the interpretation workstation, correction by appropriate service personnel must be undertaken before any further patients are imaged.

TABLE 8. TIME FRAMES FOR CORRECTIVE ACTIONS

Items requiring immediate action before any further patients are imaged <sup>a</sup>	Items requiring action within 30 days of first identified failure <sup>a</sup>
<ol style="list-style-type: none"> <li>1. Room temperature not controlled</li> <li>2. Loose parts present, paddles damaged or Bucky not clean</li> <li>3. Hoses or cables kinked or damaged</li> <li>5. Interlocks faulty</li> <li>10. Time, date and facility ID incorrect or not present on images</li> <li>14. Automatic and/or manual compression release not working</li> <li>16. Cleaning solution not available</li> </ol>	<ol style="list-style-type: none"> <li>4. Angulation indicator not functioning</li> <li>6. Gantry motion not smooth</li> <li>7. Panel switches, indicator lights and meters</li> <li>8. Field light inoperative</li> <li>9. Current technique chart not posted</li> <li>12. Breast thickness indicator inaccurate</li> <li>13. Face guard absent or damaged</li> <li>15. Operator radiation shield damaged</li> <li>17. Overall integrity questionable</li> </ol>

<sup>a</sup> Item numbers are consistent with the methodology numbering (see Section 7.3.1.3).

## 7.3.2. Full field artefacts

### 7.3.2.1. Scope

Note that this test is similar to the artefact evaluation component of the daily tests described in Section 7.1.3, and the methodology described there is largely reproduced in this section for completeness. However, on a monthly basis, the test is extended to include all applicable focal spots, filters and magnification modes, but the tests of MPV and SDNR are not required.

- Objective: To ensure that there are no artefacts in the images that might mimic structures in the breast or that might increase the difficulty of interpretation.
- Minimum frequency: Monthly, and whenever changes have been made to the digital mammography system that might affect the flat field performance.

### 7.3.2.2. Instrumentation

Uniformly thick slab of PMMA. Typically this should be 45 mm thick; however, a slab of another thickness that has been supplied by the medical physics team or the manufacturer for flat field correction would also be acceptable. The slab should be free of scratches or other imperfections that would cause artefacts. It should preferably cover the entire area of the image receptor (see Fig. 17). The same test object should be used in subsequent monthly tests.

### 7.3.2.3. Methodology

- (1) Place the test object on the breast support, centred laterally and extending slightly beyond the chest wall edge of the digital image receptor.
- (2) Apply a compression force typically used clinically (e.g. 80 N)<sup>8</sup>. Record the compression force used and the thickness indicated at the top of the full field artefacts chart (Chart 10 in Annex I).
- (3) If there is a separate AEC sensor, confirm that it is under the test object. Keep this in the same position every time the test is performed.
- (4) Acquire an image of the test object using the same technique settings that would be used for a clinical exposure of a standard breast. Normally this is achieved by using the automatic exposure mode. Otherwise, select the appropriate target, filter, kV, grid, density control position and operation mode (semiautomatic or automatic). The DICOM ‘for processing’ version of the image should be used for this test (see Section 2.3.7.1). For all tests of CR systems, the systems should be set to the modes indicated in Table 6.
- (5) Record the technique used to acquire the image on the full field artefacts chart (Chart 10 in Annex I). For CR systems, the EI should be recorded.
- (6) If patient images are interpreted in soft copy, and if suitable analysis tools are available, view the ‘for processing’ image on the acquisition workstation. Otherwise, view the image on the radiologist display workstation. Use the window width and window level recommended by the medical physicist. At these settings, the background of the phantom is displayed with a mid-grey. The window level should not be unreasonably narrow, as this can overstate noise or irrelevant artefacts. The same window width and window level settings ( $\pm 10$ ) should be used each time an image is evaluated. An appropriate choice of window width is critical for catching artefacts yet not ‘failing’ good images. Window width choice should be based on what is appropriate for typical breast images or a phantom with breast-like features.
- (7) With the same window width and window level as used above, evaluate the entire image for overall appearance and for artefacts. Examine the entire image for both broad area artefacts such as non-uniformities, blotches and streaks, and for detailed artefacts such as black or white pixels, clusters of pixels, lines or specks. Broad area

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<sup>8</sup> The actual force should be similar to the typical value used clinically, but the *same* value should be used for all testing. Note that in some systems and in some modes of operation, the compressed breast thickness is utilized in an automated algorithm to determine the technique factors; this thickness is, in turn, dependent on the degree of compression applied.

artefacts are typically best seen while observing the phantom image as a whole, not piecewise. Detailed artefacts are typically best seen while observing the phantom image at full spatial resolution, where one pixel on the display matches one pixel in the image, or even in magnified form (with a magnification greater than 1.0). Record the absence or presence of artefacts on the full field artefacts chart (Chart 10 in Annex I).

*Note:* An artefact is considered significant if it may mimic or obscure anatomic features.

- (8) Display the uniformity image with a zoom factor that displays full resolution (1:1 pixel mapping). Reduce the window width until the texture (noise pattern) becomes apparent. Pan over the entire image, examining the image for pixels that appear much brighter or darker than the background (referred to as 'bright' and 'dark' pixels, respectively) and for variations in the amount of noise and texture from place to place in the image. The texture of the image should be uniform over the entire image or at least be similar to the baseline. If this place to place variation changes over time, areas where there appears to be less noise may indicate degradation in the detector, causing a loss of sharpness. At the same time, the presence in the image of pixels that are substantially brighter or substantially darker than the average should be noted. This may indicate dead elements in, or other degradation of, the detector. Report this finding to the medical physicist and/or radiologist for further investigation and consideration of whether the problem is of a magnitude and nature that is likely to cause a reduction in diagnostic image quality.
- (9) If patient images are interpreted on hard copy, print the image using the window width and window level that would be used for a patient image. View the image on a mammographic quality viewbox, preferably the one used by the radiologist. Evaluate the entire phantom image for artefacts, recording the absence or presence of artefacts on the full field artefacts chart (Chart 10 in Annex I). Record whether the phantom image was evaluated on hard copy (H), soft copy (S) or both (B).

*Note:* It is not necessary to view the image on all available soft copy monitors. This is a test of image acquisition, not display. Monitor performance is assessed separately.

- (10) Repeat steps 1–9 for all clinically used filters and also using fine focus and magnification, if applicable.
- (11) Record the outcome of the test on the monthly, quarterly and semi-annual checklist (Chart 2 in Annex I).

#### 7.3.2.4. Interpretation of results and conclusions

- (1) There should be no blotches or regions of altered texture appearance.
- (2) There should be no observable lines or structural artefacts.
- (3) There should be no 'bright' or 'dark' pixels evident.

#### 7.3.2.5. Recommendations and corrective actions

If results are unacceptable, the tests should be repeated. If the results remain unacceptable, it may be appropriate to contact the responsible medical physicist for further advice on implementing the recommendation listed below:

If any artefacts are visible that could mimic or obscure anatomical information, or if any patterns are seen, a recalibration or flat fielding of the digital detector is needed. After this has been done, repeat the test. If artefacts persist, contact the authorized service representative.

#### 7.3.2.6. Time frame for corrective action

Immediately: If this test fails, do not image patients until corrective action has been taken.

### 7.3.3. Laser printer artefacts

#### 7.3.3.1. Scope

- Objective: To ensure that there are no objectionable artefacts on printed films.
- Frequency: Weekly is desirable; monthly or when the presence of artefacts is suspected is essential. The test is required only for sites printing hard copy mammograms.

#### 7.3.3.2. Instrumentation

- Magnifying lens (4× to 5× magnification).
- Densitometer.
- Uniform test image such as the TG18-UNL80 pattern (Fig. 25), or a uniform mid-grey image generated by the printer.

#### 7.3.3.3. Methodology

- (1) Print the uniform test image with a window level that gives an optical density of between 1.5 and 2.0. The window width should be set to maximum.
- (2) Examine the resulting film on the radiologist viewbox using a magnifying glass. Ensure that the image is of uniform optical density, with no streaks, lines, specks or blotches.
- (3) Record the test results on the laser printer artefacts chart (Chart 11 in Annex I).
- (4) Record the outcome of the test on the monthly, quarterly and semi-annual checklist (Chart 2 in Annex I).

#### 7.3.3.4. Interpretation of results and conclusions

- (1) The resulting film should be of uniform optical density.
- (2) There should be no streaks, lines, specks, blotches or other objectionable artefacts on the film that in the opinion of the radiologist could interfere with the interpretation of a mammogram.

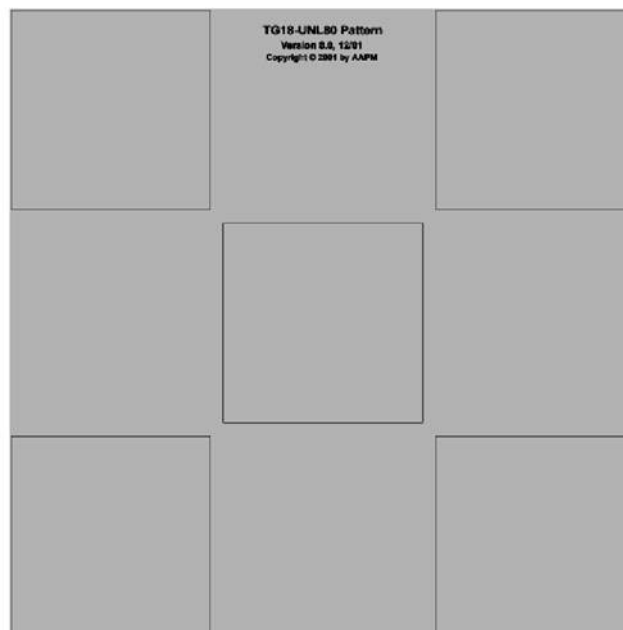


FIG. 25. The TG18-UNL80 test pattern.



#### *7.3.3.5. Recommendations and corrective actions*

If the film quality is unacceptable, the test should be repeated. If the results remain unacceptable, it may be appropriate to contact the responsible medical physicist for further advice on implementing the recommendation listed below:

If significant artefacts appear, corrective action must be taken. Service personnel should be called.

#### *7.3.3.6. Time frame for corrective action*

Immediately: Corrective action should be taken before any further patient films are printed.

## 7.4. QUARTERLY TESTS

### 7.4.1. Printed image quality

#### 7.4.1.1. Scope

- Objective: To ensure that the printed image quality is consistently high.
- Frequency: Quarterly and when reduced printed image quality is suspected. This test applies only to sites printing hard copies.

#### 7.4.1.2. Instrumentation

- (1) Magnifying lens (4× to 5× magnification).
- (2) Ruler.
- (3) Modified TG18-QC patterns (Fig. 26). Use test patterns that are specific to the digital mammography units in the facility.

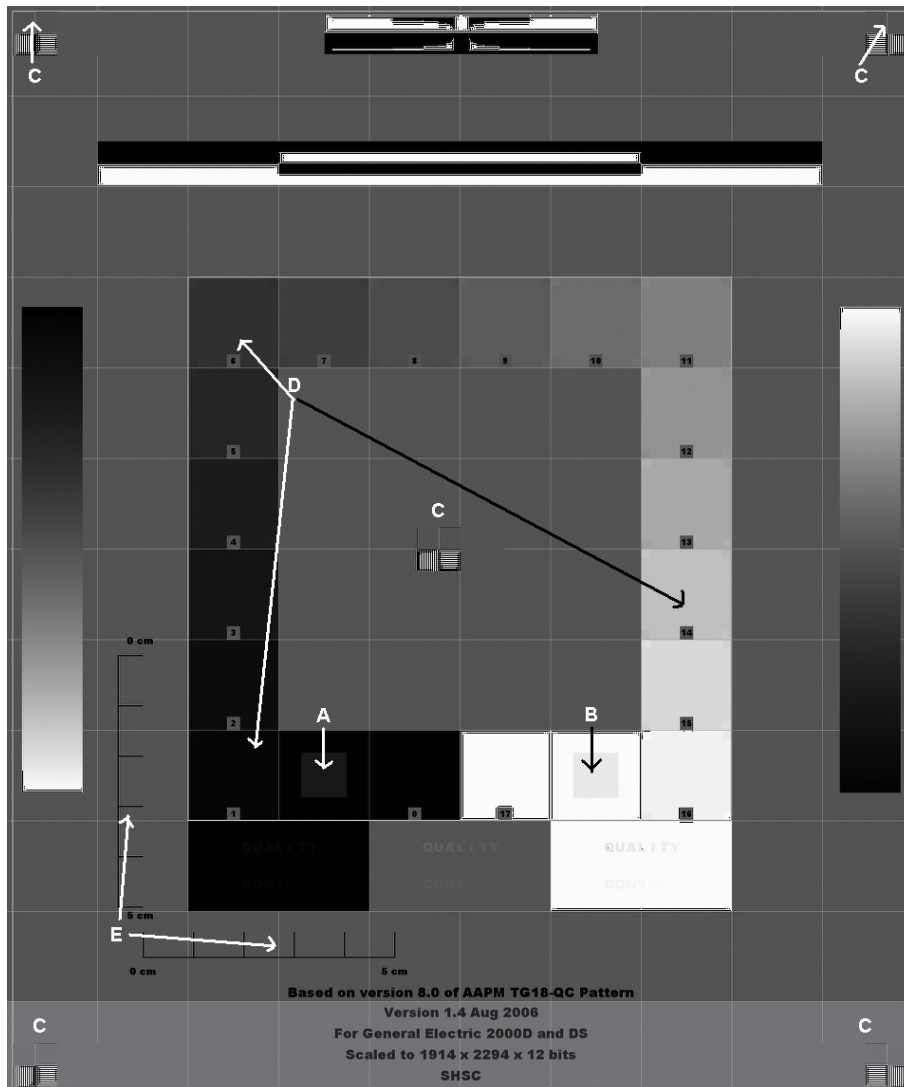


FIG. 26. Modified TG18-QC image with test objects indicated: A — 0–5% contrast square; B — 95–100% contrast square; C — horizontal and vertical line pairs; D — squares going from black to white; E — 5 cm lines.

#### 7.4.1.3. Methodology

- (1) Annotate the modified TG18-QC pattern image with rulers measuring the length of the horizontal and vertical 5 cm rulers (arrow E, Fig. 26). This should only need to be done the first time the image is used, if the annotated image is 'locked' and not deleted from the workstations.
- (2) Print (from both the acquisition workstation and the radiologist review workstation(s)) the TG18-QC test pattern appropriate for each type of digital mammography unit used to generate images for interpretation.
- (3) Examine the resulting films carefully on the radiologist viewbox, using the magnifying glass.
- (4) Record the visibility of the different test objects on the printed image quality chart (Chart 12 in Annex I).
- (5) Measure the length of the 5 cm calibration lines in the horizontal and vertical directions.
- (6) Record the outcome of the test on the monthly, quarterly and semi-annual checklist (Chart 2 in Annex I).

#### 7.4.1.4. Interpretation of results and conclusions

- (1) The 0–5% contrast square and 95–100% contrast square should be distinguishable.
- (2) The finest horizontal and vertical line pairs should be visible in all four corners (Fig. 27).
- (3) The squares of different shades from black to white should be distinct.
- (4) Lines should appear straight and even, without apparent distortions.
- (5) There should be no distracting artefacts.
- (6) The 5 cm lines should be between 4.7 and 5.3 cm long on the printed image.

#### 7.4.1.5. Recommendations and corrective action

If the printed film quality is unacceptable, the test should be repeated. If the results remain unacceptable, it may be appropriate to contact the responsible medical physicist for further advice on implementing the recommendation listed below:

If these results are not achieved, the printer should be serviced to correct the problem immediately, if there is no other means for primary interpretation.

#### 7.4.1.6. Time frame for corrective action

If this test fails, do not print patient films until corrective action has been taken.

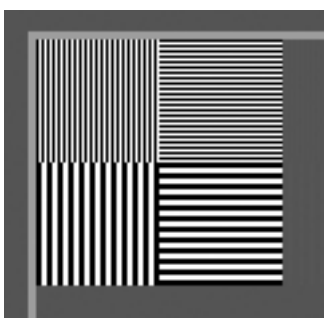


FIG. 27. Detail of horizontal and vertical line pairs from TG18-QC test pattern.

## 7.4.2. Repeat image analysis

### 7.4.2.1. Scope

- Objective: To determine the number and cause of repeated digital mammograms. Analysis of these data should help to identify ways to improve system performance and to reduce digital image repeats, associated increased patient dose and costs.
- Frequency: At least quarterly. For the repeat rates to be meaningful, a volume of at least 250 clinical examinations is needed, if possible.

*Note:* The analysis is carried out for each individual acquisition unit, rather than for the combined facility as is done in screen film mammography.

### 7.4.2.2. Instrumentation

- (1) Chart showing the digital mammography repeat records (see, e.g., Fig. 28 and Chart 13(a) in Annex I) or repeat log obtained from the acquisition workstation, provided it complies with the guidance in this publication.
- (2) Chart for performing the quarterly digital mammography repeat analysis (see, e.g., Fig. 29 and Chart 13(b) in Annex I).
- (3) Method for counting or estimating the total number of clinical images acquired during the test period.

*Note:* A repeated image is one that is taken for reasons of inadequate quality. It does not include additional views required to image selected tissue seen on the first image. It also does not include images taken for the purposes of including tissue that could not be positioned on the image receptor due to the size of the breast. Images performed for QC purposes are also excluded from repeat analysis.

Repeated images include those that are rejected at the acquisition workstation and those that are aborted before the exposure is complete. Causes of repeated exposures include problems with positioning, blurred images due to patient motion, detector under- or overexposure, unacceptable artefacts, X ray equipment failures (such as generator faults), software failures (such as the acquisition software freezing or crashing), blank images, no image appearing on the acquisition workstation although an exposure was made and other miscellaneous problems.

### 7.4.2.3. Methodology

- (1) Record each repeated exposure on the repeat record chart (Chart 13(a) in Annex I), entering the cause of repeated exposure, date, etc. Some acquisition systems and some PACSs allow for automated logging of the causes of repeated exposures. This may be an acceptable means of recording the majority of repeats, provided that the log can be easily retrieved for any specified date range and that the stated causes of repeats make up a complete list. Note that repeated exposures taken on a different date (i.e. because the radiologist remarked that the image was blurred) may not be logged by such software, and thus it is recommended that a chart be maintained for such repeats, even if repeat logging software is used.

*Note:* A 'blank image' occurs when an exposure is made and all the pixels in the resulting image file have the same value such that the image displayed is all one shade. 'No image' occurs when an exposure is made and no image at all appears on the screen — there is no image file and no digital record of the exposure exists.

- (2) At the end of each quarter, use the repeat analysis form (Chart 13(b) in Annex I) to summarize the number of repeats in each category.

## RECORD OF DIGITAL MAMMOGRAPHY REPEATS

Facility: ABC Room: 1 Unit: Novation DR  
 Date from: 1 Oct 2010 Date to: 31 Dec 2010

				Repeat initiated by	
Study #	Cause	Frequency	Date	Physician	Radiographer
1234	1	1	2/10	4	
1561	2	2	4/10		4
1345	4	1	7/10		4
1392	1	1	11/10	4	

### Causes

1. Positioning
2. Patient motion
3. Improper detector exposure
4. Artefact
5. X ray equipment failure
6. Software failure
7. Blank image
8. No image
9. Other

*FIG. 28. Sample digital repeat chart. Data shown here are for illustrative purposes only.*

- (3) Estimate the number of clinical exposures taken during the quarter. This can be done by subtracting the patient number at the beginning of the quarter from the patient number at the end of the quarter and multiplying by the average number of images per patient (typically 4–5). This method assumes sequential numbering of all patients. It may also be possible to obtain the number of exposures from a log maintained by the acquisition workstation (this varies with manufacturer and model). Be sure *not* to include images taken for QC purposes.
- (4) Calculate the overall repeat rate as the total number of repeated exposures divided by the total number of patient exposures during the analysis period, multiplied by 100.
- (5) Determine the percentage of repeated exposures in each category by dividing the number of repeated exposures in that category by the total number of repeated exposures from all categories and multiply by 100.
- (6) Record completion of the repeat analysis on the monthly, quarterly and semi-annual chart (Chart 2 in Annex I).

## QUARTERLY DIGITAL MAMMOGRAPHY REPEAT ANALYSIS

Facility: ABC Room: 1 Unit: Novation DR

Date from: 1 Oct 2010 Date to: 31 Dec 2010

**Total exposures in quarter:**

<b>1201</b>
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	Cause	Number of repeat exposures	Percentage of repeats
1	Positioning	12	38.7
2	Patient motion	8	25.8
3	Improper detector exposure	4	12.9
4	Artefact	2	6.5
5	X ray equipment failure	0	0.0
6	Software failure	1	3.2
7	Blank image	1	3.2
8	No image	0	0.0
9	Other	3	9.7
<b>Total #</b>		<b>31</b>	<b>Repeat rate (%)</b>
Repeat exposures (sum of 1 through 9)		31	2.6

**Corrective actions:** \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

*FIG. 29. Sample repeat analysis chart. Data shown here are for illustrative purposes only.*

### 7.4.2.4. Precautions and caveats

- (1) All images that are repeated should be included in the repeat analysis, not just those that the radiologist asked to have repeated. Some facilities may keep repeated images in the patient study along with good images rather than rejecting them. These repeated images should be included in the repeat analysis.
- (2) At a minimum, the repeat analysis must be done at least quarterly. This process of reviewing the rejected images provides radiographers with educational benefits. Many facilities with higher workloads choose to conduct a repeat analysis monthly.

- (3) Including examinations of at least 250 patients (approximately 1000 exposures) allows reasonable statistics for the analysis. Collecting rejected images from a larger number of patients is encouraged because doing so will yield more reliable data when evaluating causes for repeats.
- (4) Facilities that do not examine 250 patients in a quarter should still assess repeat images at least quarterly to determine the primary causes of repeated images and reap the educational benefits of the process.
- (5) There is a real danger that radiographers may alter their routine procedures or criteria for accepting images if they know their repeated images will be analysed. This can be avoided by preserving the anonymity of the individual radiographers.

#### *7.4.2.5. Tolerances*

- (1) Acceptable repeat rate: <5%.
- (2) Achievable repeat rate:  $\leq 2\%$ .
- (3) Must be based on an image volume of at least 250 patients to be meaningful.

#### *7.4.2.6. Recommendations and corrective action*

- (1) If the repeat rate exceeds the selected acceptable level or if the repeat rate changes from the previously measured rate by more than 2%, the change should be investigated and corrective action taken, if necessary. For example, if the previous repeat rate was 1.8% and the new repeat rate is 4.2%, the follow-up described above is required. On the other hand, a very low repeat rate (e.g. below 0.5%) may indicate that the radiologists are accepting/interpreting substandard images for the sake of expediency, since there will always be some patients for whom positioning the breast and obtaining a proper exposure is quite difficult.
- (2) Repeat rates that are either extremely high or extremely low may indicate that the facility is not investing adequate resources in training, equipment or QC.
- (3) Any corrective actions should be recorded on the bottom of the repeat analysis chart (see Fig. 29). In addition, the impact of the corrective actions should be assessed by examining the results of subsequent repeat analyses.
- (4) If the primary cause of excessive repeated exposures is an equipment or detector problem, the problem should be brought to the attention of the service engineer.
- (5) If the primary cause of excessive repeated exposures is a positioning or other motion problem, corrective actions such as additional training on positioning and compression should be taken. These actions are most successful if they are not treated in a punitive manner.

#### *7.4.2.7. Time frame for corrective action*

Corrective action must be taken within 30 days of the repeat analysis date.

### **7.4.3. Spatial resolution test (CR and scanning systems)**

#### *7.4.3.1. Scope*

Blurring of the digital mammogram can impair the detectability of key structures within the breast. The medical physicist will perform a sophisticated resolution test when the system is commissioned and annually thereafter. For some types of digital mammography system, spatial resolution is unlikely to vary significantly between these tests. For systems that incorporate mechanical scanning operations during image acquisition (including CR systems), there is greater potential for the spatial resolution to change. If the equipment manufacturer provides an MTF or spatial resolution test for the radiographer, this could be performed. Otherwise, the radiographer should consult the medical physicist to determine whether a suitable alternative approach is available for the system. Since this test is a constancy check, a measurement of effective resolution may be taken with the test object on the breast support plate (detector changes only) or 4.5 cm above the breast support plate (complete system).

- Objective: To verify that spatial resolution has not deteriorated.
- Frequency: Quarterly and after service of system components (scanning mechanism or CR plate reader) that could affect resolution.

#### *7.4.3.2. Methodology*

- (1) Follow the instructions provided for the manufacturer's test or for the test provided by the on-site medical physicist.
- (2) Record the test outcome on the monthly, quarterly and semi-annual checklist (Chart 2 in Annex I).

#### *7.4.3.3. Recommendations and corrective actions*

- (1) If the measured resolution is below the baseline value, the test should be repeated; if there is still a problem, the unit should be serviced.



## 7.5. SEMI-ANNUAL TESTS

### 7.5.1. Computed radiography plate sensitivity matching and plate artefacts

#### 7.5.1.1. Scope

- Objective: To confirm uniformity in the sensitivity of the CR plates used in mammography; to determine the presence of plate related artefacts.
- Minimum frequency: Semi-annually and after service to the CR reader that might affect its efficiency.

#### 7.5.1.2. Instrumentation

- (1) All plates used routinely in the mammography service.
- (2) Slab of PMMA with uniform thickness, preferably large enough to cover the entire image receptor, such as that used for the weekly tests described in Section 7.2.3.

#### 7.5.1.3. Methodology

- (1) Select all plates to be evaluated.
- (2) For each plate, record the plate number and the condition of the cassette latches on the plate sensitivity matching and plate artefacts chart (Chart 14 in Annex I).
- (3) Place the PMMA slab on the breast support of the mammography unit, ensuring that the AEC sensors are covered. It is also necessary to ensure that the sensors are under the central part of the slab.
- (4) The exposure should preferably be carried out with the AEC. If the equipment does not have an AEC, select the technique factors manually (and use the same for all cassettes). These factors should be those clinically used to obtain images of a breast corresponding to the test object. Make the exposure and record the factors (AEC mode and settings, anode, filter, kV, mAs) used to make the exposure of each cassette on the data collection sheet.
- (5) Process the plate after a constant time delay (say, 30 seconds), to minimize the impact of latent image fading, using the same menu choices and image processing for each plate (see Table 6).
- (6) Record the EI and mAs used for each cassette. Note the result on Chart 14 in Annex I.
- (7) Repeat steps 4 through 6 for all plates.
- (8) Calculate the mean value of the EI and mAs for all plates of the same size.
- (9) For each plate, determine the difference and the percentage difference between the mAs for that plate and the relevant mean value.
- (10) For each plate, determine the difference and the percentage difference between the EI for that plate and the relevant mean value.
- (11) If two plate sizes are used, determine the difference and percentage difference between the mean EIs for the two plate sizes.
- (12) View each image on the acquisition workstation and inspect (using a narrow window setting, as advised by the medical physicist) for significant artefacts (signs of scratches, scrapes, dents, etc.).
- (13) Record the presence or absence of significant artefacts on Chart 14 in Annex I.
- (14) Note the outcome of the task on the monthly, quarterly and semi-annual checklist (Chart 2 in Annex I).

#### 7.5.1.4. Interpretation of results and conclusions

The tolerances for the exposure index for CR plates are given in Table 9. In addition to the specific tolerances outlined in Table 9:

- (1) There should be no significant artefacts due to damage to or deterioration of individual plates.
- (2) Typically, the mAs used for a particular plate should be within  $\pm 5\%$  of the mean value for plates of the same size.

TABLE 9. TOLERANCES FOR EXPOSURE INDEX FOR CR PLATES<sup>a</sup>

Basic tolerance	Tolerance in terms of CR exposure index		
	Fuji, Konica, Philips	Carestream	Agfa
Variation among plates of the same size	S# for individual plates within $\pm 5\%$ of mean for same size	EI for individual plates within $\pm 20$ units of mean for same size	SAL/SALlog/PVIllog for individual plates within $\pm 2.5\%/\pm 200/\pm 290$ of mean for same size
Variation between plate sizes	S# difference for two different plate sizes $< 20\%$	EI difference for two different plate sizes $< 80$ units	SAL/SALlog/PVIllog difference for two different plate sizes $\pm 10\%/\pm 900/\pm 1200$

**Note:** This test assumes that the AEC is stable and operating properly. AEC performance can be demonstrated by performing this test several times with the same cassette.

<sup>a</sup> Tolerance is based on a variation in dose of 5% and 20%, respectively.

- (3) The difference between the mean mAs used for the large plate sizes and that used for small plate sizes should be no more than 20% of the lower value.

#### 7.5.1.5. Recommendations and corrective actions

- (1) Those plates that do not perform within acceptable tolerances should be removed from clinical use.
- (2) Plates with significant artefacts that cannot be removed by cleaning should be replaced. Note that CR plates have a limited life expectancy and should be regularly replaced.

## 8. MEDICAL PHYSICIST'S QUALITY CONTROL TESTS

Table 10 lists the QC tests to be performed by the medical physicist. In addition to the frequencies outlined in the table, all tests should be performed at commissioning (i.e. before the equipment is initially used to image patients). The tests do not necessarily have to be performed in the order in which they appear in this publication. The preferred order will depend on various factors relating to the mammography facility as well as the medical physicist's preferences, always bearing in mind that there exist tests whose results affect the execution of other tests. In some cases, the medical physicist may also be responsible for performing some of the tests described in the section on radiographer's tests (Section 7). Data collection sheets can be found in Annex II and are also available in electronic format, along with other information relevant to physics testing of digital mammography, on the IAEA web site at: <http://humanhealth.iaea.org>

For many of the tests, it is useful to carry out the analysis of images on a separate computer. For this purpose, it is desirable that test images be exported from the digital mammography system in the DICOM 'for processing' format. In addition, to facilitate testing of the soft copy and hard copy displays, it is desirable to be able to import test images to the digital mammography system in a convenient manner.

TABLE 10. MEDICAL PHYSICIST'S QUALITY CONTROL TESTS

Test	Priority <sup>a</sup>	Suggested frequency	Tolerances
<i>Mammography unit assembly</i>			
Mammography unit assembly evaluation	E	Annually (E) Semi-annually (D)	See Section 8.2.1.4
<i>Compression</i>			
Compression force and thickness accuracy	E	Annually (E) Semi-annually (D)	Powered: 150 to $\leq 200$ N; Manual: $\leq 300$ N See also Section 8.3.1.4
<i>AEC evaluation</i>			
Site technique factors for SDNR (radiographer baseline)	E	At commissioning and after changes to AEC software	Not applicable
AEC evaluation	E	Annually or after changes to AEC software	See Section 8.4.2.4
<i>Detector performance</i>			
Baseline detector performance	E	At commissioning and after detector change	Not applicable
Detector response and noise	E	Annually and after detector service	See Section 8.5.2.4
Spatial linearity and geometric distortion of the detector	E	Annually and after detector change	See Section 8.5.3.4
Detector ghosting	E	Annually and after detector change	Ghost image SDNR $\leq 2.0$
Detector uniformity and artefact evaluation	E	Annually and after detector change, etc.	See Section 8.5.5.4

TABLE 10. MEDICAL PHYSICIST'S QUALITY CONTROL TESTS (cont.)

Test	Priority <sup>a</sup>	Suggested frequency	Tolerances
<i>Evaluation of system resolution</i>			
Modulation transfer function	E	Annually and after detector change, etc.	See Section 8.6.1.4
Limiting spatial resolution	E	Annually and after detector change, etc.	See Section 8.6.2.4
<i>X ray equipment characteristics</i>			
Half value layer	E	Annually and after X ray tube change	See Section 8.7.1.5
Incident air kerma at the entrance surface of PMMA slabs	E	Annually and after X ray tube change	Not applicable
<i>Dosimetry</i>			
Mean glandular dose ( $D_G$ )	E	Annually	See Section 8.8.1.4
<i>Collimation system</i>			
Radiation field/image receptor coincidence	E	Annually and after X ray tube service/replacement	See Section 8.9.1.4
Compression paddle/breast support alignment	E	Annually and after X ray tube service/replacement	Acceptable: Paddle not visible in image and edge of paddle $\leq 5$ mm beyond chest wall edge
Missing tissue at chest wall	E	Annually and after X ray tube service/replacement	Achievable: $\leq 5$ mm Acceptable: $\leq 7$ mm
<i>Image display quality</i>			
Artefacts and uniformity (soft copy)	E	Annually	See Section 8.10.1.5
	D	Semi-annually	
Monitor luminance response and viewing conditions	E	Annually and after monitor service	See Section 8.10.2.5, Table 22
Viewbox luminance and viewing conditions	E	Annually	See Section 8.10.3.5
<i>Laser printer (where applicable)</i>			
Artefacts and uniformity	E	Annually	See Section 8.11.1.4
	D	Semi-annually	
Film densities	E	Annually	See Section 8.11.1.4
<i>Image quality</i>			
Phantom image quality	E	Annually	See Section 8.12.1.4

<sup>a</sup> E — essential, basic requirement; D — desirable.

## 8.1. NOTE ON IMAGE NAMING CONVENTION

When producing images for QC purposes, it is important that the images can be easily identified and retrieved. In most cases, it is necessary to perform test measurements on images that are in the DICOM 'for processing' format. It will often be necessary to obtain these images by exporting them from the acquisition unit, since the majority of systems are configured to send the processed ('for presentation') images to the PACS. Images on some acquisition workstations are identified only by their DICOM name, which makes it difficult or impossible to recognize to which test they correspond. To avoid such difficulties, it is sometimes useful to store each test individually as a different 'patient'. Some tests require multiple images to be produced. It is therefore important that within each 'patient' test, individual images are also identified (this can be done using radiographic numbers or by recording the real time of the acquisition image). In other systems the images are stored sequentially, despite the fact that the test has been named, so care has to be taken to avoid analysis of the wrong image. Not all systems store images in the DICOM format at the acquisition workstation. To open such images in order to analyse them with other software, the user must know the exact matrix size for each system (see Table 2). Manufacturers are encouraged to provide a method for exporting 'for processing' images in the DICOM format [23].

Where systems permit sending the unprocessed images directly to the PACS, the images should be identified by the PACS as 'non-patient' studies. This can be accomplished by adopting a distinctive and meaningful naming convention. Normally it is most convenient to conduct testing in the same manner as patient imaging would be done; therefore, it may be helpful to identify QC images in a manner analogous to that used for patients, where a family name, given name and other ID information must be provided. An optional naming convention that may be convenient uses 'Physics' as the family name, the name of the test as the given name and a unique 'patient ID number' that contains the date on which the tests were performed; for example, for the AEC thickness tracking test — last name 'Physics', first name 'Thickness' and patient ID number '9903YYMMDD'. As an alternative, the images can all be collected as one patient study and analysed in the sequence collected. In this case, the first name could be 'Test'.

## 8.2. MAMMOGRAPHY UNIT ASSEMBLY

### 8.2.1. Mammography unit assembly evaluation

#### 8.2.1.1. Scope

The mammography system contains many mechanical components. These are subject to wear or degradation over time, resulting in possible safety or performance problems. Therefore, they must be checked on a regular basis. It is also essential that the examination parameters be recorded correctly in the digital image file. For digital mammography, an appropriately populated DICOM header complies with this labelling requirement.

- Objective: To ensure that all locks, detents, angulation indicators and mechanical support devices for the X ray tube and breast support assembly are operating properly, and that the DICOM image file headers are correctly populated.
- Frequency: Semi-annually is desirable; annually is essential.

#### 8.2.1.2. Instrumentation

Thermometer, preferably mounted on the wall of the digital mammography room.

#### 8.2.1.3. Methodology

- (1) Measure the temperature in the mammography acquisition room.
- (2) Verify that the freestanding dedicated mammography unit is mechanically stable under normal operating conditions.
- (3) Visually inspect the unit for loose parts, cracks in the compression paddles, Bucky cleanliness and overall integrity.
- (4) Check that all hoses and cables are free of breaks, crimps and knots. Hoses and cables should not be located under heavy equipment.
- (5) Verify that all moving parts move smoothly, without undue friction; that cushions or bumpers appropriately limit the range of available motion; and that no obstructions hinder the full range of motion within these limits.
- (6) Set and test each lock and detent independently to ensure that mechanical motion is prevented when the lock or detent is set.
- (7) Verify that angulation indicators function correctly.
- (8) Verify that the image receptor assembly is free of wobble and vibration during normal operation.
- (9) Verify that the CR cassette slides smoothly into the holder assembly and is held securely in any orientation (for CR operation only).
- (10) Verify that it is possible to override the auto-decompression function so that compression can be maintained (for procedures such as needle localizations) and that its status is displayed continuously (if auto-decompression is available).
- (11) Verify that compression can be manually released in the event of a power failure or automatic release failure. This verification can be done by reference to type testing data for the same model. (In the type testing, the power supply to the equipment would be turned off with a phantom under compression and the manual compression control would then be used to release the compression.)
- (12) Verify that in normal operation, the patient and operator are not exposed to sharp or rough edges or other hazards, including electrical hazards.
- (13) Verify that all panel switches, indicator lights and meters are working properly.
- (14) Verify that the operator is protected by adequate radiation shielding during exposure.
- (15) Verify that current and accurate exposure technique charts are posted and confirmed by consulting with the radiographer.

- (16) On any randomly selected patient image, verify that displayed and/or printed images contain the correct institution name and address, unit number (if there is more than one on the site), patient name, patient ID number, radiographer's initials, projection, laterality, and technique factors, and that the time of image acquisition and the date are correct (note that after software upgrades, the stored time zone or other data may have inadvertently been changed and be incorrect). This can be accomplished by looking at the information included with the image on the review workstation, by inspecting printed films, if available, or by looking at the contents of the DICOM header of an image with appropriate analysis software. Record that the values of displayed information are complete or note necessary changes on the unit assembly evaluation chart (Chart 1 in Annex II).
- (17) Record a 'pass' or 'fail' of each inspection item on the data collection chart.

#### *8.2.1.4. Recommendations and corrective action*

- (1) Room temperature should be in the range recommended by the manufacturer. If the radiographer indicates that the temperature sometimes falls outside this range, a monitoring programme should be established to prevent premature failure of the equipment.
- (2) The digital mammography unit must be safely installed and must present no undue hazards.
- (3) Items that are hazardous or inoperative, or that operate improperly should be repaired by appropriate service personnel.

#### *8.2.1.5. Time frame for corrective action*

- (1) If the room temperature is not in the range recommended by the manufacturer, the heating/ventilating/air conditioning service personnel should be called immediately.
- (2) For all items in Section 8.2.1.3 except items 5 and 7, corrective action must be taken immediately, before any further patients are imaged. For items 5 and 7, corrective action must be taken within 30 days of the test date.

## 8.3. COMPRESSION

### 8.3.1. Compression force and thickness accuracy

Adequate compression is essential for high quality mammography. Compression reduces the thickness of tissue that must be penetrated by radiation, thereby reducing scattered radiation and increasing contrast, while reducing radiation exposure to the breast. Compression improves image sharpness by reducing the breast thickness, thereby minimizing focal spot blurring of structures in the image, and by minimizing patient motion. In addition, compression makes the thickness of the breast more uniform, resulting in more uniform image densities and in an image that may be easier to interpret. The displayed compressed breast thickness is often used to choose the technique factors, so it is important that this level of accuracy be achieved.

#### 8.3.1.1. Scope

- Objective: To check that the mammography system provides adequate compression in manual and automatic mode; to check the accuracy of the compression force indicator, if present on the equipment; to check the accuracy (or deviation) of the compression thickness indicator.
- Frequency: Desirable — semi-annually; essential — annually, or if there is an observed reduction in the breast compression.

#### 8.3.1.2. Instrumentation

- (1) Bathroom scales (conventional, analogue type, non-digital).
- (2) Bath towels (cloths) or blocks of rubber foam.
- (3) Slabs of PMMA used for AEC testing.

#### 8.3.1.3. Methodology

##### (a) Power compression mode

- (1) Place a bath towel on the Bucky and place the platform scale over it. Centre the scale directly under the compression paddle (Fig. 30).
- (2) Place one or more towels (or a block of rubber foam) on the scale to protect the compression paddle such that it does not obscure the reading on the scale.
- (3) Activate the compression paddle so that it operates and stops at the maximum available powered force. This may require a second activation of the compression foot pedal.
- (4) Read the value of the compression force on both the scale and the machine readout and record this in the compression–AEC evaluation chart (Chart 2 in Annex II).
- (5) Release the compression.

##### (b) Manual mode

- (1) Using the manual compression mode, move the compression paddle until it stops.
- (2) Read and record the compression force on the data collection sheet.
- (3) Release the compression.

##### (c) Compression thickness

- (1) Align the PMMA blocks (20, 45 and 70 mm) with the chest wall edge of the breast support platform. Ideally, 18 cm × 24 cm slabs of PMMA should be used, to prevent deformation of the plate and reduce measurement inaccuracies in the indication of thickness due to the tilt angle of the plate.





FIG. 30. Positioning of bathroom scale to perform compression force measurement.

- (2) In some systems, the breast thickness indicator is calibrated by the manufacturer, taking into account the tilt of the compression plate. In this case, the actual dimension of the PMMA slabs should allow the paddle to tilt during testing. Special care should be taken not to compress too much, since when this tilting occurs, the greater the compression force is, the higher the indicated PMMA thickness will be.
- (3) Apply a compression force used in the clinical setting (e.g. 80 N). Record the force value. Once the applied force for this measurement has been established, the same force should be used for all subsequent measurements.
- (4) Compare the displayed thickness value with the actual thickness of the slab.
- (5) On systems where the radiographic factors (automatically selected by the system) depend on the compressed thickness, repeat the measurements in magnification mode.

#### 8.3.1.4. Interpretation of results and conclusions

Tolerances:

- (1) Maximum compression force for *powered* compression: no less than 150 N and no greater than 200 N.
- (2) Maximum *manual* compression force: less than 300 N.
- (3) Displayed value accuracy:  $\pm 20$  N.
- (4) Acceptable: Displayed thickness within  $\pm 8$  mm of slab thickness.
- (5) Achievable: Displayed thickness within  $\pm 5$  mm of slab thickness.

#### 8.3.1.5. Recommendations and corrective action

If the measured values from these tests are outside the tolerance, the compression device should be calibrated by a qualified service engineer.

#### 8.3.1.6. Time frame for corrective action

If the force measurement is outside the tolerance, the problem should be corrected immediately, before any further patients are imaged. If the thickness indication is outside the tolerance, the problem should be corrected at the next regular servicing.

## 8.4. AEC EVALUATION

### 8.4.1. Site technique factors for SDNR (radiographer baseline)

#### 8.4.1.1. Scope

- Objective: To establish the baseline technique factors to be used by the site for the weekly SDNR check.
- Frequency: Annually and when updates or changes have been made to AEC control software.

#### 8.4.1.2. Instrumentation

- (1) The 45 mm thick PMMA test object that is used by the facility for the weekly test image.
- (2) The contrast object used by the facility.
- (3) A spacer is not used unless the facility uses a spacer.

#### 8.4.1.3. Methodology

- (1) Place the test object on the breast support centred laterally and aligned with the chest wall edge of the digital image receptor.
- (2) Place the contrast object about 40 mm from the chest wall, on the centre line of the image detector.
- (3) Apply the compression force typically used clinically (e.g. 80 N)<sup>9</sup>. Record the compression force used and the thickness indicated on the radiographer baselines and summary chart (Chart 3 in Annex II), where they will be used to provide a baseline for the radiographer's routine phantom test (Chart 7(a) in Annex I) in which the SDNR is measured.
- (4) If there is a separate AEC sensor, it is desirable that it not be directly under the contrast object. The sensor should be in the same position every time the test is performed.
- (5) Acquire an image using the same technique settings that the facility would use for a clinical exposure of a standard breast. Normally this is achieved by using the automatic exposure mode. Otherwise, select the appropriate target, filter, kV, grid, density control position and operating mode (semiautomatic or automatic). The DICOM 'for presentation' image format should be used for this test (see Section 2.3.7.2). For all tests of CR systems, the systems should be set to the modes indicated in Table 11. There should be a reasonably consistent delay between exposure and image plate readout to avoid introducing variation in the EI.

TABLE 11. SETTINGS AND EXPOSURE INDICES FOR TESTING CR SYSTEMS

Manufacturer/system	Mode setting	Exposure index
Fuji	QC Test/Sensitivity Semi	S#
Philips	QC Test/Sensitivity Semi	S#
Agfa	Systems diagnostic/flat field mammo	SAL/SALlog/PVIllog <sup>a</sup>
Carestream	Others/pattern	EI
Konica	Mammo/Test	S#

<sup>a</sup> Depending on the workstation, its configuration and the plate digitizer used.

<sup>9</sup> The actual force should be similar to the typical value used clinically, but the *same* value should be used for all testing. Note that in some systems and in some modes of operation, the compressed breast thickness is utilized in an automated algorithm to determine the technique factors; this thickness is, in turn, dependent on the degree of compression applied.

- (6) The target, filter, kV, grid, density control position and operation mode for imaging the 45 mm test object should be entered into Chart 3 in Annex II.
- (7) If patient images are interpreted in soft copy, view the 'for presentation' image of the flat field phantom taken as per the steps above on the radiologist display workstation. Window width choice should be based on what is appropriate for or typical of breast images or a phantom with breast-like features. The level should be set so that the background of the phantom is dark grey and the 1 mm thick contrast disc is light grey, but not pure white. There should be noise visible in both areas (indicating that those regions are not saturated or clipped). Record the window width and window level on the radiographer baselines and summary chart (Chart 3 in Annex II).
- (8) With the same window width and window level as used above, evaluate the entire image for overall appearance and for artefacts. Examine the entire image for broad area artefacts such as non-uniformities, blotches and streaks, and for detailed artefacts such as black or white pixels, clusters of pixels, lines or specks. Broad area artefacts are typically best seen while observing the phantom image as a whole, not piecewise. Detailed artefacts are typically best seen while observing the phantom image at full spatial resolution, where one pixel on the display matches one pixel in the image, or even in magnified form (with a magnification greater than 1.0).

*Note:* It is not necessary to view the image on all available soft copy monitors. This is a test of image acquisition, not display. Monitor performance is assessed separately.

- (9) If patient images are interpreted on hard copy, print the image using the window width and window level that would be used for a patient image. Record the window width and window level used on the radiographer baselines and summary chart (Chart 3 in Annex II). Record whether the phantom image was evaluated on hard copy (H), soft copy (S) or both (B).
- (10) View the image on a mammographic quality viewbox, preferably the one used by the radiologist. Evaluate the entire phantom image for artefacts, using the method described in step 8. (For CR systems, see also Section 7.1.4.3.)

#### 8.4.1.4. Interpretation of results

- (1) There should be no blotches or regions of altered texture appearance.
- (2) There should be no observable lines or structural artefacts.
- (3) There should be no 'bright' or 'dark' pixels evident.

#### 8.4.1.5. Recommendations and corrective action

If any artefacts are visible that might mimic or obscure anatomic information, or if any patterns are seen, a recalibration or flat fielding of the digital detector may be needed for DX systems. The compression plate and all accessible surfaces that are in the imaging field should be cleaned to remove any debris or extraneous material. After this has been done, repeat the test. If artefacts persist, contact the authorized service representative.

#### 8.4.1.6. Time frame for corrective action

Immediately: If this test fails, do not image patients until corrective action has been taken.

## 8.4.2. AEC evaluation

### 8.4.2.1. Scope

- Objective: To evaluate the ability of the system to image a clinically expected range of breast thicknesses and to ensure that images of adequate penetration and acceptable SDNR levels are produced; to determine the imaging technique factors required for the estimation of MGD.
- Frequency: Annually and when updates or changes have been made to AEC control software.

### 8.4.2.2. Instrumentation

- (1) Three slabs of PMMA: one 20 mm thick and two 25 mm thick. A semicircle 18–20 cm in diameter is the optimum phantom so that AEC systems with breast edge detection operate properly. For other systems, uniform slabs of at least 18 cm × 24 cm<sup>10</sup> will enable artefact analysis as well.
- (2) Contrast object. This can be a 1 mm thick, 25 mm diameter depression in the PMMA slab (the depression must have a flat, smooth bottom); a 1 mm thick, 25 mm diameter PMMA disc; or a 0.2 mm thick square of aluminium, 10 mm on a side.
- (3) Appropriate spacers (e.g. radiolucent U shaped rigid expanded polystyrene of the thicknesses given in Table 12, to set the compression paddle position). These spacers are required to simulate breast thicknesses for dosimetry purposes and to test the AEC (45 mm of PMMA plus an 8 mm spacer simulates a ‘standard’ breast, 53 mm thick, while a 70 mm thick PMMA disc plus a 20 mm thick spacer simulates a 90 mm thick ‘large’ breast of typical composition [48]).

### 8.4.2.3. Methodology

For all tests of CR systems, the systems should be set to the modes indicated in Table 11 and the applicable EIs given in that table should be recorded.

#### (a) Thickness behaviour

- (1) Create a ‘physics’ study with an appropriate name, with the images saved in a ‘for processing’ format. Any pre-processing algorithm other than flat field or shading (e.g. Fineview<sup>TM</sup> on GE systems) should be turned off, if this is possible. It is important that the acquired image be saved in a ‘raw’, ‘unprocessed’ or DICOM ‘for processing’ format. It may be necessary to close the study used for acquiring other images and open a new one after turning off pre-processing.

TABLE 12. SPACER THICKNESS REQUIRED TO MATCH PMMA THICKNESS TO A BREAST OF EQUIVALENT THICKNESS

Breast type	Equivalent breast thickness (mm)	PMMA thickness (mm)	Spacer thickness (mm)
Thin	21	20	0
Standard	53	45	8
Thick	90	70	20

<sup>10</sup> For the artefact test (see Section 8.5.5), one of these slabs should be large enough to cover the entire area of the detector. Alternatively, a slab provided by the equipment manufacturer can be used for this purpose.

- (2) Stack the 20 and 25 mm PMMA slabs, or use a 45 mm full field uniform phantom on the breast support platform. Place the contrast disc or square on the upper surface<sup>11</sup> such that the contrast object lies on the centre line of the breast support, approximately 40 mm from the chest wall edge, as shown in Fig. 23. Ensure that the front edge of the PMMA slab extends slightly (a few mm) beyond the chest wall edge of the breast support. Use collimation that allows the full detector area to be exposed.
- (3) Place the 8 mm spacer on top of the phantom.
- (4) Lower the compression plate and apply the compression force typically used clinically (e.g. 80 N)<sup>12</sup>.
- (5) If the AEC detector location can be adjusted, it should be placed within 1 cm of the chest wall.
- (6) Choose the exposure mode used clinically. On initial commissioning, all available automatic modes should be tested. For systems that are not fully automatic, set the AEC or kV, target and filter to the appropriate technique for the equivalent breast thickness in Table 12.
- (7) Make one exposure and record the kV, target, filter and  $mAs_{AEC}$  on the compression–AEC evaluation chart (Chart 2 in Annex II) and on the detector performance chart (Chart 5 in Annex II), where they are used to determine the reference technique. These exposure factors are required to determine the incident air kerma (see Section 8.7.2), which in turn is used to calculate the MGD.
- (8) Leaving the contrast disc or square in the same location, make exposures using the AEC, using 20 mm and 70 mm total thickness of PMMA. Each time, place the appropriate spacer above the uppermost slab (see Table 11).<sup>13</sup>
- (9) Either display the images in the ‘for processing’ format on a workstation equipped with analytical tools (ROI, mean, standard deviation) or download the ‘for processing’ images to a separate computer for analysis.
- (10) View the unprocessed images taken at the three thicknesses with the image displayed so that the contrast object is clearly visible (see Fig. 24).
- (11) According to the contrast object used, place a circular or square ROI approximately  $0.8 \text{ cm}^2$  in area (~1 cm in diameter) over and entirely contained within the contrast object area. For the aluminium square, an ROI of  $45 \text{ mm}^2$  (7.5 mm in diameter) can be used. Use the same size ROI (or as close to it as possible) each time (for further information on the choice of ROI size, see Ref. [49]). For CR systems, which might not apply any flat fielding, non-uniformity in the direction parallel to the chest wall could produce significant variations of the SDNR values, depending on the position chosen for the contrast object (if it is not embedded in the PMMA) and the distance between the measurement ROIs. This could be misinterpreted as a fluctuation of the mammography unit.
- (12) Measure the MPV, recording it as  $A$ .
- (13) Choose an ROI located just beside the contrast object, and measure the background MPV,  $B$ , and the background standard deviation,  $C$ .
- (14) Enter the results into the compression–AEC evaluation chart (Chart 2 in Annex II) and the radiographer baselines and summary chart (Chart 3 in Annex II), if applicable.
- (15) Calculate the SDNR as:

$$SDNR = |A-B|/C \quad (1)$$

- (16) For a system equipped with multiple dose modes, at commissioning the above procedure should be repeated for each of the applicable modes, recording the SDNR in each case.
- (17) For the 45 and 70 mm exposures, determine the exposure time either by direct measurement or by dividing the mAs required for the exposure by the mAs from the manufacturer’s technical information for the system.

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<sup>11</sup> For consistency of positioning and to avoid loss, it is convenient to mount the contrast object on the surface of the 20 mm thick slab.

<sup>12</sup> The actual force should be similar to the typical value used clinically, but the *same* value should be used for all testing. Note that in some systems and in some modes of operation, the compressed breast thickness is utilized in an automated algorithm to determine the technique factors; this thickness is, in turn, dependent on the degree of compression applied.

<sup>13</sup> Because the aluminium square is thin, if it is used it can be placed directly on the 20 mm slab and additional slabs can be successively placed over it during the test.

(b) Testing of density control (if applicable) and/or dose selection mode

Some digital units and all CR systems are used with X ray units that have a variable 'density control'. In digital mammography, the purpose of the density control is primarily to allow control of the image noise level. Small changes are not normally perceptible. It is desirable that use of the density control will allow the radiation dose to be increased by 25–100%, and similarly decreased by 25–50%, from the '0' or 'normal' position in several steps.

- (1) Place a total thickness of 45 mm of PMMA (plus the spacer) on the breast support as described above.
- (2) For CR systems, to test the +/- density control, make exposures using the AEC. Use two density settings below the '0' or 'normal' position, one at '0' and two above it, with each setting attempting to give about a  $\pm 25\%$  variation in mAs. A total of five exposures is required for this test.
- (3) Record the density setting and the resulting mAs used to image the PMMA each time.
- (4) For DX systems, make exposures in all applicable dose modes and determine their effect on the exposure factors.
- (5) Record the dose mode setting and the resulting mAs used to image the PMMA each time.
- (6) It is not necessary to process the image after each exposure — the digital image itself will not be used. The objective is to ensure that the density setting adjusts the mAs in a reasonable manner.
- (7) Provide a copy of the radiographer baselines and summary chart (Chart 3 in Annex II) to the radiographer at the facility, to be used as a baseline for the radiographer's tests.

8.4.2.4. *Interpretation of results and conclusions*

Tolerances:

(a) Thickness behaviour

- (1) The SDNR values for images of 20, 45 and 70 mm of PMMA should exceed the acceptable values given in Table 13 for the aluminium contrast object and those given in Table 14 for the PMMA contrast object.
- (2) SDNR performance must be achieved within the current dose limitations (see Table 21).
- (3) For contact mode mammography, exposure time should not exceed 2.0 s for 45 mm and 4.0 s for 70 mm of PMMA. This does not apply to scanning systems where the dwell time at any location is much shorter than the time taken to image the entire breast.

For each thickness of PMMA, acceptable and achievable SDNR values are provided in Tables 13 and 14. These values must be regarded as provisional at this stage, and updates, as available, will be provided in the future at <http://humanhealth.iaea.org>. Regardless of what the ultimate SDNR values are, it is expected that a DX system should be able to match the achievable SDNR using a dose that is well within the current dose tolerances (see Table 21). Some CR systems may not be able to reach the achievable SDNR values without exceeding these dose tolerances. In general, greater importance should be given to achieving adequate image quality than to lowering the dose.

Caution should be exercised in interpreting the results of SDNR measurements. For all systems, it is expected that a higher SDNR corresponds to better image quality, provided the image sharpness is unchanged. Thus an increase in radiation exposure will reduce quantum noise, resulting in an increase in SDNR and better image quality if MTF is unchanged. However, an increase in SDNR may be due to a deteriorating MTF, which would result in an overall reduction in image quality. Thus SDNR is not on its own a reliable measure of image quality but is an easy to measure parameter that is a sensitive indicator of changes that relate to image quality. Therefore any *change* in SDNR needs to be investigated to understand its cause.

TABLE 13. ACCEPTABLE AND ACHIEVABLE VALUES FOR SDNR USED FOR AEC EVALUATION: 0.2 mm THICK ALUMINIUM CONTRAST OBJECT<sup>a</sup>

System	PMMA thickness (mm)					
	20		45		70	
	Acceptable	Achievable	Acceptable	Achievable	Acceptable	Achievable
Agfa CR (MM3.0)	13.8	20.1	12.4	18.0	10.8	15.8
Agfa CR (HM5.0)	10.2	15.0	8.9	13.0	8.0	11.7
Fuji CR	9.8	14.2	8.8	12.8	7.7	11.2
Fuji Amulet	6.1	8.7	5.5	7.8	4.8	6.8
GE 2000D	8.9	12.9	7.9	11.5	6.9	10.0
GE DS	8.9	12.9	7.9	11.5	6.9	10.0
GE Essential	12.7	18.4	11.3	16.5	9.9	14.4
Hologic Selenia	4.8	7.0	4.3	6.3	3.8	5.5
IMS Giotto	7.8	11.3	7.0	10.1	6.1	8.8
Carestream CR (M2 plate)	9.5	13.9	8.5	12.5	7.5	10.9
Carestream CR (M3 plate)	11.7	17.0	10.2	14.8	9.1	13.3
Konica CR (RP-6M)	11.4	16.6	10.2	14.8	8.9	13.0
(RP-7M)	8.7	12.8	7.8	11.4	6.8	10.0
(CP-1M)	6.6	9.5	5.9	8.5	5.1	7.5
Planmed Nuance	6.3	9.1	5.0	7.2	4.3	6.2
Sectra D40	3.6	5.3	3.2	4.7	2.8	4.1
Sectra L30	3.6	5.3	3.2	4.7	2.8	4.1
Siemens Novation DR	5.1	7.4	4.5	6.6	4.0	5.8
Siemens Inspiration	4.4	6.3	3.9	5.7	3.4	5.0

<sup>a</sup> Source: NHSBSP technical evaluations published on [www.cancer.screening.nhs.uk](http://www.cancer.screening.nhs.uk)

TABLE 14. ACCEPTABLE AND ACHIEVABLE VALUES FOR SDNR USED FOR AEC EVALUATION: 1 mm THICK PMMA CONTRAST OBJECT

System	PMMA thickness (mm)					
	20		45		70	
	Acceptable	Achievable	Acceptable	Achievable	Acceptable	Achievable
Agfa CR (MM3.0)	5.8	8.7	5.1	7.8	4.3	6.7
Agfa CR (HM5.0) <sup>a</sup>						
Fuji CR	3.9	6.5	3.4	5.8	2.9	4.8
Fuji Amulet	2.1	3.4	1.8	2.9	1.5	2.5
GE 2000D	3.4	5.61	3.0	5.0	2.5	4.1

TABLE 14. ACCEPTABLE AND ACHIEVABLE VALUES FOR SDNR USED FOR AEC EVALUATION: 1 mm THICK PMMA CONTRAST OBJECT (cont.)

System	PMMA thickness (mm)					
	20		45		70	
	Acceptable	Achievable	Acceptable	Achievable	Acceptable	Achievable
GE DS	3.4	5.61	3.0	5.0	2.5	4.1
GE Essential	5.2	7.9	4.6	7.0	3.9	6.0
Hologic Selenia	1.5	2.6	1.3	2.2	1.0	1.8
IMS Giotto	2.9	4.6	2.6	4.0	2.1	3.4
Carestream CR (M2 plate)	3.8	5.8	3.3	5.1	2.8	4.4
Carestream CR (M3 plate) <sup>a</sup>						
Konica CR RP-6M	4.6	7.1	4.1	6.2	3.5	5.4
RP-7M	3.4	5.3	2.9	4.6	2.5	4.0
CP-1M	2.3	3.8	2.0	3.3	1.7	2.8
Planmed Nuance	1.2	2.0	1.6	2.7	2.4	3.9
Sectra D40	0.9	1.7	0.8	1.5	0.6	1.2
Sectra L30	0.9	1.7	0.8	1.5	0.6	1.2
Siemens Novation DR	1.6	2.7	1.4	2.4	1.1	2.0
Siemens Inspiration	1.3	2.2	1.1	1.9	0.9	1.6

<sup>a</sup> No data available.

(b) Density control

- (1) The density control should allow the operator to make adjustments to the mAs as large as 25–100% upward and 25–50% downward from the ‘0’ or ‘normal’ position.

8.4.2.5. *Recommendations for corrective action*

- (1) If the performance criteria for SDNR are not met, the medical physicist should determine that the performance of the detector has not changed, using the methods described in Section 8.5. If the detector is operating properly, the AEC should be adjusted or the technique chart should be revised, as required. The techniques chosen should not result in an exposure time greater than 5.0 s for 70 mm of PMMA, and the exposure time should be less than 2.5 s for a 45 mm PMMA slab. These time limits do not apply to scanning type systems.
- (2) If the density control does not provide the appropriate range of control, it should be adjusted.
- (3) If the exposure time exceeds the maximum acceptable time, the reason for low tube output should be investigated.

8.4.2.6. *Time frame for corrective action*

For Part (a), corrective action should be taken immediately, before any further patients are imaged. For Part (b), corrective action should be taken at the next regular servicing of the equipment.



## 8.5. DETECTOR PERFORMANCE

### 8.5.1. Baseline detector performance

#### 8.5.1.1. Scope

Strictly speaking, this is not a QC test, but it is required to provide baseline data to be used for subsequent testing of the detector.

- Objective: To establish baselines for the response and noise characteristics of the image acquisition system under standard radiation exposure conditions. The test will be performed rarely, but *the data sheet produced should be kept as a reference* to be compared against future measurements described in Section 8.5.2.
- Minimum frequency: At equipment commissioning and after replacement of the detector.

#### 8.5.1.2. Instrumentation

- (1) PMMA slab(s) of a total thickness of 45 mm.
- (2) Either the aluminium or the PMMA contrast object used for SDNR measurements.
- (3) Acquisition or radiologist workstation with ROI capability or QC software for image analysis. Alternatively, images may be downloaded to another computer and analysed using image analysis software.

#### 8.5.1.3. Methodology

CR systems should be set to the modes listed in Table 11, and the applicable EIs should be recorded as described in that table.

*Note:* These tests should be performed on flat fielded<sup>14</sup>, but unenhanced ('for processing') images (i.e. without peripheral or resolution enhancement). For example, GE Fineview<sup>TM</sup> must be turned *off*.

- (1) Create a 'patient' study with an appropriate name.
- (2) Place the 45 mm thick PMMA slab on the tabletop with its long edge aligned with the chest wall edge of the breast support. Use collimation that allows the full detector area to be exposed.
- (3) Place the contrast object on the upper surface of the PMMA in the location shown in Fig. 24.
- (4) Lower the compression plate so that it is in contact with the PMMA.
- (5) In AEC mode, with the radiographic grid in place, obtain an exposure and record the technique factors on the detector baseline performance chart (Chart 4 in Annex II).
- (6) In *manual mode* (with the radiographic grid in place), obtain an image with the same target-filter and kV selected by the AEC in step 5. Select the closest mAs value available for manual exposure; this is  $mAs_{ref}$ .
- (7) Also obtain images with three additional mAs values that cover the largest practical range spanning the range of reasonable mAs settings, for example, values that are one eighth and one half of, and 4 times as large as,  $mAs_{ref}$ . Once selected, these settings should be used for all future tests. These images will be used to characterize the detector response. For ease of analysis, ensure that the laterality (left or right breast) chosen for all images is the same, so that the chest wall edge will appear on the same side of the monitor in all images.
- (8) For CR systems, wait one minute before processing.
- (9) The air kerma at the entrance to the 45 mm thick PMMA phantom that would result from exposures at the four mAs values used is determined using the method described in Section 8.7.2 and should be recorded on the detector baseline performance chart (Chart 4 in Annex II).

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<sup>14</sup> Not applicable to CR images.

- (a) Systems with ROI capability (may not be available for CR systems)
- (1) For each image, with the image displayed so that the contrast object is clearly visible (see Fig. 24), place an ROI of approximately  $80 \text{ mm}^2$  (~10 mm in diameter) over, and entirely contained within, the contrast object. For the aluminium square, an ROI of  $45 \text{ mm}^2$  (7.5 mm in diameter) can be used. Record the MPV and label this value  $A$ ; it will be used to calculate the SDNR.
  - (2) In a region outside, but immediately adjacent to, the contrast object, record the MPV and standard deviation within an ROI of similar size to that used above as  $B$  and  $C$ , respectively.
  - (3) Calculate the SDNR<sup>15</sup> as:  $\text{SDNR} = |A-B|/C$ .
  - (4) For linear systems, plot the values of MPV ( $B$ ), the variance ( $C^2$ ) and SDNR versus the mAs. Perform a linear fit to the data and obtain the slope, intercept and correlation coefficients ( $R^2$ ). For logarithmic systems, it may be necessary to plot the MPV and variance against  $1/\text{mAs}$  to obtain a straight line.
  - (5) Some manufacturers intentionally add a pixel value offset to their image data. This value ( $B_0$ ) should be obtained from the manufacturer's technical documentation. Alternatively, the intercept obtained in the previous step can be used as  $B_0$ .
  - (6) Calculate the value of  $(B-B_0)/\text{mAs}$  for all values of the mAs and for the average value of this quantity.
- (b) CR systems without ROI capability
- (1) Plot the information using the axes as specified in Table 15, noting the values of the correlation coefficient ( $R^2$ ).

TABLE 15. EXPOSURE INDEX VERSUS mAs, BY MANUFACTURER

Manufacturer	X-axis	Y-axis
Fuji, Philips and Konica	mAs	$S\# \times \text{mAs}$
Agfa	$\log(\text{mAs})$	SALlog
	mAs	$\text{SAL}/\sqrt{\text{mAs}}$
	$\log(\text{mAs})$	PVIllog
Carestream	$\log(\text{mAs})$	EI

<sup>15</sup> Although CR systems are non-linear, the use of non-linearized pixel values will provide an acceptable approximation to the SDNR obtained from linearized data. Linearization is therefore not required.

## 8.5.2. Detector response and noise

### 8.5.2.1. Scope

- Objective: To measure the response and noise characteristics of the image acquisition system under standard radiation exposure conditions; to detect temporal changes in these quantities.
- Minimum frequency: Annually and after service to the detector.

### 8.5.2.2. Instrumentation

- (1) PMMA slab(s) of a total thickness of 45 mm used for AEC testing and either the aluminium or the PMMA contrast object used for SDNR measurements (Fig. 23).
- (2) Acquisition or radiologist workstation with ROI capability or QC software for image analysis. Alternatively, images can be downloaded to another computer and analysed using image analysis software.
- (3) Detector baseline performance chart (Chart 4 in Annex II).

### 8.5.2.3. Methodology

CR systems should be set to the modes listed in Table 11, and the applicable EIs should be recorded as described in the table.

*Note:* These tests should be performed on flat fielded<sup>16</sup> but unenhanced ('for processing') images (i.e. without peripheral or resolution enhancement). For example, GE Fineview<sup>TM</sup> must be turned *off*.

- (1) Create a 'patient' study with an appropriate name.
- (2) Place the 45 mm thick PMMA slab on the tabletop with its long edge aligned with the chest wall edge of the breast support. Use collimation that allows the full detector area to be exposed.
- (3) Place the contrast object on the upper surface of the PMMA.
- (4) Lower the compression plate so that it is in contact with the test object.
- (5) In *manual mode* (with the radiographic grid in place), obtain four images with different exposures according to the technique factors indicated in the detector baseline performance chart (Chart 4 in Annex II). These images will be used to characterize the detector response. For ease of analysis, ensure that the laterality (left or right breast) chosen for each image is the same, so that the chest wall edge will appear on the same side of the monitor in all images. All measured values are to be recorded on the detector performance chart (Chart 5 in Annex II).
- (6) For CR systems, wait one minute before processing.
  - (a) Systems with ROI capability (usually precludes CR systems)
    - (1) For each image, with the image displayed so that the contrast object is clearly visible (see Fig. 24), place an ROI of approximately 80 mm<sup>2</sup> (~10 mm in diameter) over, and entirely contained within, the contrast object. Record the MPV on the detector performance chart (Chart 5 in Annex II) and label this value *A*; it will be used to calculate the SDNR.
    - (2) In a region outside, but immediately adjacent to, the contrast object, record the MPV and standard deviation within an ROI of similar size to that used above as *B* and *C*, respectively. For CR systems, which frequently do not apply any equalization procedure, non-uniformity in the direction parallel to the chest wall could produce significant variations of the SDNR values, depending on the position chosen for the contrast object (if it is not embedded in the PMMA) and the measurement ROIs. This could be misinterpreted as a fluctuation of the mammography unit.

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<sup>16</sup> Not applicable to CR images.

- (3) Calculate the SDNR<sup>17</sup> as:  $SDNR = |A-B|/C$ .
  - (4) Compare the values of  $B$  and  $C$  and the SDNR at each mAs with baseline values and the results of previous tests. Observe changes over time and note any drifts in performance.
  - (5) For linear systems, plot the values of MPV ( $B$ ), the variance ( $C^2$ ) and SDNR versus mAs. Perform a linear fit to the data and obtain the slope, intercept and correlation coefficients ( $R^2$ ). For logarithmic systems, it may be necessary to plot the MPV and variance against  $1/mAs$  to obtain a straight line.
  - (6) Some manufacturers intentionally add a pixel value offset to their image data. This value ( $B_0$ ) should be obtained from the manufacturer's technical documentation. Alternatively, the intercept obtained in step 11 can be used as  $B_0$ .
  - (7) Calculate the value of  $(B-B_0)/mAs$  for all values of the mAs and for the average value of this quantity.
- (b) CR systems without ROI capability
- (1) Compare the values of the EI (S# for Fuji, Konica, Philips; SAL, SALlog or PVIlog for Agfa; EI for Carestream) at each mAs with the baseline and the results of previous tests.
  - (2) Plot the information using the axes as specified in Table 15, noting the values of the correlation coefficient ( $R^2$ ).

#### 8.5.2.4. Interpretation of results and conclusions

Tolerances:

The detector response and noise tolerances are given in Table 16. In addition to the tolerances specified in Table 16:

- (1) For nominally linear (DX) systems: The plot of MPV ( $B$ ) and variance ( $C^2$ ) versus mAs should be linear with  $R^2 \geq 0.95$ . All values of  $(B-B_0)/mAs$  should be within 10% of the mean value of this ratio.
- (2) For logarithmic (CR) systems: The plot of the function of the EI versus mAs should be linear with  $R^2 \geq 0.95$ .

#### 8.5.2.5. Recommendations and corrective action

- (1) For nominally linear (DX) systems: If the MPV ( $B$ ), standard deviation ( $C$ ) or SDNR has changed by more than the maximum indicated in Table 16, determine the cause of the change. First, establish that the output of the X ray unit has not changed. If the output has remained satisfactory, it will probably be necessary to consult

TABLE 16. DETECTOR RESPONSE AND NOISE TOLERANCES

System type	Parameter	Acceptable tolerance
Nominally linear (DX)	MPV ( $B-B_0$ )	$\Delta(B-B_0) \leq 10\%$
	Standard deviation ( $C$ )	$\Delta C \leq 5\%$
	SDNR	$\Delta SDNR \leq 5\%$
Non-linear (CR)	Fuji, Philips, Konica — S#	$\Delta S\# \leq 10\%$
	Agfa — SAL/SALlog/PVIlog	$\pm 5\% / \pm 430 / \pm 580$
	Carestream — EI	$\Delta EI \leq 40$ units

<sup>17</sup> Although CR systems are non-linear, the use of non-linearized pixel values will provide an acceptable approximation to the SDNR obtained from linearized data. Linearization is, therefore, not required.

the service engineer responsible for the equipment. If the plot of MPV ( $B$ ) and variance versus mAs has  $R^2$  values less than 0.95, or if the ratios of  $(B-B_0)/\text{mAs}$  are not within 10% of the mean value of the ratio, it will probably be necessary to consult the service engineer responsible for the equipment.

- (2) For logarithmic (CR) systems: If the S# (Fuji and Konica), SAL, SALlog or PVIlog (Agfa) or EI (Carestream) has changed by more than the maximum indicated in Table 16, determine the cause of the change. First, establish that the output of the X ray unit has not changed. If the output has remained satisfactory, it will probably be necessary to consult the service engineer responsible for the equipment. If the plot of the relevant function of the 'exposure index' versus mAs has  $R^2$  values less than 0.95, it will probably be necessary to consult the service engineer responsible for the equipment.

#### 8.5.2.6. *Time frame for corrective action*

Corrective action should be taken within 30 days of the test.

### 8.5.3. Spatial linearity and geometric distortion of the detector

#### 8.5.3.1. Scope

- Objective: To determine the absolute image magnification and the fidelity with which straight lines are captured in both contact and magnification mode.
- Minimum frequency: Annually for systems with moving parts (e.g. slot scan and CR systems) and after detector replacement.

#### 8.5.3.2. Instrumentation

- (1) Geometric distortion test tool with parallel lines at 20 mm spacing, lines angled at 45° to the edges of the tool (Fig. 31).

#### 8.5.3.3. Methodology

- (1) If more than one image size is available, select the largest one and install the appropriate compression paddle.
- (2) Place the geometric distortion test tool on the breast support plate, approximately centred left to right.
- (3) Create a 'patient' study with an appropriate name.
- (4) Make an exposure using the AEC technique.
- (5) Record the target filtration, kV setting, mAs setting and grid use on the spatial linearity and geometric distortion chart (Chart 6 in Annex II).
- (6) For CR systems, use the settings and record the EI as indicated in Table 11.
- (7) Make a second exposure with the distortion test tool on the magnification table.
- (8) At a workstation equipped with image analysis tools, including distance measurement, display the images of the distortion phantom, using appropriate window width and window level settings. The background of the phantom should be a mid-grey, with the lines clearly visible.
- (9) Examine the image for uniformity of sharpness across the image and for any distortion in the regular pattern.
- (10) Using image roam and zoom controls, examine the pattern to ensure that all lines are smooth and straight.
- (11) Adjust the zoom to achieve a 1:1 display, calculate the effective del size referenced to the breast support table by measuring the horizontal and vertical distances *in pixels* between reference points of known spacing in the pattern. Record the results on Chart 6 in Annex II.
- (12) Multiply the effective del size by the number of rows and columns in the image matrix in order to calculate the width and length of the image referenced to the breast support table. Record the results on Chart 6 in Annex II.

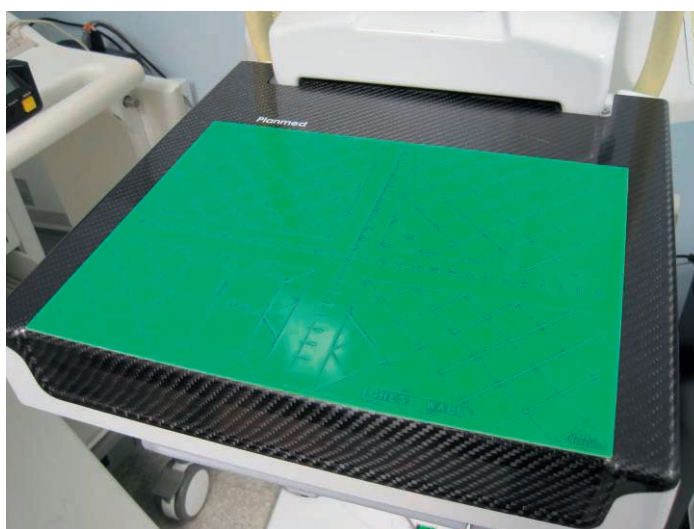


FIG. 31. Example of a geometric distortion test tool.

- (13) Using the annotation tool on the workstation, measure the length of each of the known reference distances. Record the results on Chart 6 in Annex II.

#### 8.5.3.4. *Interpretation of results and conclusions*

Tolerances:

- (1) The effective del width and length ( $x$  and  $y$ ) dimensions should be within 5% of each other.
- (2) The image size (in cm) in each dimension should be within 10% of the manufacturer's stated nominal image size.
- (3) The distances measured using the annotation tool should be within 5% of the true size. If the manufacturer specifies that the annotation tool reports distances referred to some other plane, then either the pattern can be placed in that plane or a magnification correction can be applied.
- (4) There should be less than 2% deviation from a straight line over a 100 mm length in the centre of the field (i.e. the line should not deviate from its true path by more than 2 mm over 100 mm).

*Note:* The design of some scanning systems (e.g. a curved breast support plate) may introduce a geometric distortion. In this case, the amount of distortion should be characterized at machine commissioning. Thereafter, the test should measure whether the distortion has changed over time. Note that distortions can influence the accuracy of needle placement in the breast, and this factor should be kept in mind.

#### 8.5.3.5. *Recommendations and corrective action*

- (1) If the del dimensions and/or the image size do not conform to the specifications above, seek service or advice from a qualified service engineer.
- (2) If there is any significant resolution non-uniformity or pattern distortion, rotate the image on the monitor by 90°. If the resolution non-uniformity or distortion persists, there is a detector problem; otherwise, it may be a software or monitor problem. Seek service from a qualified service engineer to have the problem corrected.

#### 8.5.3.6. *Time frame for corrective action*

Immediately: Corrective action should be taken before any further patients are imaged.

## 8.5.4. Detector ghosting

### 8.5.4.1. Scope

In this measurement, ghosting (sensitivity variation) or lag (residual signal) from a previous exposure is induced in a manner similar to clinical operation and the results are quantified. For simplicity, both phenomena are referred to in this publication as ‘ghosting’. Both qualitative and quantitative (preferred) evaluations may be undertaken, depending on the capability of the acquisition workstation. Here, a quantitative method for assessing ghosting and an alternative qualitative technique are described.

- Objective: To evaluate the severity of any artefact due to recent previous exposure to the detector in all systems except photon counting systems.
- Minimum frequency: Annually and after replacement of the detector.

### 8.5.4.2. Instrumentation

- (1) PMMA slab, 45 mm thick.

### 8.5.4.3. Methodology

*Important:* Read through these steps and understand them before starting this test. It is important that the elapsed time between acquisition of the initial image (step 4) and the ghost measurement image (step 5) be the shortest time allowed by the mammography unit, as this will replicate the clinical situation.

- (1) Create a ‘patient’ study with an appropriate name.
- (2) Place the PMMA slab on the right half of the breast support table with the edge placed at the middle of the table, running from the chest wall to the anterior edge such that approximately one half of the breast imaging area is covered (Fig. 32(a)).
- (3) Lower the paddle so that it is in contact with the breast support plate. Note where the edge of the phantom crosses the detector.
- (4) Acquire an image under manual exposure, using typical clinical exposure factors for the average breast. This is the ‘ghost creation’ image.
- (5) For CR, immediately process the cassette and retrieve the same cassette (screen) from the processing station.
- (6) Reposition the slab on the breast support table so that the middle of the slab is centred on the location of the edge of the uniform attenuator in the ghost creation image (Fig. 32(b)).
- (7) As soon after the first image is acquired that the unit allows another exposure, or as soon as the same detector plate is available, acquire a second image using the same manual technique. This is the ‘ghost measurement’ image.
- (8) View the ghost measurement image (the unprocessed version, if possible). Use the ROI tool (area  $\sim 4 \text{ cm}^2$ ) to take three measurements in two ROIs in the ghost measurement image at the locations described below:
  - (a) The MVP in the background of the phantom on the side where no attenuator was present in the first image. In Fig. 32(b), the centre of the ROI should be  $\sim 20 \text{ mm}$  to the left of the line marked D.
  - (b) The MVP in the background of the phantom on the side where the uniform attenuator was present in the first image. Here, the centre of the ROI should be  $\sim 20 \text{ mm}$  to the right of the line marked D.
  - (c) The standard deviation (SD) in the background of the phantom on the side where the uniform attenuator was present in the first image (i.e. the same ROI as for step 8(b)).
- (9) Record the results on the evaluation of ghosting chart (Chart 7 in Annex II).



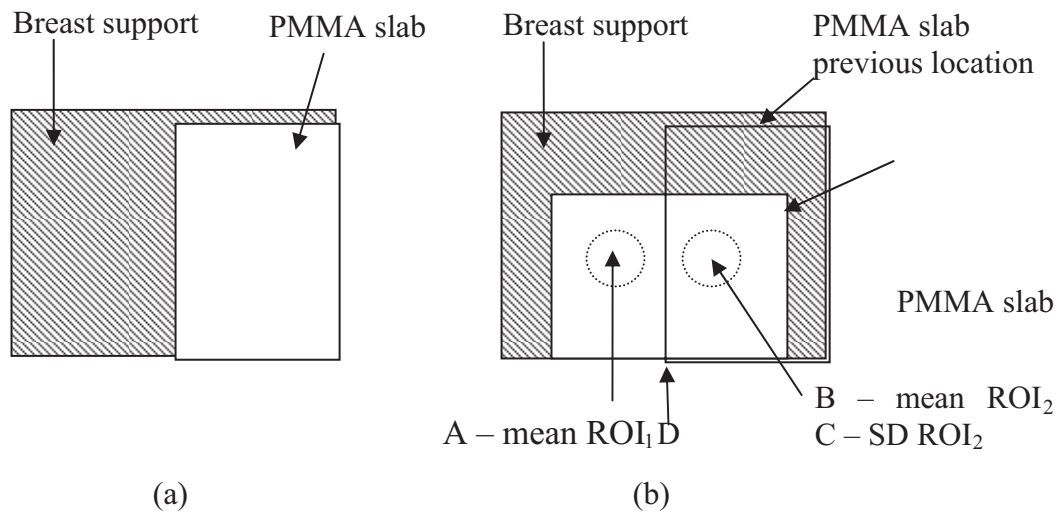


FIG. 32. Set-up for (a) ghost creation image and (b) ghost measurement image.

(10) Calculate the ghost image SDNR using the equation:

$$\text{Ghost image SDNR} = \left| \frac{A - B}{C} \right| \quad (2)$$

where the variables are as defined in Fig. 32(b).

- (11) View the 'for processing' version of the ghost measurement image on the radiologist review workstation.
- (12) Using a narrow window width (without exaggerating image noise) and an appropriate window level, inspect the central part of the image where the boundary between the two areas of exposure lies. Record the window width and window level on Chart 7 in Annex II.
- (13) Record the presence or absence of any visually observable ghost image on Chart 7 in Annex II.

#### 8.5.4.4. Interpretation of results and conclusions

Tolerance:

- (1) Acceptable: Ghost image SDNR  $\leq 2.0$ .
- (2) Alternative measure: When viewing the ghost measurement image with a typical, clinically used window setting, there should be no visible indication of the attenuator in the ghost creation image.

#### 8.5.4.5. Recommendations and corrective action

- (1) If the absolute value of the ghost image SDNR is more than the tolerance value, the service person should be contacted.
- (2) If ghosting is visible at clinically relevant window width and window level settings, the service person should be contacted.

#### 8.5.4.6. Time frame for corrective action

Immediately: Corrective action should be taken before any further patients are imaged.

### 8.5.5. Detector uniformity and artefact evaluation

#### 8.5.5.1. Scope

Here, a qualitative approach is described; more quantitative methods for assessing local variations in detector performance are also available [50].

- Objective: To assess the degree and source of artefacts visualized in full field digital mammograms or phantom images; to ensure that the flat field image is uniform in terms of signal level and noise; to establish the imaging technique and viewing parameters to be used for the monthly full field artefact check.
- Minimum frequency: Annually and after service to the X ray tube head or detector, or modifications to the image acquisition or correction software.

#### 8.5.5.2. Instrumentation

- (1) A 45 mm thick slab of PMMA or a sheet of aluminium, 2–3 mm thick, large enough to cover the entire detector.<sup>18</sup> For magnification artefact evaluation, a 25 mm PMMA slab or a 1–2 mm aluminium sheet could be used. It should be ensured that the aluminium sheet is not scratched. There must be no radiographically visible structure in the phantom.<sup>19</sup>
- (2) Acquisition or radiologist workstation. Alternatively, images may be downloaded to another computer and analysed using image analysis software.

#### 8.5.5.3. Methodology

- (1) Create a ‘patient’ study with an appropriate name.
- (2) Place the uniform phantom in the X ray field, either on the tabletop or suspended from the tube assembly, so that the front edge extends beyond the chest wall edge of the breast support plate and also extends beyond each indicated edge of the image field. Leave the grid on for large focal spot exposures and the most frequently used compression paddle in place for all images. Use collimation that allows the full detector area to be imaged.
- (3) Lower the compression paddle so that it is in contact with the test object, or to a height of 45 mm above the breast support.
- (4) Use the exposure mode for a clinical image of a breast of equivalent thickness. Turn off any image enhancements or post-processing options.
- (5) Expose the image.
- (6) For CR systems, use the settings listed in Table 11.
- (7) Enter the imaging parameters into the artefact evaluation/flat field uniformity chart (Chart 8 in Annex II).
- (8) Repeat steps 5–7 for all target–filter combinations used in clinical practice. Use a manual (or AEC, if possible) exposure technique that results in a reasonably exposed image. One image (at a typical clinical kV) is required for each target–filter combination used clinically. Record the technique factors in the radiographer baselines and summary chart (Chart 3 in Annex II) for use by the radiographers in their monthly full field artefact tests.<sup>20</sup>
- (9) Install the magnification stand (if used clinically).

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<sup>18</sup> Alternatively, provision could be made to position a smaller phantom closer to the X ray source to cover the entire image field. If this is done, care must be taken to align the plane of the phantom parallel to that of the detector. Some manufacturers supply a purpose built block of PMMA that attaches to the collimator.

<sup>19</sup> In practice, it is probable that over time any material will become scratched through handling. In the case of moderate scratching, the physicist should record the presence of such scratches so that they are not confused with problems associated with the imaging system. If defects become excessive, the material should be replaced.

<sup>20</sup> If the radiographer uses the same test object as the physicist and the Excel spreadsheets provided are used, the parameters will be entered automatically into Chart 3 in Annex II. If the radiographer uses a different test object than the physicist, different exposure factors may be required.

- (10) Place the thinner test object (25 mm PMMA or 1.27 mm aluminium) on the magnification stand.
- (11) Select the manual or AEC mode used clinically for magnification imaging of an average breast.
- (12) Expose the image. For CR systems, use the settings noted above.
- (13) Enter the imaging parameters into Chart 8 in Annex II (and into Chart 3, if required).
- (14) Repeat steps 9–13 for other magnification stand positions (magnification factors) and clinically relevant target–filter combinations. It is not necessary to exhaustively image all possible permutations of magnification stand positions and target–filter combinations, but each magnification stand position should be used at least once, and the most commonly used target–filter combinations should be tested at least once with the magnification stand.
- (15) Examine the unprocessed images on a workstation.
- (16) Select a window width and window level that allow artefact severity assessment without accentuating the noise excessively.
- (17) Record the window width and level settings used on Chart 8 in Annex II.
- (18) Carefully examine the images of the uniform phantom for artefacts. Record any visible artefacts on Chart 8 in Annex II. If possible, save images illustrating the artefacts.
- (19) For CR systems, examine the images for evidence of defects in the plates, dirt on the plates (reduced density specks) and dirt in the reader (reduced density lines across the images).
- (20) If any artefacts or non-uniformities are observed, rotate the phantom 90° and repeat the exposure and acquisition procedure. For CR systems, the cassette may be placed on the table top, rotated at a 45° angle, to determine if the artefact is caused by the filter or X ray tube versus the imaging plate or the reader. Any artefacts or non-uniformities that keep a fixed orientation relative to the image receptor in both images and that are deemed significant probably require a recalibration of the gain file specific to the target–filter combination in question.
- (21) The image should be examined for flat field uniformity to ensure that the image does not have non-uniformities across the field of view.
- (22) Review the images of all clinically used target–filter combinations.
- (23) Display the uniformity image with a zoom factor that displays full resolution (1:1 pixel mapping). Reduce the window width until the noise pattern becomes apparent. Pan over the entire image, examining it for variations in the amount of noise and in the texture of the noise from place to place in the image.
- (24) Ensure that some of the thickness tracking images are also examined, to verify that the flat fielding algorithm works well across the thickness range of 20–70 mm, and not just for the thickness of the facility’s uniform phantom.
- (25) Record all recommended technique factors and viewing window and level settings on Chart 3 in Annex II.

#### 8.5.5.4. *Interpretation of results and conclusions*

Artefacts may include: dust or dirt, ‘ghost’ images left over from repeated test or clinical exposures, blotchiness due to thickness variations of the filter, dirt or corrosion on the filter, stitching artefacts, clipping/electronic noise, spatial non-uniformities, artefacts, plus or minus signal variations, flat fielding artefacts, grid lines, streaking in the horizontal or vertical directions, bad pixels and other equipment induced artefacts. Artefacts are also caused by dirt or debris in the tube port or on the underside of the breast support plate or grid. Some examples of artefacts associated with digital mammography systems are illustrated in Section 5.7 and in Appendix III.

- (1) There should be no visible dead pixels, missing lines or missing columns of data at a level that could interfere with the detection of anatomical structures or could mimic structures that do not actually exist in the breast.
- (2) There should be no visually distracting structured noise patterns in a uniform phantom image.
- (3) There should be no regions of discernibly different density on an unprocessed image of a uniform phantom.

- (4) There should be no unexpected variation in apparent texture or magnitude of the noise across the uniform image<sup>21</sup>. If the place to place variation changes over time, areas where the noise appears to be less may indicate degradation in the detector causing a loss of sharpness. Increases in noise may indicate other detector problems. Document such problems by measuring the local SNR ((pixel value – offset)/standard deviation) in ROIs of about 100 mm<sup>2</sup> or less located in an area of ‘normal’ noise level and compare these with the area(s) where noise levels are observed to have changed.
- (5) For CR, bear in mind that the heel effect is not compensated for by the CR reader’s processing algorithms, so some non-uniformity due to the X ray beam is to be expected.

#### *8.5.5.5. Recommendations and corrective actions*

- (1) If dead pixels or other unacceptable artefacts are noted, or if significant non-uniformity is present, the service person should be contacted to investigate and correct the problem.
- (2) CR systems have no flat fielding and will require the service engineer to investigate unacceptable artefacts in a manner similar to that for screen film imaging.

#### *8.5.5.6. Time frame for corrective action*

For severe artefacts, corrective action should be taken immediately, before any further patients are imaged. For minor artefacts, corrective action should be taken at the next routine servicing of equipment.

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<sup>21</sup> Note that variations in signal level (especially in CR systems) and noise due to the heel effect are to be expected.

## 8.6. EVALUATION OF SYSTEM RESOLUTION

### 8.6.1. Modulation transfer function

In digital mammography the major system related physical factor affecting spatial resolution is the signal blurring within the detector and the integration of the signal over the area of the del to form a single reading. This can be assessed by calculating the MTF from the spread of the signal in the image of a sharp, high contrast edge. If a square object is imaged, the edges in both the horizontal and the vertical directions can be measured, and an evaluation can be performed for both signal rising and signal falling conditions. Slanting the edge slightly allows determination of the 'pre-sampled' MTF, that is, the MTF that would exist before sampling to form the digital image [51–54]. The method presented here is a field measurement of 'effective system resolution at the top surface of the breast' rather than a rigorous laboratory test. This incorporates the effects due to the focal spot as well as those due to detector characteristics.

#### 8.6.1.1. Scope

- Objective: To determine the MTF associated with the detector and focal spot of the system.
- Minimum frequency: Annually and after changes or service to the detector, tube or CR plate reader.

#### 8.6.1.2. Instrumentation

- (1) MTF test tool. A square of metal foil with very straight edges, 20–50 mm on a side. The test object may be made of a variety of materials such as copper (70  $\mu\text{m}$  thick), stainless steel [55], brass backing with tungsten or lead [56], or niobium (20–30  $\mu\text{m}$  thick) [57]. Ideally, whatever the material used, the thickness of this foil will provide measurable X ray transmission at mammographic energies so that a reliable signal is obtained beneath the foil.
- (2) A 45 mm thick slab of PMMA to support the MTF test tool (Fig. 33). Alternatively, the square can be permanently mounted on a larger (100 mm  $\times$  100 mm) 1.5–2 mm thick aluminium plate, angled slightly with respect to the edge of the sheet.
- (3) MTF software (see: <http://humanhealth.iaea.org>).

#### 8.6.1.3. Methodology

- (1) Place the MTF tool 45 mm above the breast support table such that the square is angled slightly (2–5°) with respect to the chest wall edge of the breast support table. Use of a pre-mounted square achieves this automatically.
- (2) Make an exposure using manual factors similar to those used for a clinical image of the average breast. Choose factors such that there are no pixel values in the uniform regions of the phantom or MTF square that reach the maximum pixel value for the system or that fall to the minimum value.
- (3) Download the 'for processing' image onto the computer on which the MTF software is available. Run the software according to the provider's directions to calculate the MTF from the 'for processing' image. It is desirable to obtain MTFs on both the rising edge and the falling edge of the edge spread data.
- (4) Record the spatial frequencies at which the MTF has fallen to 50 and 20% in the  $x$  and  $y$  directions on the MTF–resolution chart (Chart 9 in Annex II). Also record the MTF value at 2.5, 5 and 7.5 cycles/mm on that sheet.

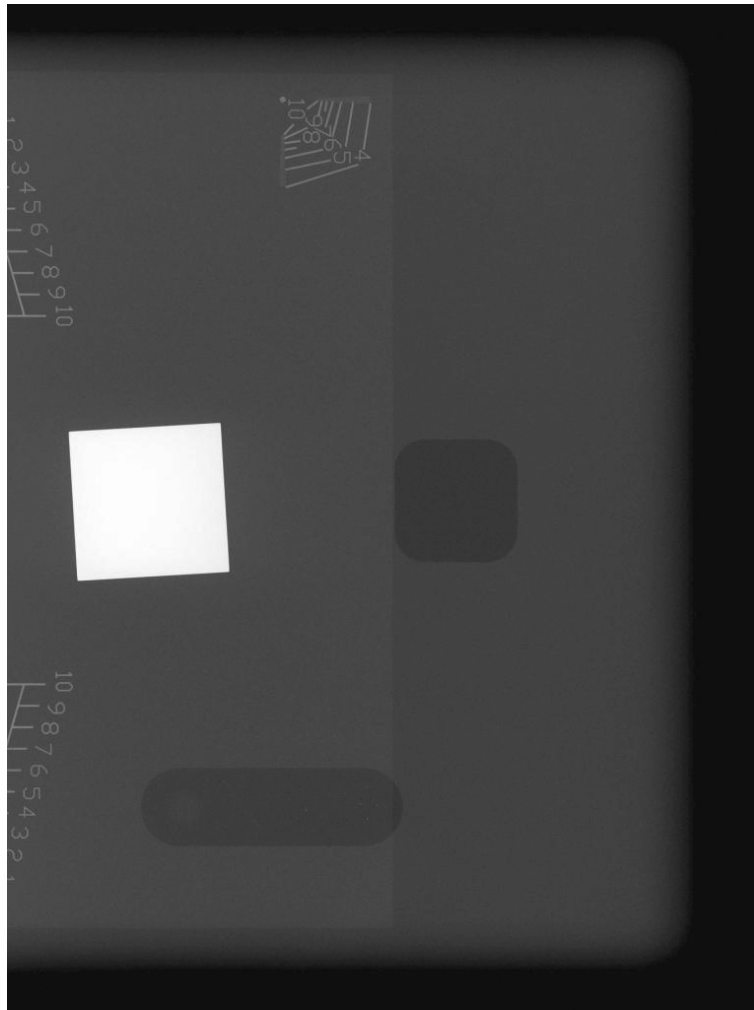


FIG. 33. Image of MTF test tool mounted on a QC test object.

#### 8.6.1.4. Interpretation of results and conclusions

Tolerances:

- (1) The spatial frequencies at which the MTF has fallen to 50 and 20% should not be less than the values specified in Table 17 for the relevant model of digital mammography equipment.
- (2) The MTF at 2.5, 5 and 7.5 cycles/mm should not change more than 10% from the value established at commissioning of the equipment.
- (3) If it is suspected that the spatial resolution may vary excessively from place to place in the image (e.g. due to detector deterioration), the MTF should be measured at different locations in the image and these measurements compared.
- (4) A variation in noise from place to place in the image (see Section 8.5.5) can be an indicator of changes in local MTF [58].

TABLE 17. ACCEPTABLE FREQUENCIES AT WHICH THE MTF FALLS TO 50% AND 20% (CYCLES/mm)  
(value perpendicular to chest wall/value parallel to chest wall)

System	Contact mode	
	50%	20%
Agfa CR (MM3.0)	2.0/2.0	4.5/3.5
Agfa CR (HM5.0)	2.5/2.0	5.5/4.5
Carestream CR (EHR-M3)	2.0/2.0	4.5/4.0
Carestream CR (EHR-M2)	1.5/1.5	3.5/3.0
Konica CR (RP-6M)	2.5/2.0	5.0/3.5
(RP-7M)	3.0/2.0	6.0/4.0
(CP-1M)	3.5/2.0	7.5/4.0
Fuji Amulet	4.5/4.5	7.5/4.5
Fuji Profect (HR-BD)	3.0/2.0	6.0/4.0
GE 2000D	2.5/2.5	5.0/5.0
GE DS	3.5/3.5	6.0/6.0
GE Essential	2.5/2.5	4.5/4.5
Hologic Selenia	6.5/6.5	9/9
IMS Giotto	4.0/4.0	6.5/6.5
Philips PCREleva	5.0/5.0	9.0/8.0
Planmed Nuance	4.5/5.5	9.0/8.0
Sectra L30	4.0/5.5	6.0/8.0
Siemens Inspiration	5.0/5.0	8.0/8.0
Siemens Novation	5.0/5.0	9.0/8.0

#### 8.6.1.5. Recommendations and corrective actions

If the 50 or 20% frequencies for the MTF, either parallel or perpendicular to the chest wall, drop below the values given in Table 17, or if the MTF at 2.5, 5 and 7.5 cycles/mm has changed by 10% or more from previously measured values, consult the manufacturer's service representative.

#### 8.6.1.6. Time frame for corrective action

Immediately: Corrective action should be taken before any further patients are imaged.

## 8.6.2. Alternative procedure: Limiting spatial resolution

If it is not possible to perform the MTF measurement, a less suitable alternative is to measure the limiting spatial resolution in a manner similar to that used for screen film mammography [8, 59, 60].

### 8.6.2.1. Scope

- Objective: To determine the high contrast resolution limit.
- Minimum frequency: Annually and after equipment changes to the detector or X ray tube.

### 8.6.2.2. Instrumentation

- (1) Star or bar resolution pattern covering at least the range 5–12 line pairs (lp)/mm.
- (2) PMMA slabs.
- (3) Magnifier lens (4× to 5× magnification).

### 8.6.2.3. Methodology

- (1) Place the resolution pattern centrally on top of 45 mm of PMMA, with the closest edge 10 mm from the chest wall and with the bars oriented at approximately, but not exactly, 90° with respect to the chest wall edge of the breast support table. The slight rotation of a few degrees is intended to avoid moiré effects.
- (2) Ensure that any image processing and detector correction algorithms (except for flat field correction) are turned off.
- (3) Confirm that the AEC sensor is not under the resolution pattern. Image the pattern using the technical factors (kV, grid, target, filter) used clinically for a compressed breast of 45 mm.
- (4) View the image on the monitor of the available workstation with at least a 1:1 zoom factor. If hard copy is normally used with the system, the image could be viewed on the printed film with the aid of a magnifying lens. Note the number of line pairs that can be observed clearly, starting with the most easily resolved.
- (5) Note the result on the data collection sheet.
- (6) Repeat the measurement with the bars oriented at approximately, but not exactly, 0°. For convenience, the two measurements can be done simultaneously, if the appropriate bar or star pattern is available.

### 8.6.2.4. Interpretation of results and conclusions

Tolerances:

- (1) Baseline value: Achievable — The limiting spatial resolution (in lp/mm) should not fall below the values listed under the 20% column in Table 17.
- (2) The limiting spatial resolution should not decrease in time by more than 10% from the baseline value.

### 8.6.2.5. Recommendations and corrective actions

- (1) If variations in the resolution are observed, the cause should be identified (e.g. detector damage, change of size of the focal spot). If necessary, consult the manufacturer's service representative for assistance in resolving the problem.
- (2) If the resolution of an image viewed on hard copy film does not meet the spatial resolution requirement, ensure that the problem is not caused by laser printing (see Section 8.11).

### 8.6.2.6. Time frame for corrective action

Immediately: Corrective action should be taken before any further patients are imaged.



## 8.7. X RAY EQUIPMENT CHARACTERISTICS

### 8.7.1. Half value layer (HVL)

#### 8.7.1.1. Scope

- Objective: To measure the HVL and to confirm that the total filtration of the X ray beam is in agreement with the minimum requirements of the national and international standards [8, 59–62].
- Minimum frequency: At commissioning, annually and after changes to or maintenance of the X ray tube, tube housing and/or collimation system.

#### 8.7.1.2. Instrumentation (see Appendix II)

- (1) Appropriate dosimeter system for mammography.
- (2) Aluminium filters.
- (3) Measuring tape.
- (4) Metal plate to shield the detector from X rays (e.g. 1 mm steel, 5 mm aluminium or >0.1 mm lead), large enough to cover the active area of the detector.

#### 8.7.1.3. Methodology

- (1) Place the metal shielding material on the breast support table to protect the detector from excessive radiation exposure that could cause artefacts.
- (2) Select the manual mode of operation and the target–filter–kV combinations selected by the AEC for 20, 45 and 70 mm thicknesses of PMMA (see Section 8.4.2).
- (3) Place the dosimeter at a height of 45 mm above the breast support, centred laterally, and 40 mm from the chest wall edge, so that the sensitive volume of the chamber remains completely within the radiation field.
- (4) Collimate the radiation field to be just slightly larger than the sensitive volume of the dosimeter using the internal collimators and/or an aperture in a heavily attenuating metal sheet placed on the compression paddle.
- (5) Place the compression paddle<sup>22</sup> approximately halfway between the X ray target and the dosimeter.
- (6) Make an exposure and record the reading on the beam quality (HVL) chart (Chart 10 in Annex II).
- (7) Place 0.3 mm of aluminium (or 0.4 mm, depending on the target–filter–kV combination that has been selected) on the compression paddle above the aperture, totally covering the active volume of the chamber, and make an exposure with the same parameters. Check that the reading is more than half the reading without the filter. If it is not, use a thinner aluminium thickness.
- (8) Add 0.1 mm (or 0.025 mm, for more precision) of aluminium and repeat the previous step. Check that the reading is less than half the reading without the filter. Otherwise, add more aluminium until the reading falls below half the reading without the filter.
- (9) Remove all the filters and repeat the exposure. Take note of the reading.
- (10) Repeat this procedure for the other selected target–filter–kV combinations.

#### 8.7.1.4. Procedure of calculation

- (1) Calculate the value of the HVL, based on the following expression:

$$HVL = \frac{t_2 \ln[2M_1/M_0] - t_1 \ln[2M_2/M_0]}{\ln[M_1/M_2]} \quad (3)$$

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<sup>22</sup> For the calculation of MGD, it is necessary to measure the HVL with the compression paddle in the beam. To compare the HVL with the manufacturer's specifications, which follow IEC standards, the measurement of the HVL would be done without the compression paddle.

where

$t_1$  and  $t_2$  are the thicknesses (in mm) of the filters used;  
 $M_0$  is the average value of readings measured in steps 6 and 9 without any added filter;  
 $M_1$  and  $M_2$  are the readings measured in steps 7 and 8 that are respectively just above and just below 50% of  $M_0$ .

(2) Note the calculated HVL on Chart 10 in Annex II.

#### 8.7.1.5. Interpretation of results and conclusions

Tolerance:

$$\text{Acceptable: } kV/100 + 0.03 \leq \text{HVL} \leq kV/100 + C$$

where

$C =$  0.12 for Mo/Mo;  
0.19 for Mo/Rh;  
0.22 for Rh/Rh;  
0.30 for W/Rh;  
0.32 for W/Ag;  
0.25 for W/Al;

and kV is the measured value for the nominal kV selected.

On Chart 10 in Annex II, record whether the value of the HVL is acceptable. If this tolerance is met, it is generally the case that regulatory requirements for total beam filtration without the compression paddle will also be satisfied.

#### 8.7.1.6. Recommendations and corrective actions

If the HVL is very low or very high, investigative action should be undertaken. This may include a measurement of the kV to confirm that the tube potential is properly calibrated. Methods are described in Ref. [34].

#### 8.7.1.7. Time frame for corrective action

Immediately: Corrective action should be taken until the problem is solved.

## 8.7.2. Incident air kerma at the entrance surface of PMMA slabs

### 8.7.2.1. Scope

- Objective: To estimate the incident kerma in air (without backscatter) at the position corresponding to the entrance surface of PMMA of thicknesses of 20, 45 and 70 mm<sup>23</sup>. The measurement can be done at a convenient distance from the X ray source and then calculated for the locations of the entrance surfaces using an inverse square law correction.
- References [8, 48, 60, 64, 65].
- Minimum frequency: Annually and after change of, or maintenance to, the X ray tube, tube housing and/or collimation system.

### 8.7.2.2. Instrumentation

- (1) Dosimeter appropriate for mammography (see Appendix II).
- (2) Exposure technique data from the AEC test (see Section 8.4.2 for target–filter combination, kV and mAs<sub>AEC</sub>) for the PMMA slabs with thicknesses of 20, 45 and 70 mm.
- (3) Metal plate to shield the detector from X rays (e.g. 1 mm steel, 5 mm aluminium or >0.1 mm lead), large enough to cover the active area of the detector.
- (4) Tape measure.
- (5) Thermometer.
- (6) Barometer.

### 8.7.2.3. Methodology

The incident air kerma without backscatter is measured using the same exposure factors selected to expose a phantom equivalent to three thicknesses of PMMA representing breasts of different attenuation. The incident kerma in air at the entrance surface of the PMMA slab(s) is determined from: (a) the mAs value used to expose the PMMA slab with the target–filter–kV combination used in Section 8.4.2 (mAs<sub>AEC</sub>); (b) the measured incident kerma in air for the given mAs<sub>AEC</sub>; and (c) the measured distance from the focus of the X ray tube to the breast support table.

- (1) Determine the distance,  $d_T$ , from the focus of the X ray tube to the breast support table and record it in the kerma and dose chart (Chart 11 in Annex II).<sup>24</sup> This can be determined using the manufacturer’s specifications or by measurement, if necessary.
- (2) Place the metal shield on the breast support table to protect the digital detector from excessive exposure. Do not scratch the table.
- (3) Attach the dosimeter to the lower surface of the compression paddle. The dosimeter should be centred laterally in the beam, approximately 40 mm into the radiation field from the chest wall edge of the beam. Set the height of the compression paddle so that the centre of the active volume of the dosimeter (the measurement point) is 45 mm above the breast support table.<sup>25</sup>

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<sup>23</sup> The measurement is made without the PMMA, because it should be done without scattered radiation. Note that the original Monte Carlo modelling [63] incorporated a correction to the incident air kerma that would have been present for a thicker breast whose attenuation corresponds to these PMMA thicknesses. Therefore the entrance kerma to the PMMA is evaluated, rather than the kerma to the entrance of the breast.

<sup>24</sup> This is difficult to measure accurately with a tape measure, and it may be best to obtain the distance from the manufacturer. This measurement need not be repeated unless there are changes to the mechanical assembly that would affect this distance.

<sup>25</sup> The dosimeter is placed at the same height as the top surface of a 45 mm PMMA slab rather than at the height of the equivalent breast thickness because the inverse square law correction to the surface of the breast is already incorporated in the conversion factors used in Table 18.

- (4) Using the same target–filter and kV combination used for imaging the 45 mm PMMA slab in the AEC test (see Section 8.4.2), make an exposure in manual mode with the previously determined mAs value,  $mAs_{AEC}$ . If it is not possible to select the exact mAs value, then the kerma ( $M_{AEC}$ ) can be estimated by extrapolation from a measurement taken at the closest available manual mAs setting,  $M_1$ , that is:

$$M_{AEC} = \frac{mAs_{AEC}}{mAs_{M_1}} M_1 \quad (4)$$

- (5) Obtain the value of the incident kerma,  $K_{i,45}$  (at the height of the top surface of the 45 mm phantom), from  $M_{AEC}$  using Eqs (5) and (6) and record the value on Chart 11 in Annex II:

$$K_{i,45} = M_{AEC} \cdot N_{mammo} \cdot k_{TP} \quad (5)$$

$$k_{TP} = \frac{(273.2 + T)}{(273.2 + T_0)} \times \frac{P_0}{P} \quad (6)$$

where

$k_{TP}$  is the dosimeter correction factor for temperature and pressure to be used if the dosimeter is a vented air ionization chamber;

$N_{mammo}$  is the value of the calibration factor for beam quality;

$T_0$  and  $P_0$  are the values of temperature and pressure at which the dosimeter is calibrated (if applicable).

- (6) Repeat steps 4 and 5 for the target, filter, mAs and kV used for 20 and 70 mm PMMA slabs, respectively.  
 (7) For these measurements, correct the incident air kerma value to the location of the entrance surface as follows:

$$K_{i,20} = K_{i,45} \left( \frac{d_T - 45}{d_T - 20} \right)^2 \quad (7)$$

$$K_{i,70} = K_{i,45} \left( \frac{d_T - 45}{d_T - 70} \right)^2 \quad (8)$$

## 8.8. DOSIMETRY

### 8.8.1. Mean glandular dose ( $D_G$ )

#### 8.8.1.1. Scope

- Objective: To estimate the MGD ( $D_G$ ) for breasts represented by PMMA thicknesses of 20, 45 and 70 mm [8, 48, 60, 64, 65].
- Minimum frequency: Annually and after equipment changes.

#### 8.8.1.2. Methodology

- (1) The MDG ( $D_G$ ) is obtained from the incident kerma in air and relevant conversion coefficients using the following formula<sup>26</sup>:

$$D_G = g_t c_t s K_{i,t} \quad (9)$$

where

$K_{i,t}$  is the entrance air kerma at the surface of the slab of PMMA (20, 45 and 75 mm thick), used to simulate the standard breast with a thickness of  $t$  mm, measured without backscatter (see Section 8.7.2);

$g_t$  is the factor that converts from air kerma to MGD for a breast having a 50% fibroglandular/50% fat composition with a thickness of  $t$  mm;

$c_t$  is the conversion factor which allows for the glandularity of a standard breast of thickness  $t$  mm;

$s$  is the s factor, which gives a correction that depends on the target–filter combination.

- (2) Use the product of the  $g$  and  $c$  factors, which are dependent on the HVL of the spectra utilized, as provided in Table 16.
- (3) The HVL value is obtained following the method described in Section 8.7.1.
- (4) Apply the values of the s factor for the relevant target–filter combination provided in Tables 19 and 20.
- (5) Record the values of  $g$ ,  $c$ ,  $s$ , HVL and  $D_G$  on Chart 11 in Annex II.

#### 8.8.1.3. Interpretation of results and conclusions

Table 21 provides acceptable and achievable limits for the MGD ( $D_G$ ).

#### 8.8.1.4. Recommendations and corrective actions

- (1) Observe the variation of  $D_G$  over time; if the limits are exceeded, investigate the possible causes and take the necessary corrective measures.
- (2) It is recommended that the MGD also be estimated from actual patient exposures periodically, and that the values be compared with the diagnostic reference levels that have been established at the local or national level [48, 64–66, 68].

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<sup>26</sup> Note that this definition uses the formula used in Europe and the United Kingdom, which uses an expected average glandular content as shown in Table 16 instead of that given previously [66], where the glandularity was assumed to be 50%.

TABLE 18. PRODUCT OF CONVERSION FACTORS  $g$  AND  $c$  FOR CALCULATING  $D_G$  FOR STANDARD BREASTS FROM MEASUREMENTS WITH DIFFERENT THICKNESSES OF PMMA PHANTOM

PMMA thickness (mm)	Equivalent breast thickness (mm)	Fibroglandular proportion of equivalent breast (%)	Product of $g$ and $c$ factors							
			HVL (mm Al)							
			0.30	0.35	0.40	0.45	0.50	0.55	0.60	
20	21	97	0.336	0.377	0.415	0.450	0.482	0.513	0.539	
30	32	67	0.245	0.277	0.308	0.338	0.368	0.399	0.427	
40	45	41	0.191	0.217	0.241	0.268	0.296	0.322	0.351	
45	53	29	0.172	0.196	0.218	0.242	0.269	0.297	0.321	
50	60	20	0.157	0.179	0.198	0.221	0.245	0.269	0.296	
60	75	9	0.133	0.151	0.168	0.187	0.203	0.230	0.253	
70	90	4	0.112	0.127	0.142	0.157	0.173	0.194	0.215	
80	103	3	0.097	0.110	0.124	0.136	0.150	0.169	0.188	

TABLE 19.  $s$  FACTORS FOR SELECTED TARGET-FILTER COMBINATIONS

Target-filter combination	Filter thickness ( $\mu\text{m}$ )	$s$ factor
Mo/Mo	30	1.000
Mo/Rh	25	1.017
Rh/Rh	25	1.061
W/Rh	50-60	1.042
W/Ag	50-75	1.042

TABLE 20.  $s$  FACTORS FOR TUNGSTEN TARGET FILTERED BY 0.5 mm OF ALUMINIUM [67]

PMMA thickness (mm)	Equivalent breast thickness (mm)	$s$ factor
20	21	1.075
30	32	1.104
40	45	1.134
45	53	1.149
50	60	1.160
60	75	1.181
70	90	1.198
80	103	1.208

TABLE 21. ACCEPTABLE AND ACHIEVABLE LIMITS FOR MEAN GLANDULAR DOSE ( $D_G$ )

Thickness of PMMA (mm)	Thickness of equivalent breast (mm)	Acceptable level for $D_G$ to equivalent breast (mGy)	Achievable level for $D_G$ to equivalent breast (mGy)
20	21	1.0	0.6
30	32	1.5	1.0
40	45	2.0	1.6
45	53	2.5	2.0
50	60	3.0	2.4
60	75	4.5	3.6
70	90	6.5	5.1

## 8.9. COLLIMATION SYSTEM

### 8.9.1. Collimation assessment

#### 8.9.1.1. Scope

Proper alignment of the edge of the compression paddle with the chest wall edge of the image receptor holder assembly is necessary for proper positioning and compression of the breast. If the edge of the compression paddle extends too far beyond the image receptor edge, the patient's chest will be pushed away from the image receptor and some breast tissue will not be recorded in the image. If the edge of the compression paddle does not extend far enough, the breast tissue will not be properly pulled away from the chest wall and compressed for visualization in the image, and a shadow of the vertical edge of the compression paddle will be visible in the image, possibly obscuring clinical information.

It is important to include as much of the breast tissue as possible in the mammogram to avoid missing the detection of a cancer. Of necessity, there is some inactive region at the chest wall edge of the detector where breast tissue is excluded.

- Objective: To determine the amount of breast tissue at the chest wall that is excluded from the image because of the imaging geometry or detector design; to ensure that the collimator allows for full coverage of the image receptor by the X ray field but does not allow radiation beyond the edges of the beam stop<sup>27</sup> except at the chest wall, and that the chest wall edge of the compression paddle aligns with the chest wall edge of the image receptor.
- Minimum frequency: Annually and following service to, or replacement of, the X ray tube, collimator or detector.

#### 8.9.1.2. Instrumentation

- (1) Two radiographic rulers (with 5 mm, or finer, markings and the '0' point at the halfway point of the ruler), or one radiographic ruler and a coin.
- (2) Five phosphorescent screen pieces<sup>28</sup>, each approximately 20 mm × 50 mm.
- (3) Opaque material (e.g. metal foil) wide enough to cover the phosphorescent strips inside the acceptable zone.
- (4) Slabs of PMMA totalling 45 mm in thickness.

#### 8.9.1.3. Methodology

*Note:* If a CR digital mammography system is being tested, screen film (if available) or CR cassettes may be used for this test, and it is suggested that the method outlined in the report Quality Assurance Programme for Screen Film Mammography (IAEA Human Health Series No. 2 [34]) be observed. However, it should be noted that the objectives and tolerances defined in that report differ from those that apply for digital mammography. With that in mind, the methodology outlined here may be preferred in all instances.

- (1) Create a 'patient' study with an appropriate name.
- (2) Tape four phosphorescent strips to the breast support, one on each edge, so that they overlap the edge of the breast support. The long dimension should be perpendicular to the edge of the breast support (Fig. 34).
- (3) Tape a fifth phosphorescent strip in the middle of the X ray field on the breast support. This strip will provide a check to ensure that the light generated by primary X ray interaction with the phosphor can be perceived.

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<sup>27</sup> 'Beam stop' refers to the material below the image receptor that provides the effective barrier for the primary X ray beam. Normally, this is the breast support table.

<sup>28</sup> The screens should be as 'bright' as possible and ideally should exhibit some persistence to facilitate observation.



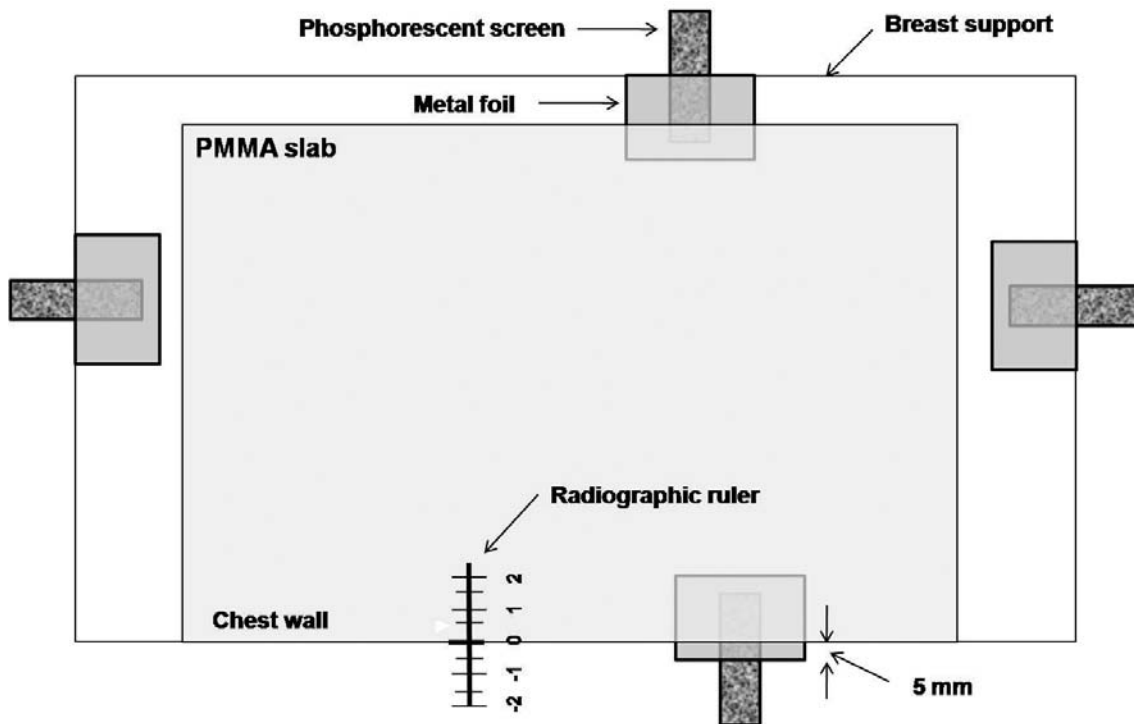


FIG. 34. Suggested layout for rulers and phosphorescent screen markers used to evaluate X ray field alignment and missing tissue. For clarity, the compression paddle with radiographic ruler attached and fifth phosphorescent screen are not shown. Details are not drawn to scale.

- (4) Using metal foils, cover those parts of the phosphorescent strips on the left, right and anterior edges that are actually on the breast support. The fourth foil should cover the phosphorescent strip on the chest wall edge up to a distance of 5 mm beyond the breast support. The pieces of phosphorescent screen are placed such that if the X ray field alignment is in compliance, the screens will not glow.
- (5) Ensure that there is a clear view of the breast support from the control console and darken the room so that the markers can be viewed to see if there is any primary radiation beyond the breast support, and verify that the phosphorescent strip in the middle of the field glows. The unit may be angulated so that the phosphorescent screens are more easily visible from behind the X ray shield at the operator's console.
- (6) Take an exposure under manual control at 28 kV and, typically, 100 mAs.
- (7) On Chart 12 in Annex II, record whether or not the phosphorescent screens glow. If any of the phosphor screens glow, this implies that the radiation field extends beyond the edge of the active area by more than the limit. If necessary, make multiple exposures to allow adequate time to observe each of the phosphor screens. Note that the digital images from these exposures are not needed for further analysis.
- (8) Place slabs of PMMA of a total thickness of 45 mm on the breast support with one edge aligned flush with the chest wall edge of the tabletop.
- (9) Place a radiographic ruler on the PMMA perpendicular to the chest wall so that the '0' marker is aligned with the edge of the PMMA. This will allow determination of the 'missing tissue'.
- (10) Tape a radiographic ruler to the underside of the compression paddle, with the zero line parallel to and aligned with the patient contact edge of the paddle at the chest wall, or tape a coin to the underside of the paddle with one edge of the coin tangent to the front edge of the paddle. Make sure that this coin does not overlap with the ruler on the PMMA. The ruler on the PMMA will provide the quantitative measurement of the position of the compression paddle edge with respect to the image receptor.
- (11) Lower the compression paddle to make light contact with the PMMA.
- (12) Make an exposure using a manual technique, matching the kV, mAs, target and filter used to image the standard breast.
- (13) Examine this digital image and determine the distance from the '0' mark on the ruler on the PMMA to the edge of the active detector. This is a measure of the 'missing tissue'.

- (14) Examine the digital image and measure the distance from the chest wall edge of the compression plate (the '0' mark on the ruler or edge of coin) to the active edge of the detector using the ruler taped to the compression paddle.
- (15) Enter the results on Chart 12 in Annex II.
- (16) Repeat steps 2 through 15 for each image receptor size. If the unit has multiple positions for the small paddle that result in different collimator blade positions (i.e. left and right, to allow better positioning for MLO views), these should be evaluated.
- (17) Ensure that the detector is fully irradiated, that is, that the collimation does not block the edges of the active field of the detector.
- (18) Repeat with the magnification table, if applicable.

#### 8.9.1.4. *Interpretation of results and conclusions*

Tolerances:

- (1) Missing tissue at the chest wall:
  - Achievable:  $\leq 5$  mm;
  - Acceptable:  $\leq 7$  mm.
- (2) Coincidence between active detector edge and radiation field:
  - Achievable: The beam completely irradiates the active area of the detector but does not extend beyond the breast support.
  - Acceptable: The beam completely irradiates the active area of the detector and does not extend beyond the breast support except at the chest wall, where it can extend beyond the breast support to a maximum of 5 mm.<sup>29</sup>
- (3) The patient contact chest wall edge of the compression paddle should not extend beyond the chest wall edge of the image receptor by more than 5 mm, and the chest wall edge of the paddle must not be visible in the image.

#### 8.9.1.5. *Recommendations and corrective action*

- (1) If the missing tissue at the chest wall is greater than 7 mm or the alignment of the compression paddle and the X ray field with the active detector area does not meet the acceptable tolerances noted above, service support is required.

#### 8.9.1.6. *Time frame for corrective action*

Corrective action should be taken within a period of 30 days.

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<sup>29</sup> Ideally, if appropriate collimation were available, the X ray field would only irradiate the entire area of the breast that lies on the image receptor. At the time of writing such a feature is not available.

## 8.10. IMAGE DISPLAY QUALITY

The accuracy of the diagnosis and the efficiency of the radiologist are influenced by the conditions under which the mammograms are viewed. Viewing conditions may affect the diagnostic potential of even the best quality mammograms. These conditions are determined by: the luminance and calibration of the monitors used for soft copy interpretation; the luminance of the viewboxes used for hard copy interpretation; the ambient room illumination or the amount of light falling on the monitor and/or viewbox surface; and effective masking of films on the viewbox.

Contrast is extremely important in the mammography image and is degraded by extraneous light. Consequently, monitors and viewboxes should be positioned so as to avoid light from windows, other monitors or viewboxes, and other sources of bright light, either direct or reflected. General lighting in the room should be diffuse and at a low level.

Ambient room lighting is as important as monitor and viewbox luminance for the radiographic reading environment. Ambient illumination should be low to improve low contrast object detectability. Glare falling upon the monitor face and being reflected into the eyes of the radiologist should be as low as possible. In the past, it was recommended that the ambient room illumination be no greater than 10 lx and ideally less than 5 lx. Currently, levels between 20 and 40 lx are considered to be more reasonable [69]. Furthermore, it recently has been suggested that there is a benefit in terms of reduced eyestrain if room lighting levels are somewhat higher and room finishes are chosen such that light the brightness of the reflected from the walls of the room in the radiologist's line of sight is similar to the average brightness emanating from the monitors when a grey image (~30% of full image brightness) is displayed. However, again it must be ensured that as little of this light as possible falls upon, and is reflected from, the monitor face. Under such conditions, ambient room lighting up to 75–100 lx may be acceptable. It should be confirmed that the luminance of light reflected off the monitor screen toward the eyes of the radiologist due to ambient light (e.g. tested with the monitor turned off) is considerably less than 1/250 of the maximum luminance provided by full image brightness. This ensures that the reflection of ambient light does not have an appreciable effect on the contrast ratio of the display.

Radiologists should experiment with the lighting conditions while viewing the TG18-QC test patterns and also while viewing clinical mammograms. Once the illumination conditions for reading have been established, they should be kept constant, and monitors should be set up for those conditions [70].

Illuminance is measured by placing the detector–filter–diffuser combination at the viewbox or monitor surface, pointed away from and parallel to the surface. These measurements can be influenced by the individual taking the measurement, especially if he or she stands between a source of light and the detector–filter–diffuser combination, or wears reflective clothing.

Some vendors provide software packages and procedures for evaluation of monitor performance. Such packages may be convenient for carrying out the assessment and tracking of display performance. If such packages are used, however, it should be ensured that all the functionality discussed below is assessed.

### 8.10.1. Artefacts and uniformity (soft copy)

#### 8.10.1.1. Scope

The procedures described below should be performed on all primary monitors used to interpret digital mammograms (radiologist workstations) and, except where indicated, on the secondary display devices. These include the monitor attached to the acquisition workstation that is used to verify patient image quality and/or the monitor(s) used to manipulate and print images. If the interpreting physicians provide final interpretations from hard copy *only*, the tests must still be performed on the secondary display devices.

Test images are required to be the same format as those produced by each model of digital mammography unit in the facility. The modified TG-18 patterns represent a simulated output from the detector of each commercial digital mammography system.

- Objective: To ensure that digital soft copy review workstation and acquisition workstation monitors have acceptably low artefact levels, with minimal geometric distortion, good contrast and good luminance uniformity.
- Minimum frequency: Annually and after software or hardware changes to the workstation.

#### 8.10.1.2. Instrumentation

- (1) Unit specific TG18-QC comprehensive display QC pattern with DICOM header and image format identical to that produced by the acquisition system (Fig. 35). Installation of images is described in Section 8.12.
- (2) MTF or resolution images from the tests described in Section 8.6.1.3 or Section 8.6.2.3.
- (3) Unit specific images of the TG18-UNL10 and TG18-UNL80 luminance uniformity patterns<sup>30</sup> (Fig. 36).
- (4) Luminance meter (see Table 24 in Appendix II).

#### 8.10.1.3. Installing test images

- (1) Install the test images on the primary and secondary display devices.
- (2) If the device can read DICOM media CDs, simply place the appropriate test image CD in the drive and import the appropriate 'patient' images.
- (3) If the device cannot read DICOM media CDs, work with the facility's PACS people to install the images onto the appropriate DICOM servers.

#### 8.10.1.4. Methodology

- (1) On each display to be tested, display the specific TG18-QC pattern provided for the acquisition system. Set the window level to half the maximum and the window width to full scale.

*Note:* The measurement procedures described here are a modified subset of those recommended by the American Association of Physicists in Medicine Task Group 18 (AAPM TG18) [71]. Additional measurements that the medical physicist may wish to include are described in the AAPM TG18 standard.

- (2) Set the room lighting to that used for image viewing.
- (3) Check that there is no evidence of smearing or bleeding noticeable in the black-to-white and white-to-black transition areas.
- (4) Inspect the image for any other artefacts, such as 'temporal variations' or 'replicated edges'.

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<sup>30</sup> These are uniformly grey images with brightness set at 20 and 80% of maximum brightness.

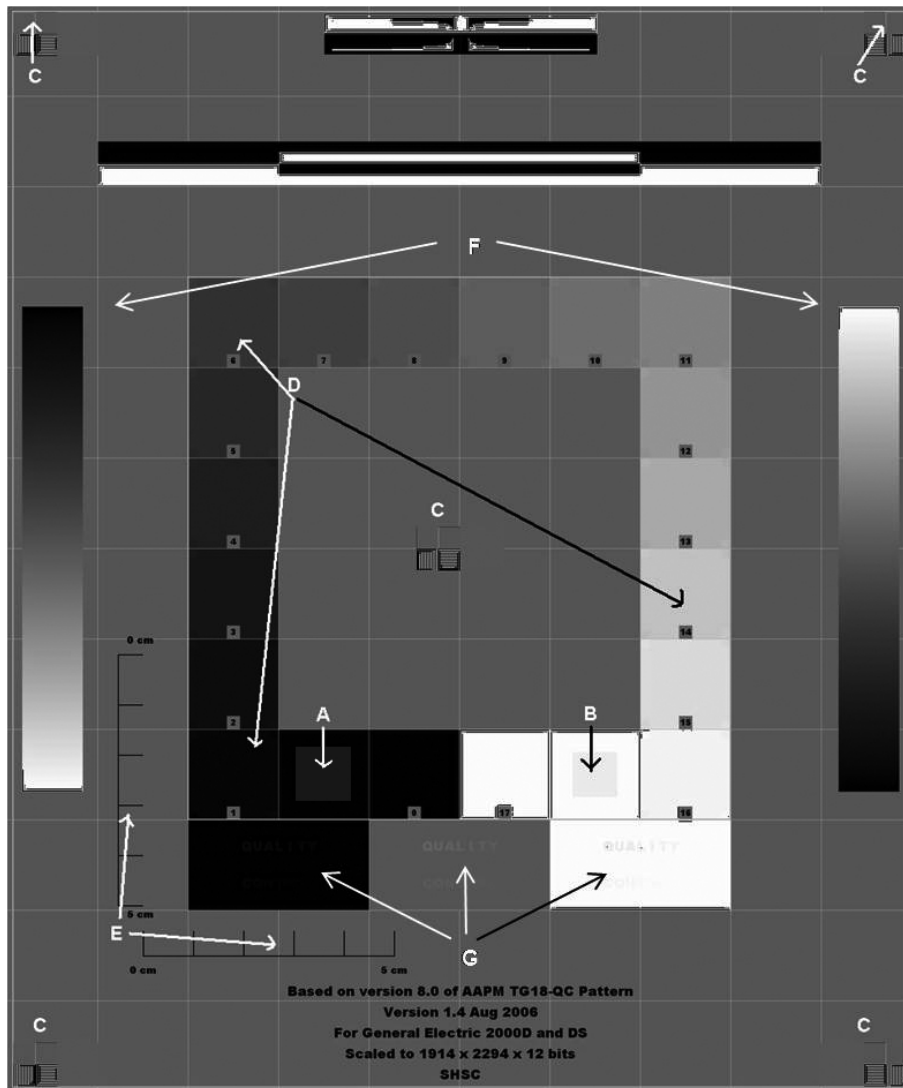


FIG. 35. Modified TG18-QC test pattern with test objects indicated: A — 0–5% contrast square, B — 95–100% contrast square, C — horizontal and vertical line pairs, D — squares going from black to white, E — 5 cm line, F— greyscale ramp, and G — ‘QUALITY CONTROL’ subjective test.

- (5) Inspect the greyscale ramps (F in Fig. 35) to ensure that they are smooth and continuous, without noticeable terracing or discontinuities.
- (6) Visually check that the lines dividing the test pattern into squares are crisp and straight, that the pattern is centred in the active image area of the monitor and that the squares are indeed square (correct aspect ratio), with right-angled corners.
- (7) Verify that the 16 grey level patches framing the central portion of the test pattern are distinguishable from one another, and that the low contrast corners in each patch are visible.
- (8) Examine the text areas (G in Fig. 35) below the central region of the pattern (only required for primary display devices/radiologist workstations). Letters spelling ‘QUALITY CONTROL’ are printed in progressively fainter text over dark, mid-grey and white backgrounds. Record the number of letters visible over each background on the acquisition monitor display quality chart (Chart 13(a) in Annex II) or the review monitor display quality chart (Chart 13(b) in Annex II), as applicable.
- (9) Verify that the 0–5% contrast box (A) is clearly discernible.
- (10) Verify that the 95–100% contrast box (B) is clearly discernible.

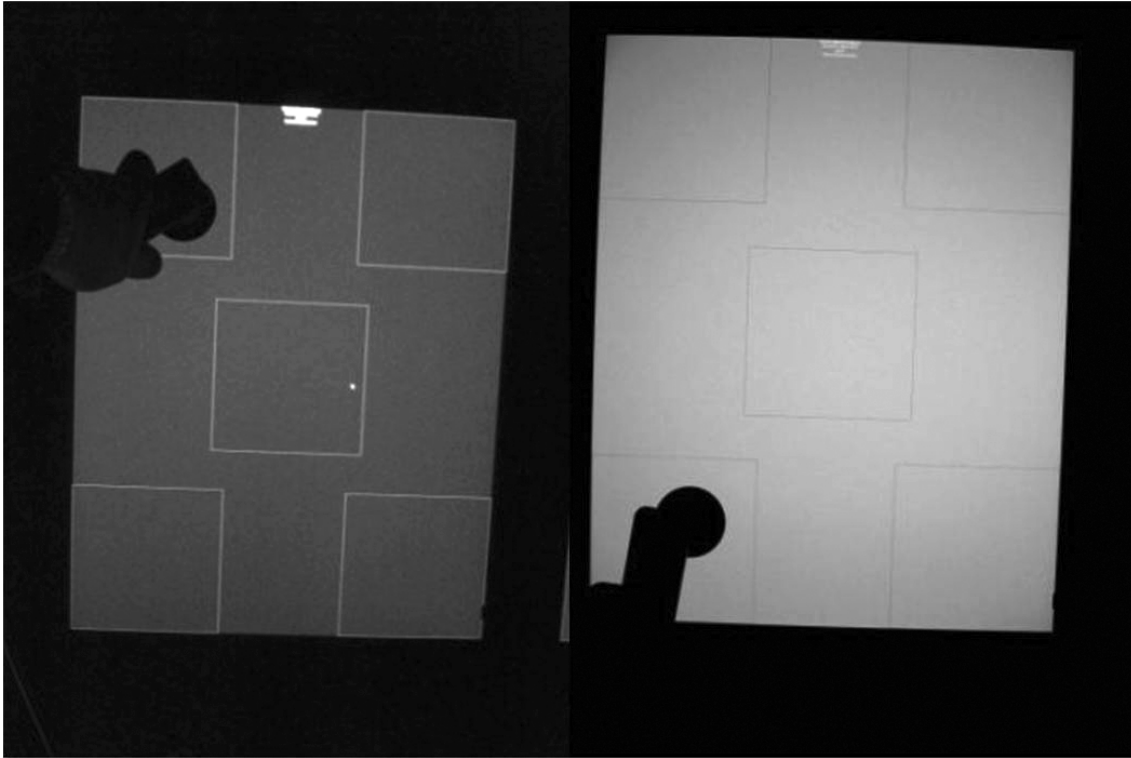


FIG. 36. Using the photometer to measure monitor luminance with the TG18-UNL10 (left) and TG18-UNL80 test patterns (right).

- (11) For primary displays, use the magnifying lens to verify that the finest (Nyquist) vertical and horizontal high contrast bars in the line pair patterns (C) are visible in all four corners and record the status on Chart 13(b) in Annex II.
- (12) For primary displays, measure the lengths of the horizontal and vertical 5 cm rulers using the display software's measurement tool and record the lengths in millimetres.
- (13) If the display system uses two monitors, repeat steps 2 through 12 on the second monitor and ensure that images on both monitors have the same appearance.
- (14) Load the MTF or resolution images taken on the acquisition workstation (one in contact mode and one magnified).
- (15) Measure the physical size of the square or resolution pattern on the phantom along one edge in both the vertical and horizontal directions, and enter these values on Chart 13(b).
- (16) Using the annotation tool, measure the size of the square or resolution pattern in the same locations for both contact and magnification images, and enter these values on Chart 13(b). This must only be done on one monitor, but it must be done on each separate workstation,
- (17) If the monitor is a primary display device, display the TG18-UNL10 image.
- (18) Measure and record the luminance in the five squares indicated (top left, top right, middle, bottom left and bottom right) in Fig. 36.
- (19) Inspect the image for artefacts such as dead or bright pixels (LCD monitors only), scratches and other brightness non-uniformities.
- (20) Repeat steps 14 through 16 with the TG18-UNL80 image.

#### 8.10.1.5. Interpretation of results and conclusions

(a) TG18-QC test pattern image

- (1) There should be no smearing or noticeable artefacts on the image. The greyscale ramps should appear smooth and continuous, without terracing or discontinuities. Artefacts might include diagonal lines, flickering, blotches, non-uniform greyscale ramps, straight lines that appear curved in the image and inappropriate bright or dark pixels.
- (2) Lines should appear straight, and the boxes should be square. The pattern should be centred in the active display area.
- (3) All 16 luminance patches should be distinct from each other in shade, and the low contrast targets should be visible in the image.
- (4) At least the letters 'QUALITY CONT' should be visible in each of the three regions of the TG18-QC image on the primary display devices (radiologist workstations).
- (5) The 5% contrast squares in the image should be visible in both the dark (0–5%) and the light (95–100%) squares (areas marked F in Fig. 36).
- (6) For primary display devices, the finest (Nyquist) vertical and horizontal high contrast bars in the patterns should be visible in all four corners and at the centre.
- (7) The length of the 50 mm line measured by the radiologist review workstation software should be between 47.5 and 52.5 mm in both the horizontal and vertical directions.
- (8) The images on paired primary display monitors (i.e. radiologist workstations) should appear to be visually identical (i.e. the same brightness and contrast).

(b) Annotation accuracy

- (1) In contact mode, the annotation tool should indicate the test object sizes to within 10% of their true size. Since the MTF tool is not on the exact plane calibrated by the manufacturer, an adjustment to that plane may be necessary. Similar performance should be demonstrated in the magnification mode.

(c) TG18-UNL test pattern images

- (1) The difference between the maximum and minimum luminance measurements taken on the TG18-UNL10 image should be within 30% of their mean.
- (2) The difference between the maximum and minimum luminance measurements taken on the TG18-UNL80 image should be within 30% of their mean.
- (3) There should be no excessively bright or dark regions, scratches, or bright or dark pixels noticeable when viewing the TG18-UNL10 or TG18-UNL80 image.

#### 8.10.1.6. Recommendations and corrective actions

- (1) Monitors need to be serviced and recalibrated by qualified service personnel if any of the following problems occur with the TG18-QC pattern:
  - Noticeable artefacts are present.
  - Lines appear curved or ragged.
  - Squares are not square.
  - Greyscale ramps are not smooth and continuous.
  - The letters 'QUALITY CONT' are not visible against the backgrounds of dark grey, mid-grey and light grey.
  - Not all 16 luminance squares or low contrast targets are discernible.
  - The horizontal and vertical high contrast finest line pair patterns cannot be resolved.
  - Measured distances are not within 5% of the true values.
  - Paired monitors have visually different appearances.

- The difference between the maximum and minimum luminance measurements taken on the TG18-UNL10 image is not within 30% of their mean.
  - The difference between the maximum and minimum luminance measurements taken on the TG18-UNL80 image is not within 30% of their mean.
  - Bright or dark regions, scratches and/or bright or dark pixels are noticeable when viewing the TG18-UNL10 or TG18-UNL80 image.
- (2) If the distance or size measuring tool does not measure the size of the physical square accurately, it will be necessary to configure the workstation to correctly indicate object sizes or to provide explanatory labelling.

*8.10.1.7. Time frame for corrective action*

Immediately: Corrective action should be taken before any further patient images are read. If the monitor being evaluated is on a review workstation, acquisition does not need to be stopped, unless repair cannot be achieved within four working days and no other approved review workstations are available for image interpretation.

*Note:* Failure of a review workstation monitor test does not mean that patient image acquisition must cease, only that interpretation of patient images using that monitor must cease until the problem is corrected.

Failure of the acquisition workstation monitor requires the cessation of patient imaging, unless the review workstation is located close enough to the acquisition workstation that each image can be checked before the next is taken.



## 8.10.2. Monitor luminance response and viewing conditions

### 8.10.2.1. Scope

The procedure outlined below should be performed on all primary medical display devices used to interpret digital mammograms.

- Objective: To ensure that digital soft copy review workstation monitors are of adequate brightness and contrast, that the luminance response is perceptually linear, and that the brightness and contrast of multiple monitors match one another such that images are displayed and printed consistently. This test also ensures that monitors meet the DICOM GDSF to enable the display of mammograms produced by any digital mammography unit adhering to the DICOM greyscale standard for presentation.
- Minimum frequency: Annually and after monitors are serviced or changes or upgrades are made to the image display software.

### 8.10.2.2. Instrumentation

- (1) TG18-LN12 image set with DICOM header exactly matching the modality produced by the acquisition system. In a PACS, these could be retrieved as Patient Name: AAPM Test Patterns and Series Name: TG18-LN.
- (2) Illuminance meter (as specified in Table 24 in Appendix II).
- (3) Luminance meter (photometer) (as specified in Table 24 in Appendix II). The photometer should *not* be the one attached to the graphics board on the workstation and used to calibrate the monitors; this test is intended to be an independent check of the system (the attached probe could be dirty or out of calibration).

### 8.10.2.3. Methodology

This procedure is to be performed for each primary display station used for diagnosis, and a separate monitor luminance response chart (Chart 14 in Annex II) should be filled out for each workstation.

- (1) Set the room lighting to that used for viewing of mammograms.

*Note:* Ambient room lighting is almost as important as the monitor and viewbox luminance when optimizing the radiographic reading environment. It is especially important that any sources of glare that will reflect from the image displays be minimized. This can be accomplished by maintaining low illuminance in the room and ensuring that as little of the room light as possible is reflected from the monitor screen into the eyes of the radiologist. Note that these measurements can be influenced by the individual taking the measurement, especially if he or she stands between a source of light and the detector–filter–diffuser combination, or wears reflective clothing.

- (2) Display the first TG18-LN12 pattern provided for the system.
- (3) Set the window level to half the maximum and the window width to full scale. Ensure that the image is scaled to fill the monitor (one image per monitor).
- (4) If the photometer used is the telescopic type, point the sensitive region of the meter at the centre of the square. If the photometer used is the near range contact type, place the sensitive region against the monitor in the centre of the square (Fig. 37). Measure the luminance of the square. Record this value on Chart 14 in Annex II and compare it with previous measurements.
- (5) Repeat steps 2–4 for each luminance level in the LN12 set.



FIG. 37. Using the photometer to measure monitor luminance with a TG18-LN test pattern.

- (6) Turn off the monitors and measure the amount of ambient light ( $L_A$ ) falling on the monitor face using the illuminance meter. If the ambient light measured has changed from the baseline value established for the reading room by more than 10 lx, adjust the room lighting until the ambient light level is within tolerance. Record the viewing conditions on the acceptable viewing conditions chart (Chart 15 in Annex II) and leave a copy on-site to be posted in the room.
- (7) If the photometer used is the near range contact type (not telescopic) the ambient luminance must be measured. With the monitor turned off, hold the photometer a distance from the monitor such that the acceptance angle includes the majority of the monitor face but excludes the monitor surroundings. This distance will vary depending on the photometer design and monitor dimensions. Care must be taken to ensure that the measurement is not affected by direct luminance sources outside the monitor face. Record the luminance reflected from the monitor face on Chart 14 in Annex II.
- (8) The automated spreadsheet in Chart 14 in Annex II will calculate and plot the test results and indicate whether performance is compliant with the GSDF.
- (9) The ratio of the maximum luminance to the minimum luminance, including the contribution from ambient lighting (contrast ratio), is also calculated by Chart 14 in Annex II.
- (10) If the workstation has paired monitors, repeat steps 2 through 8 for the second monitor.

#### 8.10.2.4. Recommendations and corrective actions

- (1) If the luminance response of the monitor(s) is unacceptable, the monitor(s) should be recalibrated. If recalibration does not correct the problem, the monitor(s) may need servicing or replacement.
- (2) If the maximum luminance difference between paired monitors is greater than 10%, recalibration is required.
- (3) If the ambient light level is non-compliant, and especially if there is noticeable glare reflected off the display, the viewing area must be redesigned.

TABLE 22. MONITOR PERFORMANCE TOLERANCES

Parameter	Acceptable	Achievable <sup>a</sup>
Maximum luminance difference between paired monitors	≤10%	≤5%
The contrast ratio (ratio between white target luminance and black target luminance, including ambient light)	≥250:1	
Plot of compliance with GSDF $(\Delta L/L)/(\text{jnd}_n - \text{jnd}_{n-1})$ versus $(\text{jnd}_n + \text{jnd}_{n-1})/2$	≤10% of the response described by DICOM soft copy GSDF	
Average number of jnds per luminance interval	≤3	
Maximum deviation from the average number of jnds per luminance interval	≤2	
Root mean square deviation from the average number of jnds per luminance interval	≤10	
Ambient light level ( $L_A$ ), or Luminance due to ambient light reflected from the monitor into radiologist's eyes	$20 \leq L_A \leq 40$ lx $\ll 1/250$ luminance of maximum image brightness	

<sup>a</sup> For most parameters there currently is not sufficient experience to define achievable levels. When these are available, they will be provided on the IAEA web site at: <http://humanhealth.iaea.org>.

#### 8.10.2.5. Interpretation of results and conclusions

The monitor performance tolerances are listed in Table 22.

#### 8.10.2.6. Time frame for corrective action

Immediately: Corrective action should be taken before any further patient images are interpreted.

*Note:* Failure of a review workstation monitor test does not mean that patient image acquisition must cease, only that interpretation of patient images using that monitor must cease until the problem is corrected.

#### 8.10.2.7. Suggested acceptable viewing conditions

- (1) The room lights should be off.
- (2) All curtains and hallway doors should be closed.
- (3) All viewboxes that could cause light to fall on the face of the monitor should be off or fully masked, if used for previous cases.
- (4) The illuminance due to ambient light in the room when used for image interpretation should be in the range of 20–40 lx.
- (5) The resulting ambient luminance of the monitors should not degrade the monitors' luminance response functions to the point where they do not comply with the DICOM GSDF.

### 8.10.3. Viewbox luminance and viewing conditions

Some facilities using digital mammography print and interpret mammograms from hard copy films. Many facilities have the need to view analogue (film) mammograms for comparison with the current (digital) study. It is important that these images be viewed under appropriate conditions. Because many of the tests described here are analogous to those performed on the soft copy displays and use the same equipment, it is convenient to perform the two sets of tests together.

#### 8.10.3.1. Scope

Viewboxes should be positioned so as to avoid light from windows, monitors, other viewboxes and other sources of bright light, either direct or reflected. Viewboxes should have functioning masks in the area around the mammograms to exclude extraneous light, which reduces image contrast and low contrast perceptibility, and also limits the maximum densities that can be seen without 'bright lighting' each image.

This procedure should be performed on all viewboxes used for interpretation of screen film mammograms or hard copy digital mammograms.

- Objective: To ensure that the luminance of the viewboxes for interpretation or QC of mammography images meets or exceeds minimum levels, that the room illuminance levels are below prescribed levels and that viewing conditions have been optimized.
- Minimum frequency: Annually.

#### 8.10.3.2. Instrumentation

- (1) Illuminance meter (as specified in Table 24 in Appendix II).
- (2) Luminance meter (photometer) (as specified in Table 24 in Appendix II).

#### 8.10.3.3. Methodology

##### (a) Viewing conditions

- (1) Reproduce the typical ambient lighting conditions for the reading room, including the overhead and task lighting that is typically used when mammograms are interpreted. Doors and window coverings should be in their normal (open or closed) positions. If light from other viewboxes can fall on the surface of the viewbox being evaluated, those viewboxes should be on, but their viewing surfaces should be covered with radiographs.
- (2) With the light level set for film reading and the viewbox turned off, measure the ambient luminance of the viewbox with film on it by pointing the photometer at the viewbox. If the photometer used is a near range contact type (not telescopic), the distance that the meter is held away from the viewbox surface should be chosen based on the meter's acceptance angle. A large amount of the viewbox should be included in the measurement without any surrounding objects.
- (3) Place the illuminance meter so that its detector is parallel to and facing away from the viewbox surface, with the rear side of the detector in contact with the viewbox surface. The meter should be held so that the medical physicist's body is not within the angle of acceptance.
- (4) Take the measurement and record the result of the illuminance falling on the viewbox surface on the viewbox luminance and room illuminance chart (Chart 16 in Annex II).
- (5) Place the illuminance meter 50 cm from the viewbox with its detector parallel to and facing towards the viewbox surface, centred on the viewbox (Fig. 38).
- (6) Take the measurement and record the result of the illuminance seen by the observer on Chart 16 in Annex II.
- (7) Confirm that the viewbox has available appropriate, functioning masks to exclude extraneous light from the light box.

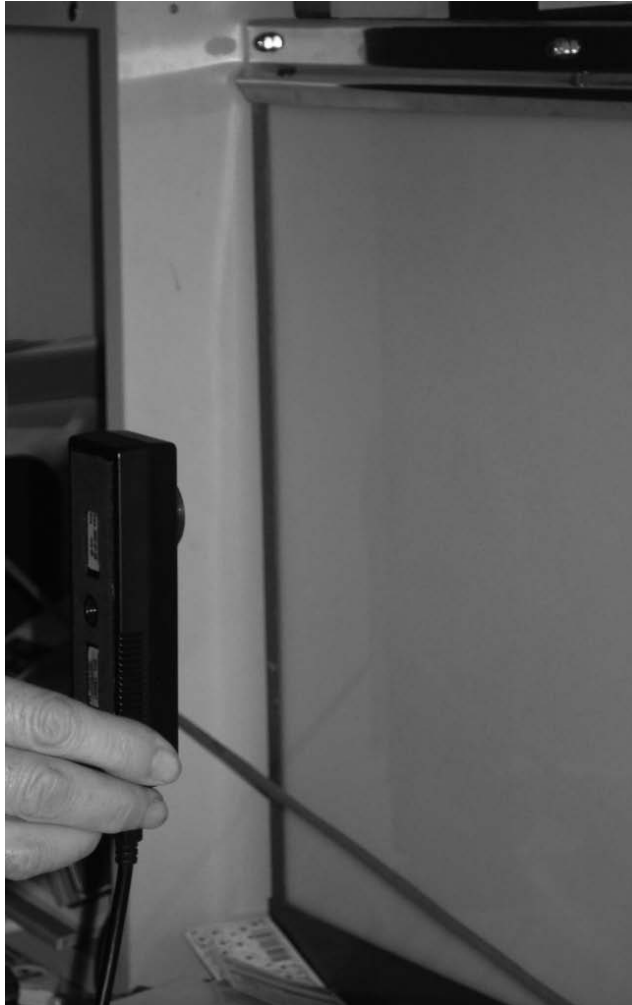


FIG. 38. Measurement of illumination at the radiologist's viewing position. The illuminance meter should be facing the viewbox at a distance of approximately 50 cm.

- (8) Confirm that the viewbox is free of obvious dirt and marks.
  - (9) Repeat the tests for all viewboxes used for interpreting printed mammograms and for the viewboxes used by the radiographer to check the printed mammograms during the examination.
- (b) Luminance and homogeneity of the viewboxes
- (1) For each viewbox that is used for mammographic interpretation, turn on the lights in the viewbox at least 20 minutes before taking the following measurements.
  - (2) Assess the need to replace defective fluorescent tubes, noting any lack of cleanliness, the colour of the tubes and the viewbox panels, vibrations, etc.<sup>31</sup>
  - (3) Record the information on the data collection sheet.
  - (4) Select five measurement points; one point should be centrally located, and the other four should be located toward the corners of the viewbox and at least 50 mm away from the edges.
  - (5) Place the luminance meter in contact with the surface of the viewbox at each selected point.

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<sup>31</sup> It is recommended that an inventory of the viewboxes in the facility be maintained, noting their location and age, and providing a history of the replacement of the fluorescent lamps.

- (6) Measure the luminance at each point. Record the values on the data collection sheet.
- (7) Repeat the tests for all viewboxes used for interpreting printed mammograms and for the viewboxes used by the radiographer to check the printed mammograms during the examination.

#### 8.10.3.4. Calculation procedure

For a single viewbox or single panel in a viewbox bank, select the central luminance value ( $L_c$ ) and the most discrepant reading recorded ( $L_{disc}$ ). Apply the following expression:

$$\text{Maximum deviation (\%)} = 100 \left| \frac{L_{disc} - L_c}{L_c} \right| \quad (10)$$

For viewboxes consisting of several panels or for viewboxes adjacent to one another, the maximum deviation between the central luminance value of any panel,  $L_{cx}$ , and the calculated mean of the central luminance of all panels,  $L_{mean}$ , is found by applying the following expression:

$$\text{Maximum deviation (\%)} = 100 \left| \frac{L_{cx} - L_{mean}}{L_{mean}} \right| \quad (11)$$

#### 8.10.3.5. Interpretation of results and conclusions

- (1) Luminance: Acceptable — maximum luminance for each panel: greater than 3000 cd/m<sup>2</sup> (nit).<sup>32</sup>
- (2) Luminance uniformity: Acceptable — less than 30% maximum deviation for different areas of a single viewbox or single panel in a viewbox bank, and less than 15% maximum deviation between central luminance of panels in a viewbox bank or between adjacent viewboxes.
- (3) Room illuminance: Acceptable — 20–40 lx.
- (4) A convenient and effective method for masking viewboxes to exclude bright light around the edges of mammograms should be available.

#### 8.10.3.6. Recommendations and corrective actions

- (1) If the ambient illumination conditions are greater than the recommended values, contact the person in charge of the maintenance service to modify the illumination of the area.
- (2) If the luminance level of the viewbox is less than 3000 cd/m<sup>2</sup>, or if the luminance or the colour of light of an individual lamp appears significantly different from those of others in the same viewbox, all lamps in the viewbox should be replaced.

*Note:* Tri phosphor or quad phosphor tubes are recommended because of their increased luminance output. If possible, all tubes in a viewbox or viewbox bank should be replaced at the same time to ensure uniformity. It is advisable to purchase fluorescent tubes in one batch to ensure that the colour matches between the tubes.

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<sup>32</sup> If the viewbox is to be used only for viewing laser printed hard copy film, a luminance of less than 3000 cd/m<sup>2</sup> is probably acceptable.

## 8.11. LASER PRINTER

### 8.11.1. Laser printer evaluation and baseline values

#### 8.11.1.1. Scope

This procedure should be performed on all printers used to print digital mammograms. Where possible, printing should be conducted directly from the acquisition workstation or radiologist review station to evaluate the integrity of the entire printing chain. It should be noted that in some facilities, the same printer is used to print out images from different types of examination (breast, chest, bones, ultrasound, CT, MRI). Each examination type or modality has a defined LUT. Therefore, the correct LUT has to be selected before mammograms or the different test patterns are printed. For this reason, it is important to ensure that the appropriate LUT is automatically selected by the printer when the images are sent to print from the mammography system.

- Objective: To ensure that high quality, uniform, artefact free images are produced; to determine the normal operating levels to be used by the radiographer for their laser printer sensitometry test.
- Minimum frequency: Initially and then annually and after service to the printer or modifications to the image display and/or printing software.

#### 8.11.1.2. Instrumentation

- (1) Unit specific TG18-QC pattern (see Fig. 35) with DICOM header and image size exactly matching the modality produced by each acquisition system or a greyscale step wedge.
- (2) Uniform test pattern such as TG18-UNL80.
- (3) Densitometer.
- (4) Magnifying lens (4× to 5× magnification).
- (5) Transparent ruler showing millimetres.
- (6) Radiologist viewbox.

#### 8.11.1.3. Methodology

- (1) Turn on the radiologist viewbox and allow it to warm up for 20 minutes to allow the light output from the lamps to stabilize.
- (2) If possible, at the workstation used for printing, using the image annotation tool, place a vertical and a horizontal line or ruler, each 5 cm in length, on the TG18-QC image near the existing rulers on the pattern.
- (3) Print the annotated TG18-QC pattern from the workstation, ensuring that the window width is set to 100% of full scale and that the window level is set to 50% of full scale.
- (4) Place the film on the radiologist viewbox for the visual verification steps.
- (5) Verify that all density steps are visible. Measure the optical density at each step and record the results on the laser printer evaluation chart (Chart 17 in Annex II). The luminance response as observed contrast/jnd difference values is plotted and the luminance ratio (dynamic range) is calculated automatically on Chart 17 in Annex II.
- (6) Verify that the low contrast squares are visible in the corners of the density steps, and record compliance on Chart 17 in Annex II.
- (7) Verify that the 0–5% and 95–100% low contrast targets are visible.
- (8) Using the magnifying lens, verify that the line pair patterns are visible in both directions for half Nyquist and full Nyquist frequencies at high and low contrast. Record the outcome on Chart 17 in Annex II.
- (9) Display the uniform image provided (e.g. TG18-UNL80). Set the window width to 100% of full scale and the window level to give a printed optical density between 1.5 and 2.0. Print the image. Record the window width and window level settings, and use the same settings each time the test is performed.
- (10) Measure the optical density in the middle of the resulting uniform film and record this value on Chart 17 in Annex II.
- (11) Examine the uniform film image for artefacts.

- (12) Using a transparent flexible ruler, measure the rulers embedded in the TG18-QC image, as well as the length of the annotation lines. Calculate the scaling factor of the printed image (i.e. 1 cm on the detector<sup>33</sup> is equivalent to how many centimetres on film?).
- (13) Record the results on the data collection sheet.
- (14) Print (and process, if a wet processor is being used) a greyscale step wedge or use the TG18-QC image.
- (15) If a TG18-QC image is printed, use the appropriate window width and window level settings. Record these values on Chart 17 in Annex II.
- (16) If a wet processor is being used, obtain five films, spaced out over at least 2 hours, but preferably over 5 days. The site radiographer can print the films, provided that he or she is shown how it should be done. Ensure that the window width and window level settings are the same each time.
- (17) If using the TG18-QC pattern, read and record the densities for the maximum optical density area ( $D_{\max}$ , border of 0–5% contrast square), the mid-density box (MD, Box 8 (47.06%)), upper density box (DD1, Box 4 (21.96%)), lower density box (DD2, Box 13 (78.43%)) and the base + fog (BF, border of 95–100% contrast square).
- (18) If using a greyscale step wedge, choose step numbers as follows:
  - Base + fog (BF) — the lightest step;
  - Mid-density (MD) — the step closest to but not below an optical density of 1.20, or the working optical density;
  - Upper density (DD1) — the step closest to but less than 2.20;
  - Lower density (DD2) — the step closest to but not less than 0.45;
  - Maximum density ( $D_{\max}$ ) — the darkest step.
- (19) If using a wet process printer, record the density values on a daily wet process printer sensitometry target values chart. If using a dry process printer, record the density values on a monthly dry process sensitometry target values chart. Use Chart 4 in Annex I as a template.
- (20) Calculate the density difference (DD) by subtracting the lower density value from the upper density value ( $DD = DD1 - DD2$ ).
- (21) If a wet process printer is being used, record these four values (BF, MD, DD and  $D_{\max}$ ). Establish the *baseline* values of each of these four parameters by calculating their average values over the five films that have been produced.
- (22) Record the target values on the daily wet process printer sensitometry target values chart or monthly dry process printer sensitometry target values chart, as appropriate.

#### 8.11.1.4. Interpretation of results and conclusions

- (1) All density steps should be distinct, and all low contrast squares in the corners of the greyscale patches should be visible. If this is the case, the density difference (contrast), maximum density and mid-density have been set appropriately and probably meet GSDF requirements.
- (2) The 5% squares at both bright and dark levels must be visible when the film is placed on the radiologist mammographic viewbox.
- (3) All line pair patterns should be distinguishable.
- (4) Measured lengths of the horizontal and vertical rulers on the TG18-QC pattern should be within 5% of actual values.
- (5) Measured lengths of the horizontal and vertical annotation lines on the film should be within 5% of actual values.
- (6) At least the letters 'QUALITY CONT' should be discernable in the displayed pattern at all three grey levels.

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<sup>33</sup> The modified TG18 patterns represent a simulated output from the detector of each commercial digital mammography system.



#### 8.11.1.5. Recommendations and corrective action

- (1) If the density steps are not distinct and/or the low contrast squares are not visible, the printer should be recalibrated to work with the current viewbox and ambient illuminance levels.
- (2) If a 5% square is not visible, the printer should be recalibrated.
- (3) The printer should be calibrated to match the DICOM soft copy GSDF when the films are read on the radiologist mammographic viewbox. The observed contrast/jnd difference  $((\Delta L/L)/(jnd_n - jnd_{n-1}))$  versus average jnd  $((jnd_n + jnd_{n-1})/2)$  should be within 20% of the response described by the DICOM GSDF.
- (4) The luminance ratio (luminance dynamic range) of the film on the radiologist mammographic viewbox should be at least 250:1.
- (5) The average number of jnds per luminance interval should be less than 3.
- (6) The maximum deviation from the average number of jnds per luminance interval should be less than 2.
- (7) The root mean square deviation from the average number of jnds per luminance interval should be less than 1.
- (8) If not all line pair patterns are distinct, the service person should be consulted.
- (9) Measured lengths of the horizontal and vertical rulers on the TG18-QC pattern should be within 5% of the actual values.
- (10) Measured lengths of the horizontal and vertical annotation lines on the film should be within 5% of their intended values.
- (11) The average length of the TG18-QC rulers should be within 5% of the average length of the annotation lines.
- (12) It should be noted that new operating levels should not need to be set, except when major changes are made to equipment. The printer should be re-calibrated to meet the expected operating levels when film or processing chemistry is changed.
- (13) If there are noticeable artefacts, the source should be identified and corrected.

#### 8.11.1.6. Time frame for corrective action

Immediately: Corrective action should be taken before any further patient films are printed.

## 8.12. IMAGE QUALITY

### 8.12.1. Evaluation of image quality

#### 8.12.1.1. Scope

It is recognized that no phantom is currently available that truly mimics the complex problem of imaging the breast. Nevertheless, it is possible to assess some key features of mammography quality by imaging a subjective breast phantom. This, for example, is the basis of image quality assessment in the IAEA QA programme for screen film mammography [34].

In digital mammography, it is useful to perform routine imaging of such a phantom to confirm that there have been no substantial changes in imaging performance from the baseline. No particular phantom can be recommended at this time. Instead, the facility should use whatever nationally or internationally recommended phantom is currently used for its screen film or digital mammography QC programmes.

- Objective: To establish a baseline level of subjective image quality; to ensure that the overall image quality has not degraded from baseline performance levels.
- Minimum frequency: At commissioning, annually and after changes.

#### 8.12.1.2. Instrumentation

- (1) Breast phantom containing structures mimicking those found in the breast.
- (2) Magnifying lens (4× to 5× magnification).

#### 8.12.1.3. Methodology

- (1) Place the phantom on the breast support positioned flush with the chest wall and centred laterally.
- (2) Lower the compression paddle to apply a compression force typically used clinically (e.g. 80 N).<sup>34</sup>
- (3) If there is a separate AEC sensor, confirm that it is correctly located under the phantom.
- (4) Select the technique factors that are used in the clinical practice for a breast having characteristics equivalent to those of the phantom. Normally this is achieved by using the automatic exposure mode. Otherwise, select the appropriate target, filter, kV, grid, density control position and operation mode (semiautomatic or automatic).
- (5) Make an exposure.
- (6) On the phantom image quality chart (Chart 18 in Annex II), record the exposure factors, the exposure indicator for CR systems and technique used.
- (7) Process the image using the algorithms that would be used clinically.
- (8) Compare this image with the baseline image obtained on this system. Determine if there are artefacts that could be confused with any of the phantom details. With the magnifying lens, carefully examine the image for non-uniform areas, dirt or dust, lines (if the grid is used), processing artefacts or any other type of artefact.
- (9) If desired, evaluate the image according to the evaluation method provided by the manufacturer.<sup>35</sup> Note the results on the data collection sheet.
- (10) Investigate the causes of any artefacts.

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<sup>34</sup> The actual force should be similar to the typical value used clinically, but the *same* value should be used for all testing. Note that in some systems and in some modes of operation, the compressed breast thickness is utilized in an automated algorithm to determine the technique factors; this thickness is, in turn, dependent on the degree of compression applied.

<sup>35</sup> A description of how this is done for the ACR accreditation phantom is provided in the IAEA publication Quality Assurance Programme for Screen Film Mammography (IAEA Human Health Series No. 2) [34].

#### 8.12.1.4. Interpretation of results and conclusions

Tolerances:

- (1) There should be no significant degradation of image quality or changes in exposure factors, or in the exposure indicator for CR systems, from the baseline image.
- (2) The image quality assessment of the phantom should yield results that are as good as, or better than, those expected with high quality screen film mammography as tested with the same phantom.

#### 8.12.1.5. Recommendations and corrective actions

If the image quality deteriorates over time, it will be necessary to carry out other investigations (e.g. kV, AEC, display, processing algorithms) to determine the source of the change.<sup>36</sup>

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<sup>36</sup> Due to the subjective component associated with the observer, it is recommended that the test always be performed by the same person, using the same criteria and viewing conditions.



## Appendix I

### MAMMOGRAPHY ROOM DESIGN<sup>37</sup>

#### I.1. LAYOUT

The layout of the mammography room should allow the radiographer easy access to the patient from all sides during the procedure. This generally means that there must be at least a 2 m distance from the centre of rotation of the gantry to the nearest wall. This will allow adequate clearance and access during an MLO view. There must be enough room at the operating console for the operator and one observer (e.g. a trainee) to stand behind the protective shield.

#### I.2. CASSETTE STORAGE FOR CR PLATES

There must be a place to store the loaded cassettes in the room, behind the protective shield (cassettes should be stored vertically, not lying flat). It is a good idea to have a number of shelves or slots with clear markings indicating where exposed cassettes are to be placed. At least four cassettes of each size must be accommodated.

#### I.3. OTHER STORAGE AND WORKING AREA

There must also be adequate, easily accessible storage for the removable grid assemblies, magnification stand, compressor plates and collimator plates. Convenient storage for the flat field phantom should be close to the unit. There should be a work surface at least large enough to accommodate the client record sheets, and a flat surface for writing.

#### I.4. VIEWBOX

A viewbox may be mounted in the mammography room for the review of prior screen film images. It should be placed at a comfortable height for the radiographer, normally with the top edge of the viewing area at 155 cm above the floor. There should be a work ledge below, not to exceed 30 cm in depth, permitting the radiographer to approach the viewbox. The intensity of this viewbox should closely match that of the viewbox used by the radiologist for reading mammograms, and a mammoviewer/magnifier and adequate masking should be available.

#### I.5. ROOM LIGHTING

To maintain a room brightness of 50 lx or less for correct viewing of images on the acquisition display monitor, and to allow visualization of the field illuminator, the room lights should be equipped with a dimmer switch. The windows (preferably frosted for privacy) should be fitted with shades and/or drapes.

#### I.6. SINK AND CLEANING PRODUCTS

A sink in the room is not a requirement; however, for infection control it is a good idea for the radiographer to wash his or her hands between each client examination, especially if there is any discharge from the nipple. If

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<sup>37</sup> This appendix has been adapted from material developed by the Ontario Breast Screening Program, Toronto, Canada. The help of that organization is gratefully acknowledged.

biopsies are performed, a sink is of higher priority. Cleaning supplies for the compression paddles and tabletop should be easily accessible and used frequently (after each client). Check with the manufacturer of the mammography unit for recommended cleaning products and instructions specific to the unit.

#### I.7. ELECTRICAL SERVICES REQUIRED

Most current digital mammography units operate from standard single phase AC circuits with a power draw of around 10 kVA instantaneous (for up to 6 s) and a standby draw of 1.5 kVA. Most units are configurable to regional power and operate on either 50 or 60 Hz. A mains isolator switch or circuit breaker fused at 25 A for 200–240V is normally required in the room. Additional line voltage receptacles for the acquisition workstation may be required if the workstation is not directly connected to the mammography unit.

#### I.8. ENVIRONMENTAL SERVICES REQUIRED

Since most mammography rooms are very small and the door remains closed during the procedure, there are often problems with environmental control. The mammography unit dissipates a considerable amount of heat, with the maximum specified being 3 kW. Often there is also a computer and monitor producing another 400 W. This heat should be considered in addition to that from the two people occupying the room for the entire day.

Digital detectors are very sensitive to temperature extremes, sometimes more so when they are not operational. Any detector that has a cooling fluid cannot tolerate freezing temperatures and may be completely destroyed if the coolant freezes inside the detector. For selenium based systems, if the room or detector temperature rises above 38°C, the detector may degrade irreversibly. If the room temperature drops below or rises above 'the comfort zone' (16–28°C), a significant length of time may be required until the operation of the detector stabilizes. Cooling units require that the room temperature be in the comfort zone, and may not be able to maintain system stability if that limit is exceeded. Always check carefully with the manufacturer for the exact requirements, as replacement detectors are expensive and are not covered by the warranty if environmental condition requirements have been exceeded.

There is a requirement for fresh make-up air as well as a cold-air return within the room. The fresh-air diffuser should not be directly in the centre of the room (over the client), as it is sometimes very uncomfortable to have air blown on a bare back and shoulders. The room should have independent heat and air conditioning control. There should be adequate humidity regulation so that there is reduced static build-up in the room. This is both for client comfort (to reduce contact static discharge) and to prevent static attraction of dust to the compression paddles and static artefacts on the films.

#### I.9. GENERAL INSTALLATION

As dedicated digital mammography systems are often of freestanding design, it should be verified that the entire system is properly installed in the examination room and is stable. Floor loading for the gantry can be up to 400 kg, concentrated on the area of the base plate of 0.33 m<sup>2</sup>. The control unit (up to 150 kg) should be level, and there should be convenient access for service and maintenance. There should be no obstruction that hinders the range of mechanical motions provided by the system. It should be ensured that the mechanical stops and magnetic locks are properly set and adjusted to prevent accidental motion or collision against other mechanical parts or the client.

#### I.10. RADIATION SHIELDING AND REGULATORY APPROVALS

The International Basic Safety Standards for the Protection against Ionizing Radiation and for the Safety of Radiation Sources (the BSS) [72] establish the requirement that all practices using ionizing radiation should be authorized. The radiology installations require, accordingly, authorization granted by the applicable regulatory

authority with regard to radiation protection. Before construction of the mammography facility begins, approval for the radiation shielding should be sought, as with any X ray facility.

The medical physicist can assist in the calculation of barrier thicknesses and provide advice on documentation requirements. Provision of adequate shielding for mammography is not normally difficult. Shielding is required only to reduce exposure from scattered radiation, since the primary beam is limited to the area of the image receptor support. Typically, a total thickness of 24 mm of gypsum wallboard (fire code rated, two standard sheets) will provide adequate shielding. The radiographer must have a transparent shield (nominally equivalent to 0.3 mm of lead) behind which he or she can stand while making an exposure. The exposure control must be designed so that it cannot be operated from outside this shielded area. The door to the room should be a solid core door; normally a fire code rated door will provide enough shielding.

#### I.11. RADIATION PROTECTIVE ACCESSORIES

In modern screening mammography, there is negligible exposure to radiation sensitive sites other than the breast. The main value of radiation protection apparel is psychological. If such apparel is to be supplied, it should only be done at the request of the patient, and the apparel should not be kept on display in the examination room. The presence of the aprons and collars in the mammography room might suggest that their use is accepted practice, which is not the case.

Both measurements and calculations show that the amount of radiation reaching the thyroid during mammography is negligible. The amount of radiation reaching the ovaries is even less, due to the attenuation by the breast support and that by the overlying tissue. Virtually all of the primary radiation is stopped by the breast and the breast support; only an extremely low level of scatter reaches other parts of the body. The calculated dose to the thyroid for one four-view examination is less than 0.03 mGy. This is about 1% of the dose that would be received by the breast during the examination and is equal to the dose that would be received by the thyroid from 3 days of natural background radiation. In other words, this would be the equivalent of the client receiving 368 days of natural background radiation per year instead of the 365 days of background radiation that would be received without the examination. Natural variations in background radiation from locality to locality represent variations much greater than this.

#### I.12. INTERNET CONNECTION

An Internet connection is generally required, but is in any case desirable, as modern systems can often be monitored, faults can be diagnosed and software can be updated remotely.

## Appendix II

### SPECIFICATIONS OF TEST EQUIPMENT

TABLE 23. SPECIFICATIONS OF TEST EQUIPMENT FOR RADIOGRAPHER'S TESTS

Item	Requirements
Flat field phantom	A uniformly thick slab of PMMA. Typically, this should be 45 mm thick; however, a slab of another thickness that has been supplied by the manufacturer for flat field correction would also be acceptable.
Contrast object	1 mm deep, 25 mm diameter depression in the PMMA slab (this depression must have a smooth, flat bottom); 1 mm thick, 25 mm diameter PMMA disc; or 0.2 mm thick square of aluminium, 10 mm on a side.
Breast phantom	Should allow assessment of background optical density, image quality and contrast. Accrediting/regulatory authorities in some jurisdictions may require that a specific make and model be used.
Modified TG18-QC (or SMPTE) test pattern	Unit specific TG18-QC comprehensive display QC pattern with DICOM header and image format identical to that produced by the acquisition system. See the IAEA web site for availability of test patterns: <a href="http://humanhealth.iaea.org">http://humanhealth.iaea.org</a>
Patient images	—
Magnifying lens	4× to 5× magnification, only for images on hard copy.
Thermometer	Preferably mounted on the wall of the digital mammography room.
Bathroom scale and towel	The scale should be a flat, conventional, analogue type. Household digital scales sample the data and may not respond properly as additional pressure is applied slowly to the scale. Digital scales designed specifically to measure compression force in mammography may be used.
Densitometer	Capable of measuring in the range of 0–4.0 OD and accurate to within $\pm 0.02$ OD.

TABLE 24. SPECIFICATIONS OF TEST EQUIPMENT FOR MEDICAL PHYSICIST'S TESTS

Item	Requirements
Breast phantom	Nationally or internationally recognized breast phantom (e.g. ACR accreditation phantom). The phantom contains structures that mimic those that must be detected in mammography.
PMMA (AEC)	Able to provide thicknesses of 20, 45 and 70 mm (suggested thicknesses: 25, 25 and 20). Thickness precision $\pm 0.5$ mm. Rectangular with dimensions $\geq 150$ mm $\times$ 100 mm, or semicircular with radius $\geq 120$ mm.
PMMA or aluminium	45 mm thick PMMA or 2.54 mm thick aluminium, large enough to cover the entire radiation field. <sup>a</sup> 25 mm thick PMMA or 1.27 mm thick aluminium for magnification test.
Spacers (rigid expanded polystyrene or equivalent)	8 mm and 20 mm thickness to fit over the AEC PMMA phantom. Other thicknesses may also be desirable.
Contrast object	Aluminium square 10 mm on a side and with a thickness of 0.2 mm, or PMMA disc with a diameter of 25 mm and a thickness of 1 mm.



TABLE 24. SPECIFICATIONS OF TEST EQUIPMENT FOR MEDICAL PHYSICIST'S TESTS (cont.)

Item	Requirements
Radiation dosimeter <sup>b</sup>	Calibrated detector at appropriate mammographic energies with an energy response of within $\pm 5\%$ ; accuracy $\pm 5\%$ , repeatability $\pm 5\%$ .
Thermometer and barometer	To be used with dosimeter when automatic temperature and pressure correction is not available.
Lead sheets with apertures of various diameters (optional)	To create narrow beam geometry for HVL measurement.
Metal plate to shield the detector from X rays	For example, 1 mm steel, 5 mm aluminium or $>0.1$ mm lead, large enough to cover the active area of the detector.
Aluminium filters	At least 99.9% pure aluminium, providing thicknesses of 0.3–0.7 mm in increments of 0.1 mm.
kV meter (required for acceptance testing, commissioning or investigation of problems only)	Capable of measurement down to 25 kV with accuracy of $\pm 1$ kV and repeatability of $\pm 0.5$ kV.
MTF test tool	A square attenuator (approximately 30 mm on a side), mounted on a backing that allows positioning on the compression plate, or 40 mm PMMA phantom at an angle of $2-5^\circ$ with respect to the chest wall at a height of 45 mm above the breast support.
Resolution pattern	Bar or star pattern covering the range of measurement of at least 2–8 lp/mm.
Densitometer <sup>c</sup>	Capable of measuring in the range 0–4.0 OD and accurate to within $\pm 0.02$ OD. For measurements on dry hard copy film, the densitometer should not take the infrared light component into account.
Optical density calibration strip	Current and traceable to an accepted standard.
Magnifier	Providing 4 $\times$ to 5 $\times$ magnification
Bathroom scale and towel	The scale should be a flat, conventional, analogue type. Household digital scales sample the data and may not respond properly as additional pressure is applied slowly to the scale. Digital scales designed specifically to measure compression force in mammography may be used.
Geometric distortion test tool	With parallel lines at 20 mm spacing, lines angled at $45^\circ$ to the edges of the tool.
Phosphorescent screens or radiochromic film (e.g. GAFCHROMIC XR-M)	To delineate area of radiation exposure during collimation tests.
Radiographic ruler with '0' at centre	For collimation and alignment tests.

TABLE 24. SPECIFICATIONS OF TEST EQUIPMENT FOR MEDICAL PHYSICIST'S TESTS (cont.)

Item	Requirements
Calibrated photometer	<p>Luminance meter (photometer) able to measure luminance between 0.5 and 1000 cd/m<sup>2</sup> with better than 5% accuracy and a precision of at least 10<sup>-2</sup>, complying with the International Commission on Illumination (CIE) standard photopic spectral response to within 3%. If the monitors are LCD technology and the photometer is a near range contact design (not telescopic), the acceptance angle must be less than 5°. The photometer should <i>not</i> be the one attached to the graphics board on the workstation and used to calibrate the monitors; this test is intended to be an independent check of the system (the attached probe could be dirty or out of calibration). It should be auto ranging and designed to measure both luminance and illuminance. For luminance measurements, a photometric filter, lens and ambient light shade should be incorporated. For illuminance measurements, a photometric filter with cosine diffuser should be used.</p> <p>Illuminance meter able to measure illuminance between 1 and 500 lx (lm/m<sup>2</sup>) with better than 5% accuracy, complying with the CIE standard photopic response to within 3%.</p>
Display test patterns (modified from AAPM TG-18)	<p>Unit specific TG18-QC comprehensive display QC pattern with DICOM header and image format identical to that produced by the acquisition system. See the IAEA web site for availability: <a href="http://humanhealth.iaea.org">http://humanhealth.iaea.org</a>.</p> <p>Generic images of the TG18-UNL10 and TG18-UNL80 luminance uniformity patterns<sup>d</sup>. See the IAEA web site for availability: <a href="http://humanhealth.iaea.org">http://humanhealth.iaea.org</a></p>

**Note:** Regular calibration of radiation detectors is essential [66].

<sup>a</sup> A smaller area of material can be used if it is raised close to the X ray tube. In this case, it must be carefully aligned parallel to the plane of the detector.

<sup>b</sup> Must comply with IEC-61674 [66, 73].

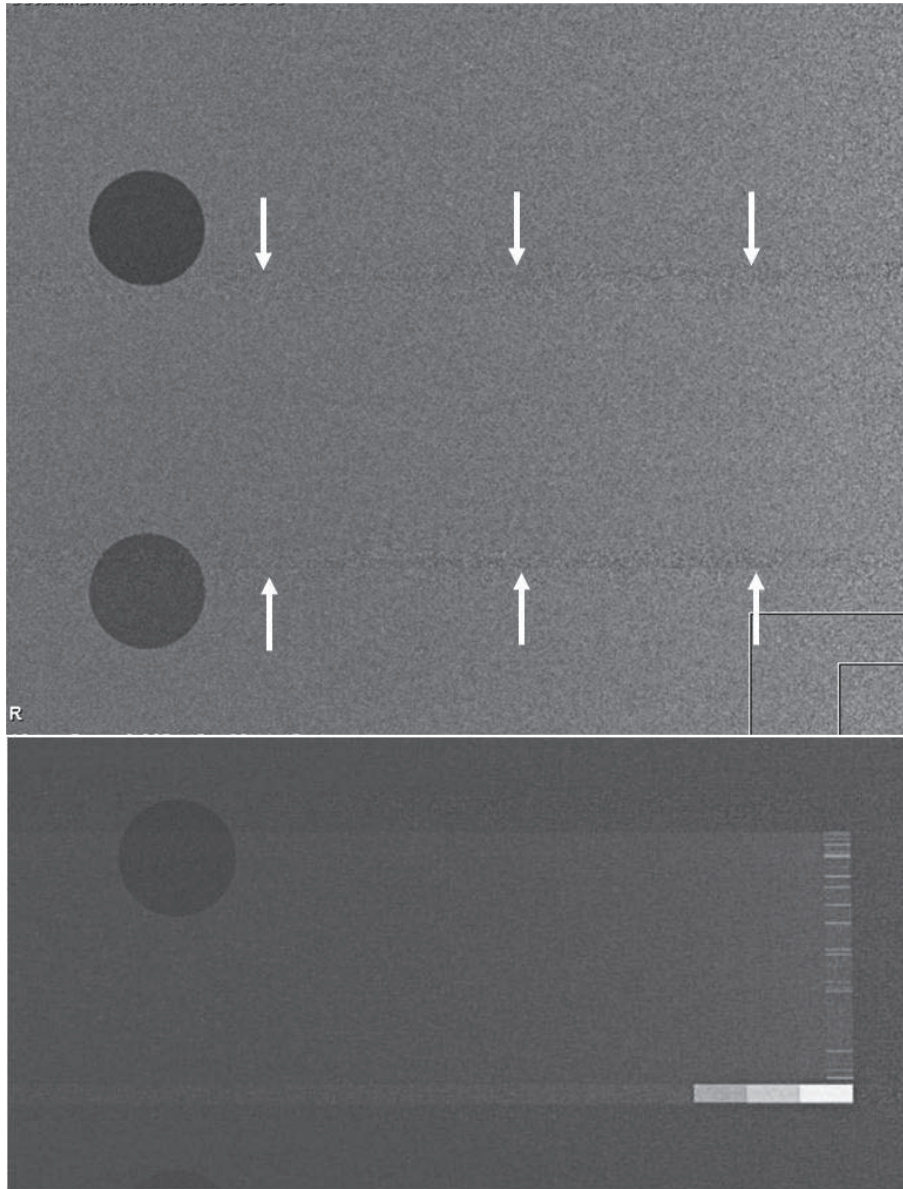
<sup>c</sup> If hard copy printing is performed in the facility.

<sup>d</sup> These are uniformly grey images with brightness set at 20 and 80% of maximum brightness.

### Appendix III

#### COMMON NON-CLINICAL ARTEFACTS ARISING IN DIGITAL MAMMOGRAPHY IMAGES

Images of clinical artefacts are presented in Section 5.7 of this publication. This appendix provides further pictorial examples of non-clinical image artefacts that may be observed during routine QC testing or annual physicist testing (Figs 39–45). This summary of artefacts should not be regarded as complete. Further examples can be found in the literature [74].



*FIG. 39. The top image is of a uniform QC test object displayed with a narrow window acquired with an early model scanning digital mammography unit demonstrating linear registration artefacts (arrows). These artefacts arise from the image reconstruction method and are not regarded as clinically significant. The lower image, illustrating part of the same test object, indicates a more serious issue of an electronic (application specific integrated circuit (ASIC)) failure.*

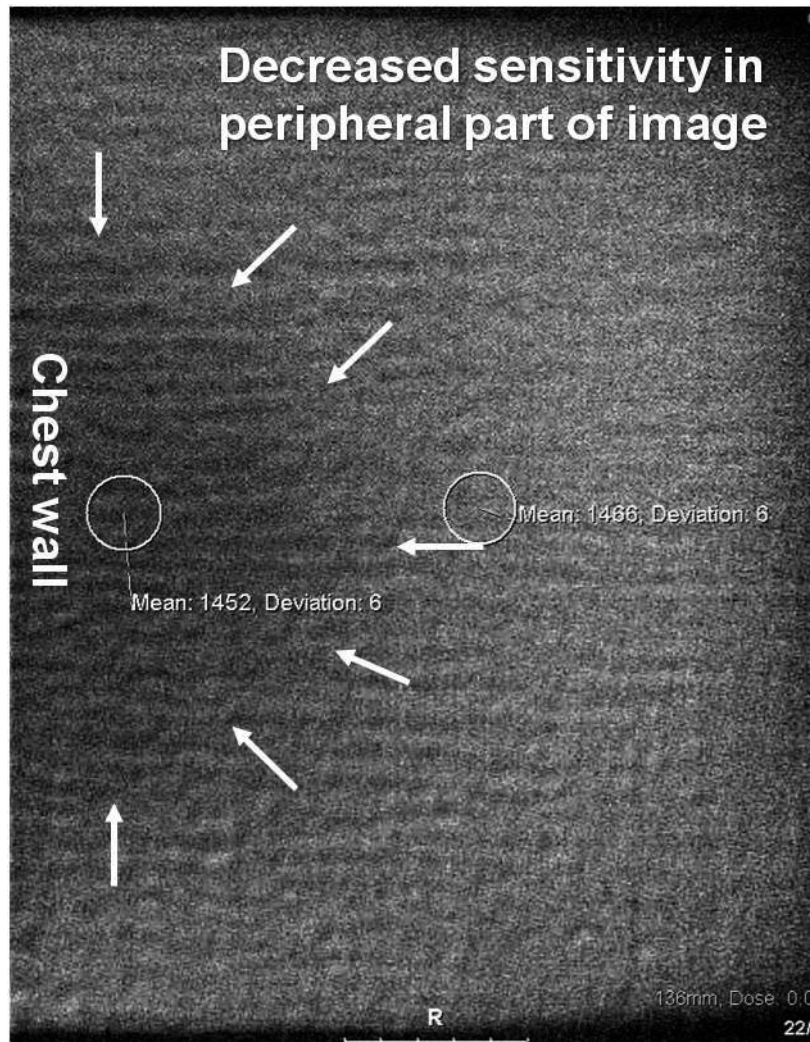


FIG. 40. Image acquired with a uniform PMMA test object illustrating an area of very slightly decreased detector sensitivity outside the region normally occupied by the compressed breast. Note that in this 'processed image', a high pixel value would normally imply lower dose. This is often referred to as 'ghosting' and is caused by the detector retaining a history of previous exposures and ultimately suffering minor radiation damage where it has intercepted the primary un-attenuated X ray beam. This particular example is not considered clinically significant because the image has been displayed with a very narrow window width and the difference in the pixel values (1466 versus 1452) in the two regions is minimal.

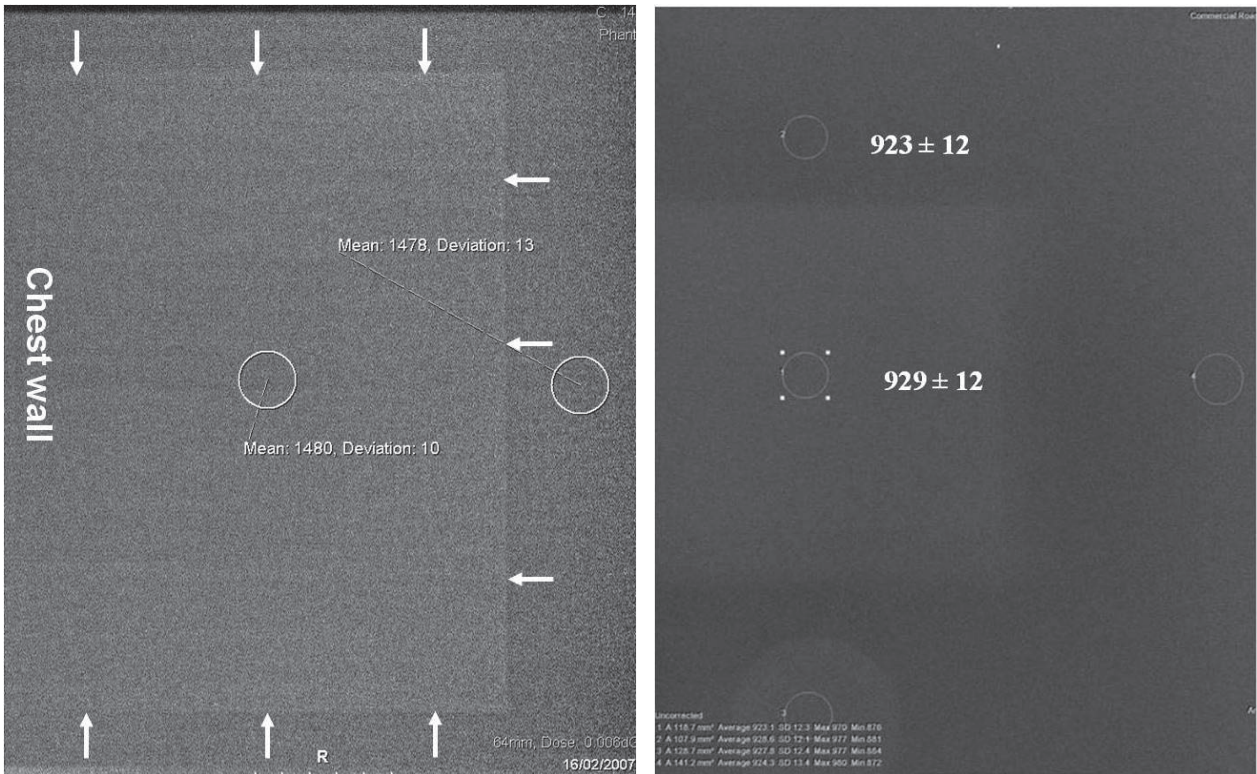


FIG. 41. Two examples of image persistence or lag in images of a large, uniform PMMA QC test object acquired immediately after an earlier image had been acquired with a slab of PMMA that covered only a part of the detector. The window width is extremely narrow, as demonstrated by the small difference in pixel values in the regions within and outside the smaller slab. In both cases, this was not regarded to be clinically significant.

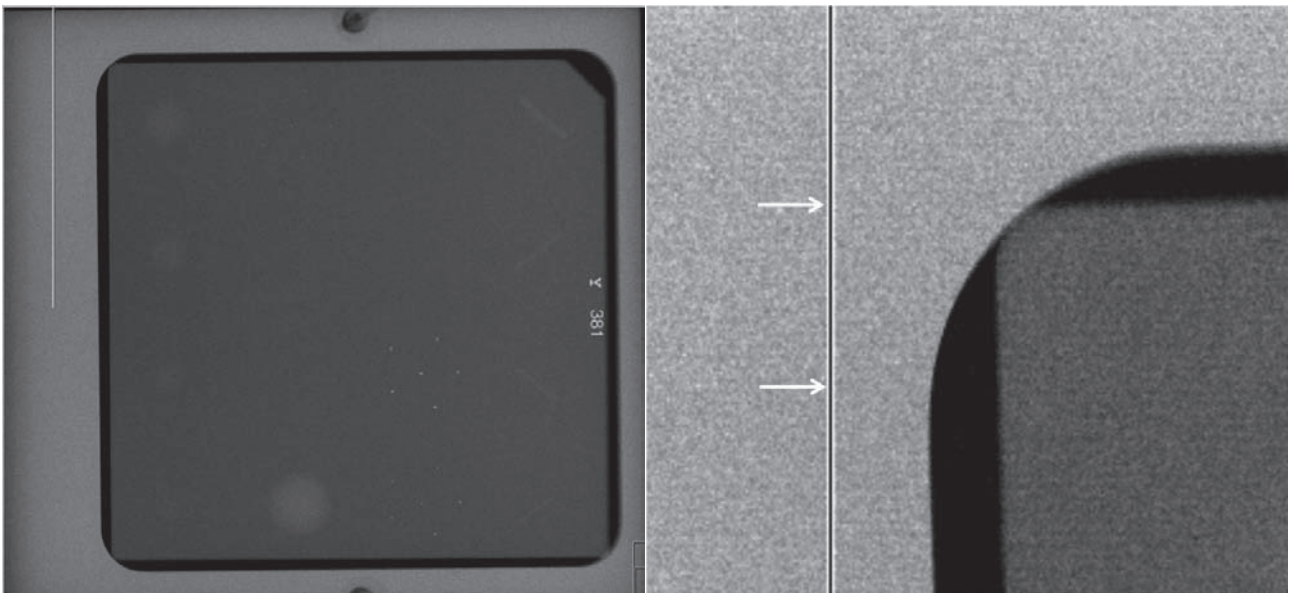
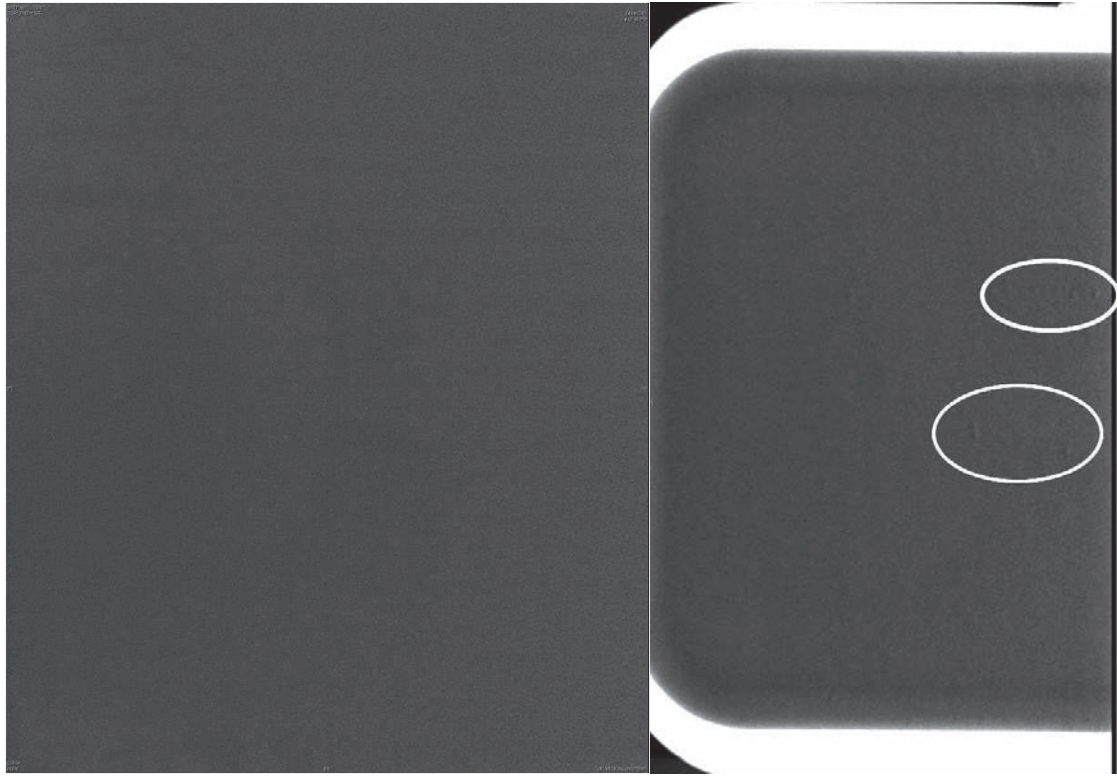
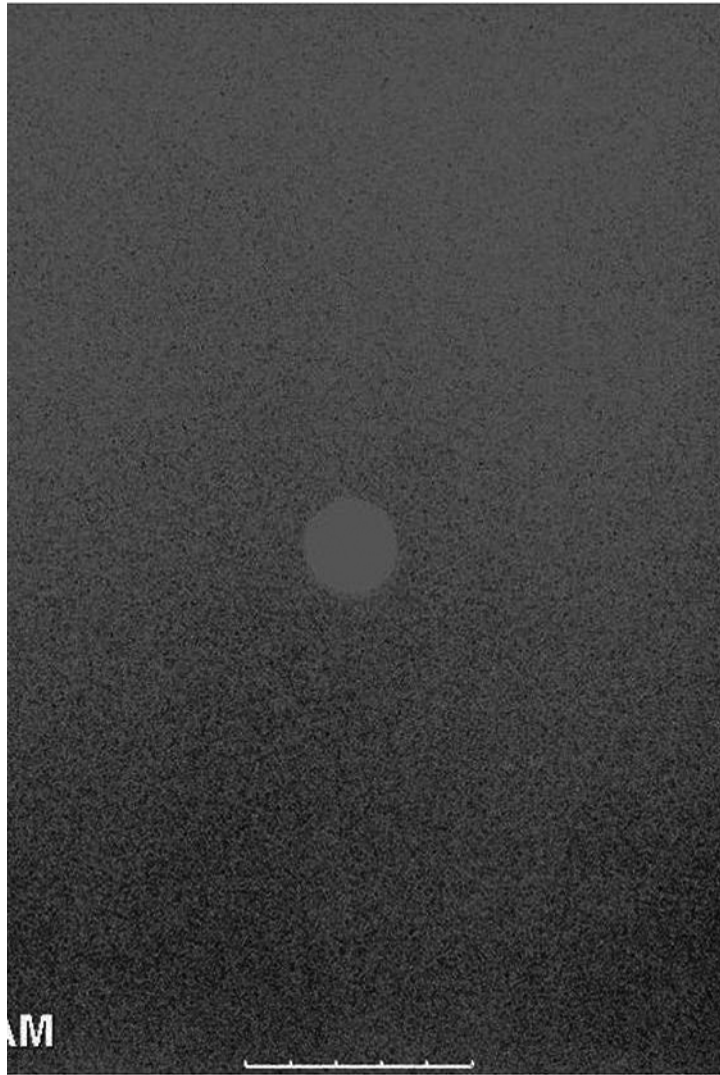


FIG. 42. The image of the ACR accreditation phantom on the left indicates additional detail in the form of a vertical line running parallel to the chest wall. Closer examination using electronic zoom, on the right, more clearly demonstrates that a line of detector elements has failed, necessitating detector replacement.



*FIG. 43. The left hand image is part of an artefact free flat field image taken in contact mode. This should be compared with the magnification image on the right, acquired subsequently with the same target–filter combination. A number of subtle dimple like artefacts are apparent. These are attributed to the flat field map acquired in contact mode not being able to correct for the difference between the grid environment and that with the magnification table in place.*



*FIG. 44. An example of poor storage of CR cassettes. The cassette was placed in the normal work storage environment with a coin taped to its surface. After a few hours, the plate was processed and the image of the coin was obvious.*

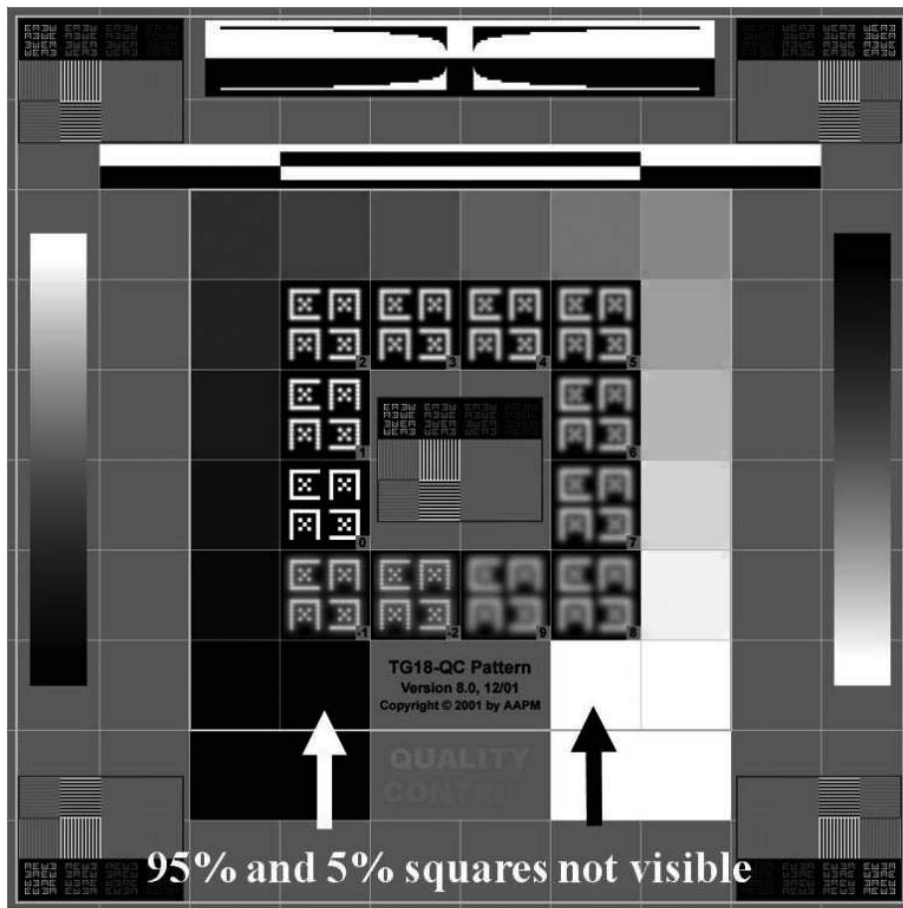


FIG. 45. A TG18-QC test pattern displayed demonstrating several problems. First, the resolution elements in the centre and corners of the pattern are not clearly resolved. Second, the 95% and 5% contrast boxes (arrows) are not visible. Finally, the letters spelling 'QUALITY CONT' are not visible in all three of the boxes near the bottom of the pattern. The monitor requires adjustment of its look-up table to better meet the DICOM part 14 GSDF.



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## Annex I

### RADIOGRAPHER DATA COLLECTION SHEETS

List of data collection sheets in this annex:

- Chart 1 — Digital mammography (DM) QC checklist: Daily and weekly tests
- Chart 2 — Digital mammography (DM) QC checklist: Monthly, quarterly and semi-annual
- Chart 3 — Establishing laser printer sensitometry reference operating levels (ROLs)
- Chart 4 — Laser printer sensitometry QC
- Chart 5 — Weekly display monitor QC: Radiologist workstation
- Chart 6 — Weekly display monitor QC: Acquisition workstation
- Chart 7(a) — Weekly QC test object: Data recording
- Chart 7(b) — Weekly QC test object: Plot
- Chart 8 — Image quality with breast mimicking phantom
- Chart 9 — Safety and function checklist of examination room and equipment
- Chart 10 — Full field artefacts
- Chart 11 — Laser printer artefacts
- Chart 12 — Printed image quality
- Chart 13(a) — Record of digital mammography repeats
- Chart 13(b) — Quarterly digital mammography repeat analysis
- Chart 14 — CR plate sensitivity matching and plate artefacts

The electronic version of these data collection sheets can be found by accessing the IAEA web site at [http://www-pub.iaea.org/MTCD/publications/PDF/Pub1482Files/Annex\\_1\\_Radiographer\\_data\\_collection\\_sheets.xls](http://www-pub.iaea.org/MTCD/publications/PDF/Pub1482Files/Annex_1_Radiographer_data_collection_sheets.xls)

**Chart 1 — DIGITAL MAMMOGRAPHY (DM) QC CHECKLIST: DAILY AND WEEKLY TESTS**

Room/Unit:  Month/Year

Checkmark (✓) = Pass/Adequate; (✗) = Fail; Initial when complete		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	20	21	22	23	24	25	26	27	28	29	30	31	
Ref.	Date																															
	Initials																															
7.1.1	Monitor inspection and cleaning																															
7.1.1	Monitor viewing conditions																															
7.1.2	DM equipment daily checklist																															
7.1.3	Daily flat field image																															
7.1.4	Visual inspection for artefacts (CR systems only)																															
7.1.5	Laser printer sensitometry — wet (daily)																															
7.1.6	Image plate erasure (CR systems only)																															
7.2.1	Monitor QC (weekly)																															
7.2.2	Viewbox cleanliness (weekly)																															
7.2.3	QC test object and full field artefacts (weekly)																															
7.2.4	Image quality with breast mimicking phantom (weekly)																															
Date:	Test:	Comment:																														

**Chart 2 — DIGITAL MAMMOGRAPHY (DM) QC CHECKLIST: MONTHLY, QUARTERLY AND SEMI-ANNUAL**

Room/Unit:		Month/Year:											
Checkmark (✓) = Pass/Adequate; ✗ = Fail; Value when relevant; Initial when complete													
Date	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	
Initials													
7.1.5 Laser printer sensitometry — dry (monthly)													
7.3.1 Safety and function checks of examination room and equipment (monthly)													
7.3.2 Full field artefacts (monthly)													
7.3.3 Laser printer artefacts (monthly)													
7.4.1 Printed image quality (quarterly)													
7.4.2 Repeat image analysis (quarterly)													
7.4.3 Spatial resolution test (CR and scanning systems) (quarterly)													
7.5.1 CR plate sensitivity matching and plate artefacts (semi-annually)													
Medical physicist review (annually)													
Date:	Test:												
	Comment:												

**Chart 3 — ESTABLISHING LASER PRINTER SENSITOMETRY  
REFERENCE OPERATING LEVELS (ROLs)**

Date values valid from:							
	Step/Box #	Date					Mean
<b>D<sub>max</sub></b>							
<b>DD1</b>							
<b>Mid-density (MD)</b>							
<b>DD2</b>							
<b>Density difference (DD = DD2 – DD1)</b>							
<b>Base + fog</b>							

	<b>ROL</b>
<b>Density difference (DD)</b>	
<b>Mid-density (MD)</b>	
<b>Base + fog</b>	
<b>D<sub>max</sub></b>	

**Reason for setting new target values:**





**Chart 5 — WEEKLY DISPLAY MONITOR QC: RADIOLOGIST WORKSTATION**

<b>Facility:</b>	<input style="width: 95%;" type="text"/>	<b>Room/Unit:</b>	<input style="width: 95%;" type="text"/>
<b>Workstation Mfr:</b>	<input style="width: 95%;" type="text"/>	<b>Monitor Mfr:</b>	<input style="width: 95%;" type="text"/>

Checkmark (✓) = Pass/Adequate; ✗ = Fail; Initial when complete

Year												
Month												
Day												
Initials												
Monitor	Left	Right	Left	Right	Left	Right	Left	Right	Left	Right	Left	Right
<b>General Image Quality (Pass/Fail)</b>												
No smearing												
No artefacts												
Ramps cont.												
<b>Geometric Distortion (Pass/Fail)</b>												
Lines straight												
Pattern greyed												
Boxes square												
<b>Luminance (Pass/Fail)</b>												
Patches distinct												
0–5% visible												
95–100% visible												
<b>Number of Letters Visible (at least 12 or “QUALITY CONT”)</b>												
Dark												
Mid-grey												
Light												
<b>Clinical Image Check (Pass/Fail)</b>												
Background (non-breast) area is black												
Background areas on 2 monitors match												
Dense breast tissues on 2 monitors match												
Contrast on 2 monitors matches												
<b>Overall Pass/Fail</b>												
<b>Remarks:</b>												
Date:	Action:											

**Chart 6 — WEEKLY DISPLAY MONITOR QC: ACQUISITION WORKSTATION**

Facility:

Workstation Mfr:

Room/Unit:

Monitor Mfr:

Checkmark (✓) = Pass/Adequate; ✗ = Fail; Initial when complete

Year												
Month												
Day												
Initials												
Monitor	Left	Right	Left	Right	Left	Right	Left	Right	Left	Right	Left	Right
<b>General Image Quality (Pass/Fail)</b>												
No smearing												
No artefacts												
Ramps cont.												
<b>Geometric Distortion (Pass/Fail)</b>												
Lines straight												
Pattern greyed												
Boxes square												
<b>Luminance (Pass/Fail)</b>												
Patches distinct												
0–5% visible												
95–100% visible												
<b>Overall Pass/Fail</b>												
<b>Remarks:</b>												
Date:	Action:											

**Chart 7(a) — WEEKLY QC TEST OBJECT: DATA RECORDING**

<b>Facility:</b>		<b>Room/Unit:</b>	
<b>Manufacturer:</b>		<b>Model:</b>	
<b>Phantom Serial #:</b>			

**Uniform phantom baseline**

**mAs baseline**

Exposure mode (AEC/AOP)		Average mAs	
Target-Filter		+10% limit	
kV		-10% limit	
Compression thickness (mm)			
Compression force (N)			

**MPV (signal) baseline**

MPV in disc (A)	
Upper action limit = MPV × 1.1	
Lower action limit = MPV × 0.9	

**SDNR Baseline**

**SDNR = (B - A)/C where**  
**A = MPV in disc**  
**B = MPV in background**  
**C = standard deviation in background**

Average SDNR value	
Upper action limit = Average SDNR × 1.1	
Lower action limit = Average SDNR × 0.9	

<b>Year</b>										
<b>Month</b>										
<b>Day</b>										
<b>Initial</b>										
<b>A</b>										
<b>B</b>										
<b>C</b>										
<b>SDNR</b>										
<b>Artefacts</b>										
<b>Acceptable</b>										
<b>Soft copy</b>										
<b>Hard copy</b>										

<b>Date:</b>	<b>Remarks:</b>

**Chart 7(b) – WEEKLY QC TEST OBJECT: PLOT**

	Year										
	Month										
	Day										
	Initial										
mAs value											
	10%	-----									
Baseline											
MPV (signal A) or exposure index											
	10%	-----									
Baseline											
SDNR (A-B/C)											
	10%	-----									
Baseline											

**Comments**

Date	Action

### Chart 8 — IMAGE QUALITY WITH BREAST MIMICKING PHANTOM

(This example chart may be suitable for scoring the ACR accreditation phantom)

Phantom used			
CR cassette size (if applicable)			
CR cassette ID (if applicable)			
	<b>Previous Image</b>	<b>Current Image</b>	<b>Change</b>
Date			
Operation mode (manual, semiautomatic, automatic)			
Target–filter			
kVp setting			
AEC detector position			
Density control (if applicable)			
mAs			
Exposure index (CR)			
Number of fibres seen			
Number of fibre-like artefacts			
<b>Fibres seen after deduction</b>			
Number of micro-calc. groups seen			
Number of micro-like artefacts			
<b>Speck groups after deduction</b>			
Number of masses seen			
Number of mass-like artefacts			
<b>Masses seen after deduction</b>			
<b>Tolerance*</b>			
<b>Fibres: <math>\geq 4</math>; micro-calcifications: <math>\geq 3</math>; masses: <math>\geq 3</math></b>			
<b>Pass (Y/N)?</b>			
<b>Change in fibres, microcalcifications, masses <math>\leq 0.5</math></b>			
<b>Pass (Y/N)?</b>			

\* The tolerances should almost certainly be more stringent for digital than for screen film mammography.

**Comments:**

**Note:** Use ALT+ENTER for a new line in comments box

**Chart 9 — SAFETY AND FUNCTION CHECKLIST OF EXAMINATION ROOM AND EQUIPMENT**

<b>Facility:</b>		<b>Room/Unit:</b>	
<b>Manufacturer:</b>		<b>Model:</b>	
<b>Year:</b>			

Checkmark (✓) = Pass/Adequate; ✕ = Fail; Initial when complete												
Year												
Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Date												
Initials												
Room temperature												
No loose parts												
Cleanliness												
No cracks in paddle												
Automatic compression release												
Compression release on power failure												
Overall integrity												
Hoses and cabling unobstructed												
Angulation indicator												
Locks (all)												
Field light												
Smoothness of motion												
Breast thickness indicator accuracy												
Face guard integrity												
Panel switches/lights/meters												
Technique charts												
Time and date on images correct												
Facility ID on images correct												
Operator radiation shield												
Cleaning solution												

If a failure of a test listed above is noted, document corrective action:

**Chart 10 — FULL FIELD ARTEFACTS**

<b>Facility:</b>	<input style="width: 95%;" type="text"/>	<b>Room/Unit:</b>	<input style="width: 95%;" type="text"/>
<b>Manufacturer:</b>	<input style="width: 95%;" type="text"/>	<b>Model:</b>	<input style="width: 95%;" type="text"/>
<b>Compression force (N):</b>	<input style="width: 95%;" type="text"/>	<b>Year:</b>	<input style="width: 95%;" type="text"/>
<b>Image processing:</b> e.g. EDR, S#, "Raw", "unprocessed"	<input style="width: 95%;" type="text"/>	<b>AEC Mode:</b>	<input style="width: 95%;" type="text"/>
		<b>Window width:</b>	<input style="width: 95%;" type="text"/>
		<b>Window level:</b>	<input style="width: 95%;" type="text"/>

<b>Month</b>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
<b>Day</b>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
<b>Initials</b>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
<b>CR cassette ID</b>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
<b>Target</b>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
<b>Filter</b>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
<b>kV</b>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
<b>mAs</b>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
<b>No significant artefacts present</b>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
<b>Hard copy (H)</b>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
<b>Soft copy (S)</b>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
<b>Both (B)</b>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>

<b>Date:</b>	<input style="width: 95%;" type="text"/>
<b>Remarks:</b>	<input style="width: 95%;" type="text"/>
<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
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<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>



### Chart 11 — LASER PRINTER ARTEFACTS

Facility:	
Year:	

Printer:	
Manufacturer:	
Model:	

Checkmark (✓) = Pass/Adequate; ✘ = Fail; NA = not applicable; Initial when complete

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Day												
Initials												
Uniform OD												
No streaks												
No specks												
No other artefacts												

Date	Remarks (Document resolution if failure noted)

**Chart 12 — PRINTED IMAGE QUALITY**

**Facility:**   
**Pattern printed from:**   
**Year:**

**Printer:**   
**Manufacturer:**   
**Model:**

Checkmark (✓) = Pass/Adequate; ✕ = Fail; NA = not applicable; Initial when complete

Year												
Quarter	1	2	3	4	1	2	3	4	1	2	3	4
Date												
Initials												
0–5% square												
95–100% square												
Horizontal line pairs												
Vertical line pairs												
Grey patches												
Lines straight												
Artefact free												
Length of 5 cm horizontal ruler is $5.0 \pm 0.3$ cm												
Length of 5 cm vertical ruler is $5.0 \pm 0.3$ cm												

Date	Remarks (Document resolution if failure noted)

### Chart 13(a) — RECORD OF DIGITAL MAMMOGRAPHY REPEATS

Enter any repeated exposures that required the patient to have additional dose beyond that of the normal examination
--

<b>Facility:</b>		<b>Room/Unit:</b>	
<b>Manufacturer:</b>		<b>Model:</b>	
<b>Date from:</b>		<b>Date to:</b>	

Study #	Causes	Frequency	Date	Repeat initiated by:	
				Physician	Radiographer

**Causes:**

- 1          Positioning**
- 2          Patient motion**
- 3          Improper detector exposure**
- 4          Artefact**
- 5          X ray equipment failure**
- 6          Software failure**
- 7          Blank image**
- 8          No image**
- 9          Other**

**Chart 13(b) — QUARTERLY DIGITAL MAMMOGRAPHY REPEAT ANALYSIS**

<b>Facility:</b>		<b>Room/Unit:</b>	
<b>Manufacturer:</b>		<b>Model:</b>	
<b>Date from:</b>		<b>Date to:</b>	

**Total exposures:**

Category	Cause	Number of exposures	Percentage of repeats
1	Positioning		
2	Patient motion		
3	Improper detector exposure		
4	Artefact		
5	X ray equipment failure		
6	Software failure		
7	Blank image		
8	No image		
9	Other		

	Total #	Repeat rate (%)
Repeat exposures (Sum 1 to 9)		

**Corrective actions**

**Chart 14 — CR PLATE SENSITIVITY MATCHING AND PLATE ARTEFACTS**

Facility:		Room:	
Manufacturer (X ray):		Model:	
Density control setting:		AEC position:	
Target:		Filter:	
kVp:		Phantom:	
IP manufacturer:		IP type:	
Month:		Year:	

Plate size = 18 cm × 24 cm					Plate size = 24 cm × 30 cm				
IP ID	mAs	Exposure index	Latches OK (Y/N)	Artefacts (Y/N)	IP ID	mAs	Exposure index	Latches OK (Y/N)	Artefacts (Y/N)
Min.					Min.				
Max.					Max.				
Mean					Mean				
Dev. (%)					Dev. (%)				

Deviation in exposure index between IP plates of different size (%) =

Acceptable tolerances on deviation from mean within same IP size			
mAs	Fuji, Philips & Konica (S#)	Kodak (EI)	Agfa (SAL/SALlog/PVIllog)
≤5%	≤5%	≤20 units	≤2.5%/±220/±290

Acceptable tolerances on deviation between means of different IP sizes			
mAs	Fuji, Philips & Konica (S#)	Kodak (EI)	Agfa (SAL/SALlog/PVIllog)
≤20%	≤20%	≤80 units	≤10%/±900/±1200

## Annex II

### MEDICAL PHYSICIST'S DATA COLLECTION SHEETS

- Chart 1 — Unit assembly evaluation
- Chart 2 — Compression–AEC evaluation
- Chart 3 — Radiographer baselines and summary
- Chart 4 — Detector baseline performance
- Chart 5 — Detector performance
- Chart 6 — Spatial linearity and geometric distortion
- Chart 7 — Evaluation of ghosting
- Chart 8 — Artifact evaluation/flat field uniformity
- Chart 9 — MTF–resolution
- Chart 10 — Beam quality (HVL)
- Chart 11 — Kerma and dose
- Chart 12 — Collimation
- Chart 13(a) — Acquisition monitor display quality
- Chart 13(b) — Review monitor display quality
- Chart 14 — Monitor luminance response
- Chart 15 — Acceptable viewing conditions
- Chart 16 — Viewbox luminance and room illuminance
- Chart 17 — Laser printer evaluation
- Chart 18 — Phantom image quality

The electronic version of these data collection sheets can be found by accessing the IAEA web site at [http://www-pub.iaea.org/MTCD/publications/PDF/Pub1482Files/Annex\\_2\\_Medical\\_physicist\\_data\\_collection\\_sheets.xls](http://www-pub.iaea.org/MTCD/publications/PDF/Pub1482Files/Annex_2_Medical_physicist_data_collection_sheets.xls). No hard copy is provided due to the complex nature of some of the sheets.

## **Annex III**

### **THE MAMMOGRAPHY EXTRACT**

The Integrating the Healthcare Enterprise (IHE) mammography handbook is useful for those who prepare request for proposal (RFP) documents for digital mammography ([http://www.ihe.net/Resources/upload/IHE\\_Mammo\\_Handbook\\_rev1.pdf](http://www.ihe.net/Resources/upload/IHE_Mammo_Handbook_rev1.pdf)).

To help the reader to understand the concepts and language of the IHE standard, selected sections of the IHE manuals pertinent to digital mammography have been abstracted. The extract is a snapshot in time, and may become obsolete, as corrections and updates may subsequently be made to the current technical framework. This framework can be found on the IHE web site at [http://www.ihe.net/Technical\\_Framework/index.cfm#radiology](http://www.ihe.net/Technical_Framework/index.cfm#radiology).

An electronic version of this extract can be found at [http://www-pub.iaea.org/MTCD/publications/PDF/Pub1482Files/Annex\\_3\\_IHE\\_MammoExtract.pdf](http://www-pub.iaea.org/MTCD/publications/PDF/Pub1482Files/Annex_3_IHE_MammoExtract.pdf) and by accessing the IAEA web site at: <http://nucleus.iaea.org/HHW/Home/index.html>.

## Annex IV

### EXPOSURE INDICES FOR MAMMOGRAPHY

The wide dynamic range of a digital imaging system will allow images produced by a wide range of detector doses to be displayed with similar greyscale appearance. Consequently, changes to the detector dose may not be readily observed unless an exposure index (EI) is provided giving an indication of the previous dose. Without such an index it is possible that breast doses may drift from the optimum; this is a particular concern if they increase markedly above the level deemed sufficient for diagnosis.

Fortunately, most digital radiography (DX) systems provide a direct indication of breast dose, based on the exposure parameters and the compressed breast thickness. These values are all carried in DICOM tags accompanying the image. In contrast, computed radiography (CR) systems are not able to provide the exposure parameters unless specific hardware and software are employed to transfer the details from the mammography X ray unit to the CR reader. Additionally, they are unable to calculate an estimate of the breast dose. However, they do provide an EI that is indirectly related to the detector dose. In all instances the relationship between the EI (Table IV–1) and the detector dose should be clearly specified in the manufacturer’s documentation along with the calibration conditions. The conditions for general radiographic systems [A–1] differ substantially from those for mammography systems. Developing a universal EI for mammography would be useful.

TABLE IV–1. EXPOSURE INDICES FOR COMPUTED RADIOGRAPHY SYSTEMS IN MAMMOGRPHY

Manufacturer	Exposure index	Calibration equation	Calibration conditions
Agfa	SAL, SALlog or PVIlog	$SAL = 253 \cdot \sqrt{K}$ $SALlog = 10\,000 \cdot \log_{10}(K) + 8\,581$ $PVIlog = 13\,287.7 \cdot \log_{10}(K) + 23\,824$	Agfa suggest using 28 kVp, Mo/Mo with 2 mm Al filtration.
Carestream	EI	$EI = 1000 \cdot \log_{10}(K) + 1000$	28 kVp, Mo/Mo with 2 mm Al filtration
Fuji	s value	$s \text{ value} = 2400/K$	25 kVp, Mo/Mo with no paddle
Konica	s value	$s \text{ value} = 2400/K$	No specific advice offered by manufacturer — use of Fuji calibration conditions is suggested
Philips	s value	See Fuji entry	See Fuji entry

**Note:** K is the air kerma incident on the plate, in mR (1 mR = 8.76 μGy).

### REFERENCE FOR ANNEX IV

- [A–1] AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, An Exposure Indicator for Digital Radiography: Report of AAPM Task Group 116, AAPM Rep. 116, AAPM, New York (2009), [http://www.aapm.org/pubs/reports/RPT\\_116.pdf](http://www.aapm.org/pubs/reports/RPT_116.pdf)



## GLOSSARY

**air kerma.** The energy deposited per unit mass in air. The unit used to measure air kerma is the gray (Gy). For X rays with energies less than 300 kilo-electron volts (keV), the magnitude of air kerma and absorbed dose in air are equivalent.

**amorphous selenium (a-Se, or  $\alpha$ -Se).** Amorphous selenium layers have the same structure as single crystals over short distances, but are less ordered over larger distances. As a result, amorphous selenium layers provide uniform X ray detection over the large areas needed by flat panel X ray detectors. When X rays are absorbed in a-Se, electron-hole charge pairs are created and these can be collected under an electric field applied between the two faces of the detector to form the signal. The a-Se can be deposited onto amorphous silicon TFT arrays to provide readout of the signal.

**amorphous silicon (a-Si, or  $\alpha$ -Si).** A type of silicon which has the same structure as single silicon crystals over short distances but is less ordered over larger distances. The ability to produce relatively large areas of amorphous silicon at a cost that is very much lower than that for single crystal silicon has enabled fabrication of flat panel TFT arrays large enough to be used as the readout structure for all flat panel X ray detectors.

**artefact.** Any structure or pattern visible in the image that is not part of the object being imaged.

**automatic exposure control (AEC) systems.**

*Fully automatic AEC.* A device designed to determine the spectrum (target material, filtration material and kV) and/or the exposure (mAs) needed to produce an adequately penetrated X ray image. This is typically done by sampling the X ray intensity after it passes through the patient and image receptor.

*Automatic exposure time (photo timing).* The beam quality parameters are selected manually and the exposure time is controlled automatically.

**bit depth.** The number of bits used to digitize the detector signal, giving rise to the number of digital signal levels (greyscale). For a bit depth of  $n$ , the number of possible grey levels is equal to  $2^n$  (i.e. 12 bits = 4096 shades of grey). Bit depth cannot be changed after equipment is purchased and is a vendor specific system characteristic.

**cassette.** A light-tight case usually made of thin, low X ray absorption plastic, for holding intensifying screens and film or the CR plate. The screen stores the latent image and requires further processing to produce a visible image.

**compression device.** A plastic paddle used to flatten and immobilize the breast. Compression helps reduce motion blurring in the breast, separates structures within the breast, and decreases the thickness of breast tissue. This minimizes the amount of radiation required and the amount of scattered radiation reaching the image receptor. Ideally, the compression device is made of rigid, thin plastic and has a flat bottom surface that is parallel to the plane of the image receptor, with edges perpendicular to the plane of the image receptor to assist in moving breast tissue away from the chest wall and into the field of view.

**contrast resolution.** The smallest relative exposure change that can be usefully imaged by a system. Ultimately, contrast resolution is limited by the dynamic range and the quantization (number of bits per pixel) of the detector. Increased contrast resolution is considered one of the major advantages of digital receptors and tends to counteract the lower spatial resolution of many digital systems.

**control chart.** A graphical means of displaying data in which the variable of interest is plotted on the vertical axis as a function of time on the horizontal axis. The control chart allows for easy and rapid review of the data to determine whether the process is within the desired control limits ('in control').

**control limit.** The upper and lower values indicating that the process is 'out of control' and requiring that corrective action be taken. It is prudent to immediately repeat the measurement to verify that the system is 'out of control' before taking corrective action. If the repeated measurement is 'out of control', then corrective action is required immediately (or in some cases within 30 days). Synonym for action limit.

**$D_{\max}$ ,  $D_{\min}$ .** The maximum and minimum optical density on a film.  $D_{\max}$  is the darkest area of the film, where the highest exposure of X rays occurs.  $D_{\min}$  is the base plus fog optical density of the film.

**del.** A physical detector element that determines the sampling aperture of the detector.

**densitometer.** An instrument for measuring the optical density or degree of blackening of film.

**density difference (DD).** The difference in optical density between the high density and the speed index. This provides an index of contrast of the mammography film.

**detective quantum efficiency (DQE).** DQE is a measure of the efficiency of an imaging system in transferring information from the X ray pattern incident on the detector to the output image. Specifically it is evaluated by dividing the square of the signal-to-noise ratio (SNR) of the output image by the square of the SNR in the incident X ray pattern. DQE ranges between 0 and 1. The only source of noise in an ideal detector results from the incident X ray quantum statistics. DQE is reduced if not all of the incident X rays are absorbed by the detector and/or the noise is increased from its theoretical value due to sources of noise added by the detector.

**dry processing.** Laser film printers that use thermal processes to produce and fix the blackness on the transparency film. They use a heat sensitive development process rather than chemicals and normally have frequent self-recalibration to ensure stability of images.

**dynamic range.** The range of exposures over which a detector can acquire image data in a single image. Typical digital systems will respond to exposures as low as 1  $\mu\text{Gy}$  and as high as 50 mGy outside the breast.

**effective resolution.** The limiting spatial resolution measured with a line pair test pattern located at the level of the top surface of the average breast. It is affected by both focal spot size and detector resolution. The effective resolution is typically measured in the orthogonal directions parallel to and perpendicular to the anode-cathode axis.

**exposure.** The act of initiating and producing X radiation from an X ray unit.

**exposure index (EI).** An index that gives an indicative relative value of the amount of radiation absorbed by a CR plate. Currently different manufacturers have different proprietary exposure indices.

**exposure time.** The duration of primary X rays striking the breast and image receptor.

**fog.** The unwanted signal added to an image by the exposure of the image receptor to light, radiation or heat between patient exposures.

**heel effect.** Non-uniformity of the radiation field striking the image receptor caused by the geometry of the X ray target. X ray intensity is higher toward the chest wall than toward the nipple, due to the increased path length through the target and filter of X rays striking the nipple side of the image receptor.

**illuminance.** A photometric quantity describing the light intensity per unit area falling on a surface. The SI unit for illuminance is the lux (candela-steradians per square meter).

**image noise.** See radiographic noise.

**image quality.** The overall merit of a radiographic image. Image sharpness, image contrast and image noise are three common measures of image quality.

**image receptor.** A device that detects and records the distribution of X rays to form an image.

**image sharpness.** The overall impression of detail in a radiographic image.

**just noticeable difference (jnd).** The smallest detectable difference between a starting and secondary level of a particular sensory stimulus. Since the visual system is not linear and has varying response depending on illumination levels, the video display must be set up so that similar changes in pixel values should be equally visible in both the dark and light regions of an image.

**kilovoltage, peak (kVp).** The maximum value of the potential difference (kV) between anode and cathode in an X ray tube. The kVp determines the maximum energy of X rays emitted by the X ray tube, usually measured in kilo-electron volts (keV).

**linearity.** System response where the output increases in direct proportion to the input signal.

**luminance.** A photometric quantity describing the light power per unit area per unit solid angle emitted by a light source. The SI unit for luminance is candelas per square meter (or nit).

**lux.** The SI unit of illuminance. One lux equals one lumen per square meter. The lumen is derived from the candela and is the luminous flux emitted into a unit solid angle (1 steradian) by an isotropic point source having a luminous intensity of 1 candela.

**mean glandular dose (MGD).** The energy absorbed per unit mass of fibroglandular tissue (the most radiosensitive tissue in the breast) averaged over all the fibroglandular tissue in the breast. The MGD is calculated from values of entrance air kerma, the X ray beam quality (half value layer), and compressed breast thickness.

**modulation transfer function (MTF).** A parameter that describes the transfer object contrast by the imaging system as a function of spatial frequency.

**Nyquist frequency.** The highest spatial frequency that can be recorded by a digital detector. The Nyquist frequency is determined by the pixel pitch. The pixel pitch is determined by sampling frequency for cassette based PSP systems and by del spacing for TFT flat panels. The Nyquist frequency is half the number of pixels per millimetre. A digital system with a pixel density of 10 pixels/mm would have a Nyquist frequency of 5 line pairs/mm.

**phantom.** A test object that simulates some aspect of human anatomy. A breast phantom simulates a typical breast in terms of size, composition and X ray attenuation, and may contain test objects that simulate anatomy in the breast.

**pixel.** A 'picture element', or pixel, is the smallest element represented in a digital image.

**polymethyl methacrylate (PMMA).** Also known by the generic name acrylic and the trade names Plexiglas, Acrylate, Lucite and Perspex.

**radiographic noise.** Fluctuations in image optical density due to the discrete nature of X ray photons and the resulting random fluctuations in the number of photons contributing to the image at each location. Also called quantum noise or quantum mottle, radiographic noise increases with increasing X ray fluence, but less rapidly than the radiographic signal.

**reference operating level (ROL).** The central value about which day to day measurements are expected to fluctuate, for example, the empirically determined speed index on a sensitometric film.

**resolution pattern.** A tool for determining the limiting spatial resolution of an imaging system. It is composed of groups of several highly X ray attenuating strips spaced by an equal width of non-attenuating material, each strip and adjacent spacer being referred to as a 'line pair'. The reciprocal of the total width (in millimetres) occupied by the line and the space determines the number of line pairs per millimetre (lp/mm) for that group. Each group of strips is smaller than the previous group; that is, it consists of more line pairs per millimetre. The last group in which each bar is visible as a distinct line indicates the limiting spatial resolution (in lp/mm) of the system.

**screening mammography.** X ray breast examination of asymptomatic women in an attempt to detect breast cancer when it is small, nonpalpable and confined to the breast.

**source to image distance (SID).** The shortest distance between the point of X ray production (focal spot) and the image receptor (detector).

**spatial frequency.** A spatial pattern such as an image can be represented as the summation of a set of spatial sinusoidal functions of appropriate amplitudes, each sinusoid covering a specific distance (e.g. millimetres) per cycle. The spatial frequency is the reciprocal of that distance and is specified in cycles/millimetre.

**spatial resolution.** The fineness of spatial detail that an imaging system can demonstrate. This can be measured from the image of a resolution pattern in terms of the number of line pairs per millimetre (see resolution pattern). Spatial resolution can be affected by the size of the X ray source, geometric magnification, blurring of signal in the X ray detector, the del size and pitch, and the pixel size. The limit imposed by data sampling is that the maximum spatial resolution (Nyquist frequency — line pairs per millimetre or lp/mm) is equal to one half the number of pixels/mm (i.e. if the sampling frequency is 5 pixels/mm, the maximum spatial resolution is 2.5 lp/mm). Spatial resolution depends on the sampling frequency for cassette based systems and the detector element size for cassette-less systems. With TFT based detectors, the actual spatial resolution is near the Nyquist frequency. With PSP based CR systems, the spatial resolution is less than the Nyquist frequency to the light spread from the PSP plate during image extraction. Unlike screen film systems, there is little correlation between exposure level and spatial resolution.

**standard breast.** A 53 mm thick compressed breast consisting of 29% fibroglandular and 71% adipose tissue used as the 'average' breast for dosimetry calculations. This may be represented by 45 mm of PMMA, a thickness that attenuates approximately the same amount as the standard breast.

**structured noise.** A background pattern in a radiograph that often adds visual clutter and degrades or masks the detection of a lesion. In a clinical image, normal anatomy can provide structured noise. In phantom images, structured noise is typically the result of systematic artefacts such as roller marks in screen film images, grid lines or poor flat fielding of digital images.

**system spatial resolution.** Resolution of the whole system and not just one component, such as the focal spot or geometric resolution or the detector resolution.

**tolerance values.** Values that express the range over which the parameter is allowed to vary before the item is no longer considered to be operating within limits. These ranges are classified into two categories: 'achievable' and 'acceptable'.

**viewbox.** A device providing a relatively uniform surface luminance for viewing mammographic films. Mammographic viewboxes should have a luminance level of at least 3000 cd/m<sup>2</sup> (nit).

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