European protocol for the quality control of the physical and technical aspects of mammography screening

2a *Screen-film mammography*

2b *Digital mammography*

Executive summary

A prerequisite for a successful screening project is that the mammograms contain sufficient diagnostic information to be able to detect breast cancer, using as low a radiation dose as is reasonably achievable (ALARA). This quality demand holds for every single mammogram. **Quality Control (QC)** therefore must ascertain that the equipment performs at a constant high quality level.

In the framework of 'Europe Against Cancer' (EAC), a European approach for mammography screening is chosen to achieve comparable high quality results for all centres participating in the mammography screening programme. Within this programme, **Quality Assurance (QA)** takes into account the medical, organisational and technical aspects. This section is specifically concerned with the quality control of physical and technical aspects of medical imaging in mammography and the dosimetry.

The intention of this part of the guidelines is to indicate the basic test procedures, dose measurements and their frequencies. The use of these tests and procedures is essential for ensuring high quality mammography and enables comparison between centres. This document is intended as a minimum standard for implementation throughout the EC Member States and does not reduce more comprehensive and refined requirements for QC that are specified in local or national QA Programmes. Therefore some screening programmes may implement additional procedures.

Quality Control (QC)
Mammography screening should only be performed using modern dedicated X-ray equipment and appropriate image receptors.

QC of the physical and technical aspects in mammography screening starts with specification and purchase of the appropriate equipment, meeting accepted standards of performance. Before the system is put into clinical use, it must undergo acceptance testing to ensure that the performance meets these standards. This holds for the mammography X-ray equipment, image receptor, film processor, viewing device and QC test equipment. After acceptance, the performance of all equipment must be maintained above the minimum level and at the highest level possible.

The QC of the physical and technical aspects must guarantee that the following objectives are met:

1. The radiologist is provided with images that have the best possible diagnostic information obtainable when the appropriate radiographic technique is employed. The images should at least contain the defined acceptable level of information, necessary to detect the smaller lesions (see CEC Document EUR 16260).
2. The image quality is stable with respect to information content and optical density and consistent with that obtained by other participating screening centres.
3. The breast dose is As Low As Reasonably Achievable (ALARA) for the mammographic information required.

QC Measurements and Frequencies
To attain these objectives, QC measurements should be carried out. Each measurement should follow a written QC protocol that is adapted to the specific requirements of local or national QA programmes. **The European Protocol for the Quality Control of the Physical and Technical Aspects of Mammography Screening** gives guidance on individual physical, technical and dose measurements, and their frequencies, that should be performed as part of mammography screening programmes.

Several measurements can be performed by the local staff. The more elaborate measurements should be undertaken by medical physicists who are trained and experienced in diagnostic radiology and specifically trained in mammography QC. Comparability and consistency of the results from different centres is best achieved if data from all measurements, including those performed by local technicians or radiographers are collected and analysed centrally.

Image quality and breast dose depend on the equipment used and the radiographic technique employed. QC should be carried out by monitoring the physical and technical parameters of the mammographic system and its components. The following components and system parameters should be monitored:

- X-ray generator and exposure control system
- Bucky and image receptor
- Film processing (for screen-film systems)
- Image processing (for digital systems)
- System properties (including dose)
- Monitors and printers (for digital systems)
- Viewing conditions

The probability of change and the impact of a change on image quality and on breast dose determine the frequencies at which the parameters should be measured. The protocol gives also the acceptable and achievable limiting values for some QC parameters. The acceptable values indicate the minimal performance limits. The achievable values indicate the limits that are achievable. Limiting values are only indicated when consensus on the measurement method and parameter values has been obtained. The equipment required for conducting QC tests are listed together with the appropriate tolerances in Table II.
Methods of dosimetry are described in the 'European Protocol on Dosimetry in Mammography' (EUR16263). It provides accepted indicators for breast dose, from both measurements on a group of women and test objects.

The first (1992) version of this document (REF: EUR 14821) was produced by a Study Group, selected from the contractors of the CEC Radiation Protection Actions. In the second (1996) and third (1999) version the test procedures and limiting values have been reviewed critically based on literature, the experience gained by users of the document and comments from manufacturers of equipment and screen-film systems. Due to the introduction of digital mammography an addendum on digital mammography was made in 2003. The current version incorporates both screen-film and digital mammography and is based on further practical experience with the protocol, comments from manufacturers and the need to adapt to new developments in equipment and in the literature.

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2a European protocol for the quality control of the physical and technical aspects of mammography screening

Screen-film mammography

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2a.1 Introduction to the measurements

This protocol describes the basic techniques for the quality control (QC) of the physical and technical aspects of mammography screening. It has been developed from existing protocols (see section 5, bibliography) and the experience of groups performing QC of mammography equipment. Since the technique of mammographic imaging and the equipment used are constantly improving, the protocol is subject to regular updates.

Many measurements are performed using an exposure of a test object. All measurements are performed under normal working conditions: no special adjustments of the equipment are necessary.
Two standard types of exposures are specified:

- The **reference exposure-** which is intended to provide information on the system under **defined** conditions, independent of the clinical settings
- The **routine exposure-** which is intended to provide information on the system under **clinical** settings

For the production of the reference or routine exposure, an object is exposed using the machine settings as follows (unless otherwise mentioned):

	Reference exposure:	**Routine exposure:**
test object thickness	45 mm[1]	45 mm
test object material	PMMA	PMMA
tube voltage	28 kV	as used clinically
target material	molybdenum	as used clinically
filter material	molybdenum	as used clinically
compression device	in contact with test object	in contact with test object
anti scatter grid	present	present
source-to-image distance	matching with focused grid	matching with focused grid
phototimer detector	in position closest to chest wall	in position closest to chest wall
automatic exposure control	on	as used clinically
optical density control	as leading to the reference optical density	as leading to the target optical density

The optical density (OD) of the processed image is measured at the **reference ROI,** which lies 60 mm from the chest wall side and laterally centred. The **reference optical density** is preferably 1.60 ± 0.15 OD.

All measurements should be performed with the same cassette to rule out differences between screens and cassettes except when testing individual cassettes (as in section 2a.2.2.2).

Limits of acceptable performance are given, but often a better result would be achievable. Both the acceptable and achievable limits are summarised in section 2a.4, table 1. Occasionally no limiting value is given, but only a typical value as an indication of what may normally be expected. The measurement frequencies indicated in the protocol (summarised in section 2a.4) are the

minimum required. When the acceptable limiting value is exceeded the measurement should be repeated. If necessary, additional measurements should be performed to determine the origin of the observed problem and appropriate actions should be taken to solve the problem.
For guidance on the specific design and operating criteria of suitable test objects; see the Proceedings of the CEC Workshop on Test Phantoms (see section 2a.5, Bibliography). Definition of terms, such as the 'reference ROI' and the 'reference density' are given in section 2a.1.2. The evaluation of the results of the QC measurements can be simplified by using the forms for QC reporting provided in section 2a.6.

2a1.1 Staff and equipment

Several measurements can be performed by the local staff. The more elaborate measurements should be undertaken by medical physicists who are trained and experienced in diagnostic radiology and specifically trained in mammography QC. Comparability and consistency of the results from different centres is best achieved if data from all measurements, including those performed by local technicians or radiographers are collected and analysed centrally.

The staff conducting the daily/weekly QC-tests will need the following equipment[2] at the screening site:

- Sensitometer
- Densitometer
- Thermometer
- PMMA plates[4,5]
- Standard test block[3] (45 mm PMMA)
- QC test object
- Reference cassette

The medical physics staff conducting the other QC-tests will need the following additional equipment and may need duplicates of many of the above:

- Dosemeter
- kVp-meter
- Exposure time meter
- Light meter
- QC test objects
- Aluminium sheets
- Focal spot test device + stand
- Stopwatch
- Film/screen contact test device
- Tape measure
- Compression force test device
- Rubber foam
- Lead sheet
- Aluminium stepwedge

2a.1.2 Definition of terms

Accuracy

Gives how close the measured value of a quantity is to the true value. In this document accuracy is used to check the correspondence between nominal and measured values of high voltage applied to an x-ray tube. The nominal value is taken as true value. The accuracy is calculated as relative difference between measured (m) and true (t) value, according to (m/t - 1), or as percentage, (m/t -1) x 100%.

Air kerma

Quotient of d_{Etr} by dm where d_{Etr} is the sum of initial kinetic energies of all the charged ionising particles liberated by uncharged ionising particles in a mass of air dm (adapted from ICRU 1980). The common unit for air kerma is milliGray (mGy).
Air kerma measures, employing a ionization chamber or another dose detector calibrated in mammography energy range, can be used to evaluate the entrance dose (Entrance Surface Air Kerma – ESAK).

Antiscatter grid — Device positioned close to the entrance surface of an image receptor for reducing the amount of scattered radiation reaching the receptor.

Automatic Exposure Control (AEC) — Operation mode of an X-ray machine by which the tube loading is automatically controlled and terminated when a preset radiation exposure to a dose detector located under the image receptor is reached. Some more sophisticated equipment also allow the automatic selection of tube potential (kV), target and filter materials.

Average glandular dose (AGD) — Reference term (ICRP 1987) for radiation dose estimation from X-ray mammography i.e. the average absorbed dose in the glandular tissue in a uniformly compressed breast. AGD value depends on X-ray beam quality (HVL), breast thickness and composition. If breast thickness and composition are not known, AGD can be referred to a standard breast.

Baseline value — Value of a parameter defined on basis of many repeated measurements (at least 10), that can be considered typical for a system. Generally, the baseline value is used when absolute limits for a parameter do not exist.

Breast compression — Application of a compression force to the breast during image acquisition. This immobilises the breast, which limits motion artifacts, and reduces breast thickness, which limits scatter effects and makes breast thickness approximately uniform.

Compression paddle — Thin device (few millimetres) rectangular shaped, made of plastic material (typical PMMA or polycarbonate) that can be positioned parallel to and above the breast table of a mammography apparatus.

Contrast threshold — Contrast level that produces a just visible difference between an object and the background.

D_{min} — Optical density obtained after processing of a non-exposed film. D_{min} is not zero due to the absorption of light in the film support and emulsion itself. In practice, for QC measurements, the density of the first step of a sensitometric strip is taken as D_{min}. It is taken as a measure of the 'base+fog' value.

D_{max} — Maximum optical density achievable with an exposed film; usually the density of the darkest step of a sensitometric strip. It corresponds to the saturation zone of a film response curve.

Film gradient — Index used to evaluate the film contrast.

Grad — See Film gradient.

Heel effect — Decreasing optical density measurable on a film in the cathode-anode direction, caused by the non-uniform intensity distribution of the X-ray beam. It is due to the geometric setup of the X-ray tube.

Half Value Layer (HVL) — Thickness of absorber which attenuates the air kerma of non-monochromatic X-ray beams by half. The absorber normally used to evaluate HVL of low energy X-ray beams, such as mammography beams, is high purity aluminium (≥ 99.9%). It should be noticed

	that a correct measurement of HVL requires 'good geometry' conditions (proper distances among source, attenuator and image receptor, collimation and perpendicular incidence at image receptor entrance), rather far from geometry imposed by mammography equipment. Thereby, the HVL measurement is a sort of verification about the compatibility of radiation spectra with standard values measured with calibrated beams.
Image quality	There is not a definition of image quality univocally accepted. Commonly, it is possible to define quality indices representing the information content of the image; this is often done by test objects including details whose visibility can be quantified by means of proper scoring criteria.
Limiting value	Maximum or minimum limit of a possible range, considered acceptable for a given parameter.
Mean gradient (MGrad)	Parameter describing the film contrast in the exposure range, which contains most diagnostic information. MGrad is calculated as the slope of the line through the points $D_{0.25}$ = (D_{min} + 0.25) OD and D_2 = (D_{min} + 2.00) OD. Since the film curve is constructed from a limited number of points, $D_{0.25}$ and D_2 must be obtained by interpolation. Linear interpolation will result in sufficient accuracy.
Measurement error	Standard deviation if the number of repeated measurements is large enough (at least 5); maximum error [(max-min)/2] for few measures.
Middle gradient ($Grad_{1,2}$)	Parameter describing the film contrast in the middle of the diagnostic range. $Grad_{1,2}$ is calculated as the slope of the line through the points D_1 = (D_{min}+ 1.00) OD and D_2 = (D_{min}+ 2.00) OD. Since the film curve is constructed from a limited number of points, D_1 and D_2 must be obtained by interpolation. Linear interpolation will result in sufficient accuracy.
Net optical density	Optical density excluding base and fog. Base+fog value is determined measuring the optical density into a non-exposed area of film (see D_{min}).
Optical density (OD)	Logarithm (base 10) of the ratio between light intensity produced by a visible light source and perpendicularly incident on a film (Io), and light intensity transmitted by the film (I): OD = $\log_{10}$ (Io/I) Optical density is measured by an instrument named densitometer, that measures transmitted light intensity into an area of the order of mm^2. Variations in optical density should be measured along a direction parallel to the major axis of image receptor (perpendicular to cathode-anode direction), to avoid influences by the angular distribution of X-ray intensity (heel-effect).
Patient dose	Generic term for a variety of radiation dose quantities applied to a (group of) patient(s).
PMMA	The synthetic material polymethylmethacrylate. Trade names include Lucite, Perspex and Plexiglas.
Precision	See Reproducibility.

Quality assurance — As defined by the WHO (1982): 'All those planned and systematic actions necessary to provide adequate confidence that a structure, system or component will perform satisfactorily in service (ISO 6215-1980). Satisfactory performance in service implies the optimum quality of the entire diagnostic process i.e., the consistent production of adequate diagnostic information with minimum exposure of both patients and personnel.'

Quality control — As defined by the WHO (1982): 'The set of operations (programming, coordinating, carrying out) intended to maintain or to improve [. . .] (ISO 3534-1977). As applied to a diagnostic procedure, it covers monitoring, evaluation, and maintenance at optimum levels of all characteristics of performance that can be defined, measured, and controlled.'

QC test object — Object made of tissue simulating material (typically PMMA) for image quality evaluation; it generally includes objects simulating mammographic lesions (microcalcifications, fibers, masses) and/or resolution patterns and step wedges to measure parameters such as spatial resolution or contrast, related to image quality.

Radiation quality — See HVL.

Reference cassette — Cassette, properly identified, used for QC tests. Using a single cassette permits to exclude variations in optical density caused by changes in absorption from different cassettes or individual screen efficiencies.

Reference exposure — Exposure of the standard test object with predetermined values of parameters to provide an image at reference conditions.

Reference optical density — Optical density of (1.6 ± 0.1) OD, measured in the reference ROI.

Reference ROI — Considering an image obtained by the standard test block, the reference ROI is centred 60 mm perpendicular from the chest wall in the middle of the major film axis.

Relative error — Ratio between measurement error and mean value.

Reproducibility — Indicates the measurement precision or the reliability of tested equipment.

Region Of Interest (ROI) — Measurement area of optical density whose boundaries can be virtually defined on an image. ROI size can be around 1 cm^2.

Routine exposure — Exposure of the standard test block under the conditions that would normally be used to produce a mammogram having the routine optical density into the reference ROI. The routine exposure is used to check optical density and dose stability under clinical conditions.

Routine optical density — Optical density measured in the reference ROI of a standard block image obtained by a routine exposure. This value is chosen by the site personnel as optimal value for mean clinical mammograms provided by a specific imaging chain. The routine net optical density should be included into the interval [1.4-1.9] OD.

Spatial resolution (at high or low contrast)

Describes the smallest detectable detail at a defined contrast level to a given background. It is commonly evaluated by means of bar patterns, i.e. test objects constituted by groups of absorbing lines (typically Pb or Au) alternated to transparent lines of the same size. Line groups have increasing spatial frequency (typically expressed in 'line pairs/mm'); the frequency at which line paires remain distinguishable is taken as the limiting spatial resolution. In conditions of 'high contrast', that can be obtained by exposing the bar pattern only, this evaluation provides an estimation of the limiting spatial resolution of the whole mammography unit. The spatial resolution test can also be performed for 'low contrast' conditions, in order to simulate the degradation of both spatial resolution and contrast typical of clinical images. Image quality test objects including among the details one ore more bar patterns are available on the market.

Speed

Synonym of film sensitivity, is a parameter inversely proportional to dose. Speed is defined as the reciprocal of dose necessary to produce on a film an optical density equal to 1.00 + D_{min}; conventionally, it has been established that speed 100 means the film needs 10 µGy to produce 1.00 OD above base+fog, while speed 400 means the film requires 2.5 µGy to obtain the same result. If film Speed is higher, the dose necessary to obtain a same value of optical density is lower. Since in practice the sensitometric curve is constructed from a limited number of points, the film speed must be obtained by interpolation. Linear interpolation will result in sufficient accuracy.

Standard breast

Mathematical model generally used for calculations of glandular dose in Monte Carlo simulations. It consists of a 40 mm thick central region comprising a certain mixture by weight of adipose tissue and glandular tissue (dependent on compressed breast thickness and age) surrounded by a 5 mm thick superficial layer of adipose tissue (simulating skin absorption). The standard breast is semicircular with a radius ≥ 80 mm and has a total thickness of 50 mm (40+5+5). It is commonly assumed that a uniform PMMA block 45 mm thick is equivalent in absorption to a standard breast. (Note that other definitions of a standard breast have been used in other protocols. As an example, in the UK the standard breast has a total thickness of 45 mm with a 35 mm thick central region.)

Standard test block

PMMA test object to simulate the absorption of a standard breast. Its thickness is (45.0 ± 0.5) mm and the remaining dimensions can be either rectangular ≥ 150 mm x 100 mm or semi-circular with a radius of ≥ 100 mm. The standard test block can be used to check the AEC behaviour or to evaluate a mean value of AGD.

Typical value

Value of a parameter found in most facilities in comparable measurements. The statement of typical value is an indication about values that could be expected, without imposing any limits to obtainable results.

Tube loading

Product of the X-ray tube current (milliampere, mA) and the exposure time (seconds, s). It is quantified in units of mAs.

Tube potential

The potential difference in units of kilovolt (kV) applied across the anode and cathode of an X-ray tube during a radiographic exposure.

Tube yield Ratio between air kerma (mGy) measured without any test object and the tube loading (mAs), for a known distance between the X-ray source and the dosimeter and for preset exposure parameters.

X-ray spectrum Distribution of photon energies in an X-ray beam. It depends on anode and filter material and tube potential, as well on all attenuators (tube output window, compression device, air gap) between anode and breast.

2a.2 Description of the measurements

Generally when absolute measurements of dose are performed, make sure that the proper corrections for temperature and air pressure are applied to the raw values. Use one and the same box of (fresh) film throughout the tests described in this protocol.

Local basic safety tests should be followed. If no local basic safety tests are available, an example of such tests can be found in appendix 1.

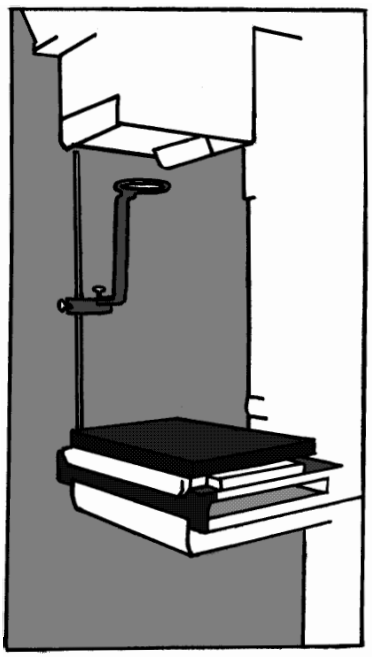
2a.2.1 X-ray generation

2a.2.1.1 X-ray source

The measurements to determine the focal spot size, source-to-image distance, alignment of X-ray field and image receptor, radiation leakage and tube output, are described in this section.

2a.2.1.1.1 Focal spot size

The measurement of the focal spot size is intended to determine its physical dimensions at installation or when resolution has markedly decreased. The focal spot size must be determined for all available targets of the mammography unit. For routine quality control the evaluation of spatial resolution is considered adequate.



The focal spot dimensions can be obtained by using one of the following methods.

- Star pattern method; a convenient method (routine testing)
- Slit camera; a complex, but accurate method for exact dimensions (acceptance testing)
- Pinhole camera; a complex, but accurate method to determine the shape (acceptance testing)
- Multi-pinhole test tool, a simple method to determine the size across the field (routine/acceptance testing)

Some fully automated digital devices to measure focal spot size are available. If validated they may be used.
When doing focal spot size measurements, it is advised to use one of the above mentioned methods consistently.

A magnified X-ray image of the test device is produced using a non-screen cassette. This can be achieved by placing a black film (OD ≥ 3) between screen and film. Select the focal spot size required, 28 kV tube voltage and a focal spot charge (mAs)

Fig. 2.1 Focal spot size measurement using the star pattern method

to obtain an optical density between 0.8 and 1.4 OD base and fog excluded (measured in the central area of the image). The device should be imaged at the reference ROI of the image plane, which is located at 60 mm from the chest wall side and laterally centred. Remove the compression device and use the test stand to support the test device. Select about the same focal spot charge (mAs) that is used to produce the standard image of 45 mm PMMA, which will result in an optical density of the star pattern image in the range 0.8 to 1.4.
According the IEC/NEMA norm, an 0.3 nominal focal spot is limited to a width of 0.45 mm and a length of 0.65 mm. A 0.4 nominal focal spot is limited to 0.60 and 0.85 mm respectively. No specific limiting value is given here, since the measurement of imaging performance of the focal spot is incorporated in the limits for spatial resolution at high contrast. (see 2a.2.5.2)

Focal spot size: star pattern method
The focal spot dimensions can be estimated from the 'blurring diameter' on the image (magnification 2.5 to 3 times) of the star pattern. The distance between the outermost blurred regions is measured in two directions: perpendicular and parallel to the tube axis. Position the cassette on top of the bucky (no grid).
The focal spot is calculated by applying formula 2.1, which can also be found in the completion form.

$$f = \frac{\pi . \theta}{180} \frac{d_{blur}}{(m_{star} - 1)} \qquad (2.1)$$

where q is the angle of the radiopaque spokes, and d_{blur} is the diameter of the blur.
The magnification factor (m_{star}) is determined by measuring the diameter of the star pattern on the acquired image (d_{image}) and the diameter of the device itself (d_{star}), directly on the star, and is calculated by:

$$m_{star} = d_{image} / d_{star} \qquad (2.2)$$

Limiting value	None.
Frequency	At acceptance and when resolution has changed.
Equipment	Star resolution pattern (spoke angle 1° or 0.5°) and appropriate test stand.

Focal spot size: slit camera method
To determine the focal spot dimensions (f) with a slit camera, a 10 mm slit is used. Remove the compression device and use a test stand to support the slit. Produce two magnified images (magnification 2.5 to 3 times) of the slit, perpendicular and parallel to the tube axis.
The dimensions of the focal spot are derived by examining and measuring the pair of images through the magnifying glass. Make a correction for the magnification factor according to $f=F/m_{slit}$, where F is the width of the slit image. The magnification factor (m_{slit}) is determined by measuring the distance from the slit to the plane of the film ($d_{slit\text{-}to\text{-}film}$) and the distance from the focal spot to the plane of the slit ($d_{focal\ spot\text{-}to\text{-}slit}$). m_{slit} is calculated by:

$$m_{slit} = d_{slit\text{-}to\text{-}film} / d_{focal\ spot\text{-}to\text{-}slit} \qquad (2.3)$$

Note: $m_{slit} = m_{image} - 1$, and the method requires a higher exposure than the star pattern method.

Limiting value	None.
Frequency	At acceptance and when resolution has changed.
Equipment	Slit camera (10 µm slit) with appropriate test stand and magnifying glass (5-10x), having a built-in graticule with 0.1 mm divisions.

Focal spot size: pinhole method

To determine the focal spot dimensions (f) with a pinhole, a µ30 m gold/platinum alloy pinhole is used. Produce a magnified image (magnification 2.5 to 3 times) of the pinhole.

The dimensions of the focal spot are derived by examining the images through the magnifying glass and correcting for the magnification factor according to $f = F/m_{pinhole}$, where F is the size of the imaged focal spot. The magnification factor ($m_{pinhole}$) is determined by measuring the distance from the pinhole to the plane of the film ($d_{pinhole\text{-}to\text{-}film}$) and the distance from the focal spot to the plane of the pinhole ($d_{focal\ spot\text{-}to\text{-}pinhole}$). $m_{pinhole}$ is calculated by:

$$m_{pinhole} = d_{pinhole\text{-}to\text{-}film} / d_{focal\ spot\text{-}to\text{-}pinhole} \quad (2.4)$$

Note: The method requires a higher exposure than the star pattern method.

Limiting value	None.
Frequency	At acceptance and when resolution has changed.
Equipment	Pinhole (diameter 30 µm) with appropriate test stand and magnifying glass (5-10x), having a built-in graticule with 0.1 mm divisions.

The multi-pinhole device is used similarly. It allows an estimate of the focal spot size at any position in the x-ray field. This method is not suitable for measuring the dimension of fine focus because of the relatively large size of the pin-holes.

2a.2.1.1.2 Source-to-image distance

Measure the distance between the focal spot indication mark on the tube housing and the top surface of the bucky. Add distance between bucky surface and the top of the image receptor.

The source-to-image distance can be determined more accurately by imaging an object with known dimensions a (≥ 10 cm) positioned on the breast support table and positioned at a distance d (≥ 20 cm) above the breast support table. Measure the dimensions of the imaged object on image 1 (object on breast support table) and image 2 (object at distance d above the breast support table). Using formula 2.5 the source-to-image distance can be calculated.

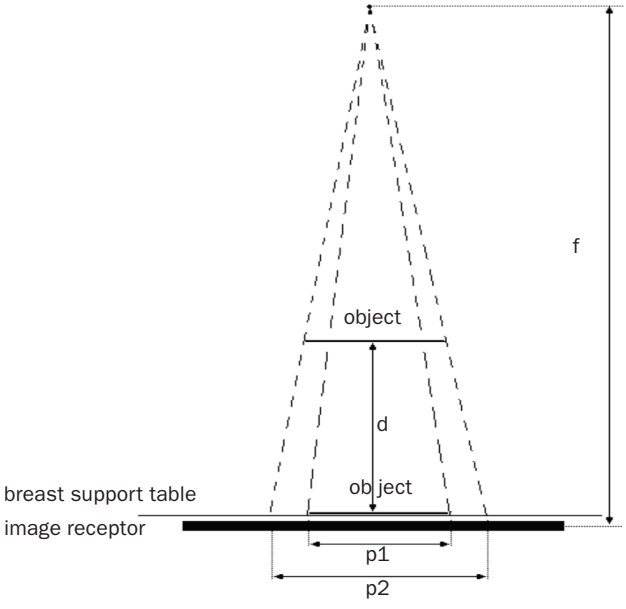


Fig. 2.2 Source-to-image distance measurement

$$f = \frac{d}{a * \left(\frac{1}{p1} - \frac{1}{p2} \right)} \quad (2.5)$$

f = source-to-image distance
d = distance between the object in position 1 and 2
a = size of the imaged object
p1 = size of the object on image 1 (object on the breast support table)
p2 = size of the object on image 2 (object at a distance d above the breast support table)

Limiting value	Manufacturers specification, typical 600-650 mm.
Frequency	At acceptance, if the source-to-image distance is adjustable: every six months.
Equipment	Tape measure, arbitrary test object.

2a.2.1.1.3 Alignment of X-ray field/image receptor

The alignment of the X-ray field and image receptor at the chest wall side can be determined with two loaded cassettes and two X-ray absorbers, e.g. coins.

Place one cassette in the bucky tray and the other on top of the breast support table. Make sure the second cassette has a film loaded with the emulsion side away from the screen. It must extend beyond the chest wall side about 30 mm. Mark the chest wall side of the bucky by placing the absorbers on top of the cassette. Automatic exposure will result in sufficient optical densities. Reposition the films on a light box using the imaged absorbers as a reference. The alignment between the film, X-ray field and chest wall edge of the bucky should be measured.

Fig. 2.3 Alignment of X-ray field/image receptor measurement

Note 1: The lateral edges of the X-ray field should at least expose the image receptor. A slight extension beyond any edge of the image receptor is acceptable.

Note 2: If more than one field size or target is used, the measurement should be repeated for each.

Limiting value	For all focal spots: All sides: X-rays must cover the film by no more than 5 mm outside the film. On chest wall edge: distance between film edge and edge of the bucky must be ≤ 5 mm.
Frequency	Yearly.
Equipment	X-ray absorbers - e.g. coins, rulers, iron balls, tape measure.

2a.2.1.1.4 Radiation leakage

The measurement of leakage radiation comprises two parts; firstly the location of leakage and secondly, the measurement of its intensity.

Position a beam stopper (e.g. lead sheet) over the end of the diaphragm assembly such that no primary radiation is emitted. Enclose the tube housing with loaded cassettes and expose to the maximum tube voltage and a high tube current (several exposures). Process the films and pin-point any excessive leakage. Next, quantify the amount of radiation at the 'hot-spots' at a distance of 50 mm of the tube with a suitable detector. Correct the readings to air kerma rate in mGy/h (free in air) at the distance of 1 m from the focal spot at the maximum rating of the tube.

Limiting value	Not more than 1 mGy in 1 hour at 1 m from the focus at the maximum rating of the tube averaged over an area not exceeding 100 cm^2, and according to local regulations.
Frequency	At acceptance and after intervention on the tube housing.
Equipment	Dose meter and appropriate detector.

2a.2.1.1.5 Tube output

The specific tube output (μGy/mAs) and the output rate (mGy/s) should both be measured using a Molybdenum-Molybdenum target-filter combination at 28 kVp on a line passing through the

focal spot and the reference ROI, in the absence of scatter material and attenuation (e.g. due to the compression plate). A tube load (mAs) similar to that required for the reference exposure should be used for the measurement. Correct for the distance from the focal spot to the detector and calculate the specific output at 1 metre and the output rate at a distance equal to the focus-to-film distance (FFD).
If the measurements are used for dosimetry, tube output measurements should be performed at all relevant spectra with the compression plate in position.

Limiting values	Acceptable: > 30 µGy/mAs at 1 metre, achievable > 40 µGy/ mAs at 1 metre > 70% of value at acceptance for all target-filter combinations.
Frequency	Every six months and when problems occur.
Equipment	Dose-meter, exposure timer.

Note: A high output is desirable for a number of reasons e.g. it results in shorter exposure times, minimising the effects of patient movement and ensures adequate penetration of large/dense breasts within the setting of the guard timer. In addition any marked changes in output require investigation.

2a.2.1.2 Tube voltage and beam quality

The radiation quality of the emitted X-ray beam is determined by tube voltage, anode material and filtration. Tube voltage and Half Value Layer (i.e. beam quality assessment) can be assessed by the measurements described below.

2a.2.1.2.1 Reproducibility and accuracy

A number of tube voltages should be checked, which cover the range of clinically used settings. The reproducibility is measured by repeated exposures at one fixed tube voltage that is normally used clinically (e.g. 28 kVp).

Note: Consult the instruction manual of the kVp-meter for the correct positioning.

Limiting value	Accuracy for the range of clinically used tube voltages: < ± 1 kV, reproducibility < ± 0.5 kV.
Frequency	Every six months.
Equipment	kVp-meter.

2a.2.1.2.2 Half Value Layer (HVL)

The Half Value Layer can be assessed by adding thin aluminium (Al) filters to the X-ray beam and measuring the attenuation.
Position the exposure detector at the reference ROI (since the HVL is position dependent) on top of the bucky. Place the compression device halfway between focal spot and detector. Select a molybdenum/molybdenum target/filter combination, 28 kV tube voltage and an adequate tube loading (mAs-setting), and expose the detector directly. The filters can be positioned on the compression device and must intercept the whole radiation field. Use the same tube load (mAs) setting and expose the detector through each filter. For higher accuracy (about 2%) a diaphragm, positioned on the compression paddle, limiting the exposure to the area of the detector may be used (see European Protocol on Dosimetry in Mammography, ISBN 92-827-7289-6). At acceptance the measurements should be repeated for all relevant spectra for average glandular dose calculations. The HVL is calculated by applying formula 2.5.

$$HVL = \frac{X_1 \ln\left(\frac{2Y_2}{Y_0}\right) - X_2 \ln\left(\frac{2Y_1}{Y_0}\right)}{\ln\left(\frac{Y_2}{Y_1}\right)} \qquad (2.6)$$

The direct exposure reading is denoted as Y_0; Y_1 and Y_2 are the exposure readings with added aluminium thickness of X_1 and X_2 respectively.

Note 1: The purity of the aluminium ≥ 99.9% is required. The thickness of the aluminium sheets should be measured with an accuracy of 1%.
Note 2: For this measurement the output of the X-ray machine needs to be stable.
Note 3: The HVL for other (clinical) tube voltages and other target materials and filters may also be measured for assessment of the average glandular dose (see appendix 5 and the European Protocol on Dosimetry in Mammography, ISBN 92-827-7289-6).
Note 4: Alternatively a digital HVL-meter can be used, but correct these readings under extra filtration following the manufacturers' manual.

Limiting value	For 28 kV Mo/Mo the HVL must be over 0.30 mm Al equivalent, and is typically < 0.40 mm Al. Typical values of HVL for relevant target-filter combinations and tube voltages, are shown in appendix 5, table A5.3.
Frequency	Yearly.
Equipment	Dosemeter, aluminium sheets: 0.30, 0.40, 0.50, 0.60 mm.

2a.2.1.3 AEC-system

The performance of the Automatic Exposure Control (AEC) system can be described by the reproducibility and accuracy of the automatic optical density control under varying conditions, like different object thickness and tube voltages. Essential prerequisites for these measurements are a stable operating film-processor and the use of the reference cassette. If more than one breast support table, with a different AEC detector attached, is used then each system must be assessed separately.

2a.2.1.3.1 Optical density control setting: central value and difference per step

To compensate for the long term variations in mean density due to system variations the central optical density setting and the difference per step of the selector are assessed. To verify the adjustment of the optical density control, produce exposures in the clinically used AEC mode of the standard test object with varying settings of the optical density control selector.
A target value for the mean optical density at the reference ROI should be established according to local preference, in the range: 1.4 – 1.9 OD, base and fog included.

Limiting value	The optical density (base and fog included) of the step used clinically at the reference ROI should remain within ± 0.15 OD of the target value. The change produced by each step in the optical density control should be about 0.10 OD. Step-sizes within the range 0.05 to 0.20 OD are acceptable. The acceptable value for the range covered by full adjustment of the density control is > 1.0 OD.
Frequency	Step-size and adjustable range: every six months. Density and mAs-value for clinically used AEC setting: daily.
Equipment	Standard test block, densitometer.

2a.2.1.3.2 Back-up timer and security cut-off

The AEC system should also be equipped with a back-up timer or security cut-off which will terminate the exposure in case of malfunctioning of the AEC system or when the required exposure is not possible. Record the mAs-value at which the system terminates the exposure e.g. when using increasing thickness of PMMA plates.

Warning: An incorrect functioning of the back-up timer or security cut-off could damage the tube. To avoid excessive tube load consult the manual for maximum permitted exposure time.

Limiting value	The back-up timer and/or security cut-off should function properly.
Frequency	Yearly.
Equipment	PMMA plates or sheet of lead covering the detector.

2a.2.1.3.3 Short term reproducibility

Position the dosemeter in the x-ray beam but without covering the AEC-detector. The short term reproducibility of the AEC system is calculated by the deviation of the exposure meter reading of ten routine exposures (45 mm PMMA).
If it is noticed that the system switches between two spectra, release the compression paddle and compress again or use another PMMA thickness (add for example 0.5 cm PMMA) to force the choice of one single spectrum and repeat the measurement.

Limiting value	Deviations from the mean value of exposures < ± 5%, achievable < ± 2%.
Frequency	Every six months.
Equipment	Standard test block, dosemeter.

Note: For the assessment of the reproducibility, also compare these results from the short term reproducibility with the results from the thickness and tube voltage compensation and from the optical density control setting at 45 mm PMMA at identical settings. Any problem will be indicated by a mismatch between those figures.

2a.2.1.3.4 Long term reproducibility

The long term reproducibility can be assessed from the measurement of optical density and tube load (mAs) resulting from the exposures of a PMMA-block or the QC test object in the daily quality control. Causes of deviations can be found by comparison of the daily sensitometry data and tube load (mAs) recordings (see 2a.2.3.2).

Limiting value	The variation from the target value must be within < ± 0.20 OD; achievable < ± 0.15 OD.
Frequency	Daily.
Equipment	Standard test block or QC test object, densitometer.

2a.2.1.3.5 Object thickness and tube voltage compensation

Compensation for object thickness and tube voltage should be measured by exposures of PMMA plates in the thickness range 20 to 70 mm in the clinically used AEC mode. If the system only incorporates a semi-automatic exposure control, spectrum should be manually increased with thickness, see appendix 4. At acceptance all AEC modes should be checked. Record the spectrum, which is chosen by the AEC at all thicknesses. Record the value of the thickness indicator at all thicknesses. Measure the optical density in the reference ROI.

Limiting value	All optical density variations from the chosen target optical density must be within ± 0.15 OD. Achievable: ± 0.10 OD. Typical spectra for each PMMA thickness can be found in appendix 4. The value of the thickness indicator must be within ± 0.5 cm of the thickness of the PMMA plates.
Frequency	Every six months: full test. Weekly: 20, 45, 65 mm PMMA exposed as for clinical setting.
Equipment	PMMA: plates 10x180x240 mm^3, densitometer.

2a.2.1.3.6 Correspondence between AEC sensors

Some mammography systems incorporate several independent AEC sensors. For these systems it should be checked whether the optical density of images made with different sensors correspond and if the correct sensor is chosen by the system.
To test correspondence, images of a homogeneous PMMA plate (45 mm thick) should be made

with each AEC sensor. Choose the sensors manually. The optical density at the position of the AEC sensor, which was used for that particular image, should be measured.
To test whether the correct AEC sensor is chosen, extra attenuation material (for example: 2 or 3 aluminium sheets used for HVL measurements) should be positioned above one AEC sensor position. The markers on the compression paddle can be used as guidance. The whole sensor should be covered and adjacent sensors should not be covered. The sensor, above which the extra attenuation has been placed, must be chosen automatically by the system. If another sensor is chosen, increase the amount of attenuating material until the correct sensor is chosen or until it is beyond any doubt that the sensor does not work properly. This procedure must be repeated for all sensor positions.

Note: If the Heel effect is large, it may be necessary to add extra attenuating material for sensor positions near nipple side. The marker on the compression paddle may not always completely coincide with the real position of the sensor.

Limiting value	The variation in optical density between all AEC sensors should be within 0.20 OD. The correct AEC sensor must be chosen.
Frequency	Every six months: full test.
Equipment	Standard test block, densitometer.

2a.2.1.4 Compression

The compression of the breast tissue should be firm but tolerable. There is no optimal value known for the force, but attention should be given to the applied compression and the accuracy of the indication. All units must have motorised compression.

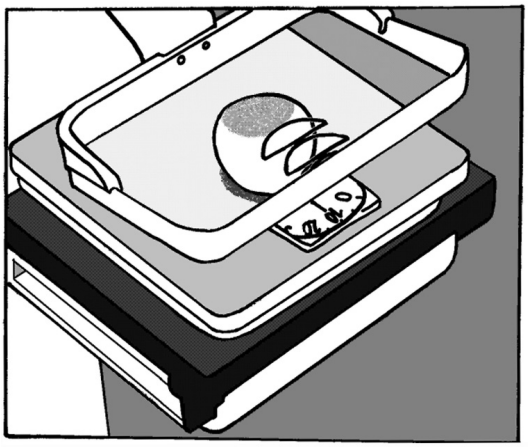


Fig. 2.4 Compression force measurement

2a.2.1.4.1 Compression force
The compression force can be adequately measured with a compression force test device or a bathroom scale (use compressible material e.g. a tennis ball to protect the bucky and compression device). The compression device should be examined for possible cracks (which might only be clearly visible under compression) and sharp edges.

When compression force is indicated on the console, it should be verified whether the figure corresponds with the measured value. It should also be verified whether the applied compression force is maintained over a period of 1 minute. A loss of force over this time may be explained, for example, by a leakage in the pneumatic system.

Limiting value	Maximum automatically applied force: 130 - 200 N. (~ 13-20 kg), and must be maintained unchanged for at least 1 minute. The indicated compression force should be within ± 20 N of the measured value. The compression device should not contain any cracks or sharp edges.
Frequency	Yearly.
Equipment	Compression force test device.

2a.2.1.4.2 Compression plate alignment

The alignment of the compression device at maximum force can be visualised and measured when a piece of foam-rubber is compressed. Measure the distance between bucky surface and compression device on each corner. Normally, those four distances are equal. Misalignment normal to the chest wall side is less disturbing than in the parallel direction, as it compensates for the heel effect. The upright edge of the device must be projected outside the receptor area and optimally within the chest wall side of the bucky.

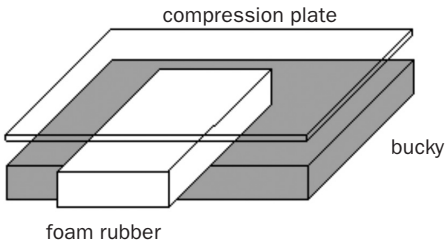


Fig. 2.5 Compression plate alignment measurement, symmetrical load

Limiting value	Minimal misalignment is allowed, the difference between the measured distances at the left and the right side of the compression paddle should be ≤ 5 mm for symmetrical load.
Frequency	Yearly.
Equipment	Foam rubber (specific mass: about 30 mg/cm^3), tape measure.

2a.2.2 Bucky and image receptor

If more than one bucky and image receptor system is attached to the imaging chain than each system must be assessed separately.

2a.2.2.1 Anti scatter grid

The anti scatter grid is composed of strips of lead and low density interspace material and is designed to absorb scattered photons. The grid system is composed of the grid, a cassette holder, a breast support table and a mechanism for moving the grid.

2a.2.2.1.1 Grid system factor

The grid system factor can be determined by dose measurements. Produce two images, one with and one without the grid system. Use manual exposure control to obtain images of about reference optical density. The first image is made with the cassette in the bucky tray (imaged using the grid system) and PMMA on top of the bucky. The second with the cassette on top of the bucky (imaging not using the grid system) and PMMA on top of the cassette. The grid system factor is calculated by dividing the dose meter readings, corrected for the inverse square law and optical density differences.

Note: Not correcting the doses for the inverse square law will result in an over estimation of 5%.

Typical value	< 3.
Frequency	At acceptance and when dose or exposure time increases suddenly.
Equipment	Dosemeter, standard test block and densitometer.

2a.2.2.1.2 Grid imaging

To assess the homogeneity of the grid in case of suspected damage or looking for the origin of artefacts, the grid may be imaged by automatic exposure of the bucky at the lowest position of the AEC-selector, without any added PMMA. This in general gives a good image of the gridlines.

Remark: For some systems it is not possible to image the grid due to the minimum required exposure time.

Limiting value	No significant non uniformity.
Frequency	Yearly.
Equipment	None.

2a.2.2.2 Screen-film

The current image receptor in screen-film mammography consists of a cassette with one intensifying screen in close contact with a single emulsion film. The performance of the stock of cassettes is described by the inter cassette sensitivity variation and screen-film contact.

2a.2.2.2.1 Inter cassette sensitivity and attenuation variation and optical density range

The differences between cassettes can be assessed with the reference exposure (section 2a.1). Select an AEC setting (should be the normal position and using a fixed tube voltage, target and filter) to produce an image having about the clinically used mean optical density on the processed film. Repeat for each cassette using films from the same box or batch. Make sure the cassettes are identified properly. Measure the exposure (in terms of mGy or mAs) and the corresponding optical densities on each film at the reference ROI. To ensure that the cassette tests are valid the AEC system in the mammography unit needs to be sufficiently stable. It will be sufficient if the variation in repeated exposures selected by the AEC for a single cassette is (in terms of mGy and mAs) < ± 2%.

Limiting value	The exposure, in terms of mGy (or mAs), must be within ± 5% of the mean for all cassettes. The maximum difference in optical density between all cassettes: ± 0.10 OD is acceptable, ± 0.08 OD is achievable.
Frequency	Yearly, and after introducing new screens.
Equipment	Standard test object, dosemeter, densitometer.

2a.2.2.2.2 Screen-film contact

Clean the inside of the cassette and the screen. Wait for at least 5 minutes to allow air between the screen and film to escape. Place the mammography contact test device (about 40 metal wires/inch, 1.5 wires/mm) on top of the cassette and make a non grid exposure to produce a film with an average optical density of about 2 OD at the reference ROI. Regions of poor contact will be blurred and appear as dark spots in the image. Reject cassettes only when they show the same spots when the test is repeated after cleaning. View at a distance of 1 meter. Additionally the screen resolution may be measured by imaging a resolution pattern placed directly on top of a cassette.

Limiting value	No significant areas (i.e. > 1 cm^2) of poor contact are allowed in the diagnostically relevant part of the film.
Frequency	Every six months and after introducing new screens.
Equipment	Mammography screen-film contact test device, densitometer and viewbox.

2a.2.3 Film processing

The performance of the film processing greatly affects image quality. The best way to measure the performance is by sensitometry. Measurements of temperature and processing time are performed to establish the baseline performance.

2a.2.3.1 Baseline performance of the processor

2a.2.3.1.1 Temperature verification and baseline

To establish a baseline performance of the automatic processor, the temperature of developer and fixer are measured. Take care that the temperature is measured at a fixed point, as recommended by the manufacturers. The measured values can be used as background information when malfunction is suspected. Do not use a glass thermometer because of the contamination risk in the event of breakage.

Limiting value	Compliance with the manufacturer's recommendations.
Frequency	Every six months.
Equipment	Electronic thermometer.

2a.2.3.1.2 Processing time

The total processing time can be measured with a stopwatch. Insert the film into the processor and start the timer when the signal is given by the processor. When the processed film is available, stop the timer. When malfunction of the processor is suspected, measure this processing time exactly the same way again and check to see if there is any difference.

Limiting value	Compliance with the manufacturer's recommendations.
Frequency	At acceptance and when problems occur.
Equipment	Stopwatch.

2a.2.3.2 Film and processor

The films used in mammography should be specially designed for that purpose. Light sensitometry is a suitable method to measure the performance of the processor. Disturbing processor artefacts should not be present on the processed image.

2a.2.3.2.1 Sensitometry

Use a sensitometer to expose a film with light and insert the exposed side into the processor first. Before measuring the optical densities of the step-wedge, a visual comparison can be made with a reference strip to rule out a procedure fault, like exposure with a different colour of light or exposure of the base instead of the emulsion side.
From the characteristic curve (the graph of measured optical density against the logarithm of exposure by light) the values of base and fog, maximum density, speed and film gradients can be derived. These parameters characterise the processing performance. A detailed description of these ANSI-parameters and their clinical relevance can be found in appendix 2, film parameters.

Typical values:	base and fog:	0.15 – 0.25 OD
	contrast:	MGrad: 3.0 - 4.0 [see note]
		$Grad_{1-2}$: 3.5 – 5.0
Frequency	Daily.	
Equipment	Sensitometer, densitometer.	

Note: There is no clear evidence for the optimal value of film gradient; the ranges quoted are based on what is typical of current practice and are dependent on the film, which is used. At the top end of these ranges the high film gradient may lead to under- and over exposure of parts of the image for some types of breast, thereby reducing the information content.

A further complication of using a very high film contrast is that stable conditions with very low variability of the parameters are required to achieve any benefit in terms of overall image quality (See appendix 3).

2a.2.3.2.2 Daily performance

The daily performance of the processor is assessed by sensitometry. After the processor has been used for about one hour each morning, perform the sensitometry as described above. The variability of the parameters can be calculated over a period of time e.g. one month (see calculation of film parameters in appendix 2).

Limiting value See table below.
Frequency Daily and more often when problems occur.
Equipment Sensitometer, densitometer.

The assessment of variations can be found in the use of the following table, where the values are expressed as a **range** (Max value - Min value). Acceptable and achievable ranges are quoted in the table below. For centres where computer facilities for calculating speed and film gradient (Mgrad and $Grad_{1,2}$) are not available, speed and contrast indices are given. However, this approach is less satisfactory as these indices are not pure measures of speed and contrast.

Assessment of variations	**acceptable**	**achievable**
base and fog	< 0.03	< 0.02 OD
speed	< 0.05	< 0.03
mean gradient (Mgrad)	< 10% of baseline value	< 5% of baseline value
mid gradient ($Grad_{1,2}$)	< 0.40	< 0.20
speed index	< 0.30	< 0.20 OD
contrast index	< 0.30	< 0.20 OD

2a.2.3.2.3 Artefacts

An image of the standard test block obtained daily, using a routine exposure, should be inspected. This should show a homogeneous density, without significant scratches, shades or other marks indicating artefacts.

Limiting value No artefacts.
Frequency Daily.
Equipment Standard test block or PMMA plates 40-60 mm and area 18X24 cm, viewing box.

2a.2.3.3 Darkroom

Light tightness of the darkroom should be verified. It is reported, that about half of darkrooms are found to be unacceptable. Extra fogging by the safelights must be within given limits.

2a.2.3.3.1 Light leakage

Remain in the darkroom for a minimum of five minutes with all the lights, including the safelights, turned off. Ensure that adjacent rooms are fully illuminated. Inspect all those areas likely to be a source of light leakage. To measure the extra fog as a result of any light leakage or other light sources, a pre-exposed film of about 1.2 OD is needed. This film can be obtained by a reference

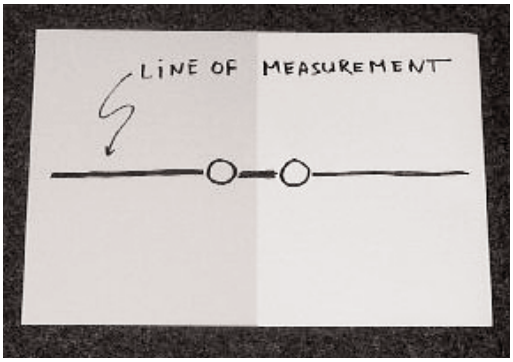


Fig. 2.6 Line of measurement when performing the light leakage measurement

exposure of a uniform PMMA block. Always measure the optical density differences in a line perpendicular to the tube axis to avoid influence of the heel effect.

Open the cassette with pre-exposed film and position the film (emulsion up) on the (appropriate part of the) workbench. Cover half the film and expose for two minutes. Position the cover parallel to the tube axis to avoid the influence of the heel effect in the measurements. Measure the optical density difference of the background (D_{bg}) and the fogged area (D_{fogged}). The extra fog (ΔD) equals:

$$\Delta D = D_{fogged} - D_{bg} \quad (2.7)$$

Limiting value	Extra fog: $\Delta D \leq 0.02$ OD in 2 minutes.
Frequency	Yearly and when light leakage is suspected.
Equipment	Film cover, densitometer.

2a.2.3.3.2 Safelights

Perform a visual check that all safelights are in good working order (filters not cracked). To measure the extra fog as a result of the safelights, repeat the procedure for light leakage but with the safelights on. Make sure that the safelights were on for more than 5 minutes to avoid start-up effects.

Limiting value	Extra fog: $\Delta D \leq 0.10$ OD in 2 minutes.
Frequency	Yearly and every time the darkroom environment has changed.
Equipment	Film cover, densitometer.

2a.2.4 Viewing conditions

Since good viewing conditions are important for the correct interpretation of the diagnostic images, they must be optimised. Although the need for relatively bright light boxes is generally appreciated, the level of ambient lighting is also very important and should be kept low. In addition it is imperative that glare is minimised by masking the film.

The procedures for photometric measurements and the values required for optimum mammographic viewing are not well established. However there is general agreement on the parameters that are important. The two main measurements in photometry are luminance and illuminance. The luminance of viewing boxes is the amount of light emitted from a surface measured in candela/m^2. Illuminance is the amount of light falling on a surface and is measured in lux (lumen/m^2). The illuminance that is of concern here is the light falling on the viewing box, i.e. the ambient light level. (An alternative approach is to measure the light falling on the film reader's eye by pointing the light detector at the viewing box from a suitable distance with the viewing box off.) Whether one is measuring luminance or illuminance one requires a detector and a photometric filter. This combination is designed to provide a spectral sensitivity similar to the human eye. The collection geometry and calibration of the instrument is different for luminance

and illuminance. To measure luminance a lens or fibre-optic probe is used, whereas a cosine diffuser is fitted when measuring illuminance. Where the only instrument available is an illuminance meter calibrated in lux it is common practice to measure luminance by placing the light detector in contact facing the surface of the viewing box and converting from lux to cd/m^2 by dividing by π. Since this approach makes assumptions about the collection geometry, a correctly calibrated luminance detector is preferred.
There is no clear consensus on what luminance is required for viewing boxes. It is generally thought that viewing boxes for mammography need to be higher than for general radiography. In a review of 20 viewing boxes used in mammographic screening in the UK, luminance averaged 4500 cd/m^2 and ranged from 2300 to 6700 cd/m^2. In the USA the ACR recommend a minimum of 3500 cd/m^2 for mammography. However some experts have suggested that the viewing box luminance need not be very high provided the ambient light is sufficiently low and that the level of ambient light is the most critical factor. The limiting values suggested here represent a compromise position until clearer evidence is available.

2a.2.4.1 Viewing box

2a.2.4.1.1 Luminance

The tendency to use a high optical density for mammography means that one must ensure that the luminance of the viewbox is adequate. Measure the luminance in the centre of each viewing panel using a luminance meter calibrated in cd/m^2. An upper limit is included to minimise glare where films are imperfectly masked.

Limiting value	Luminance should be in the range 3000-6000 cd/m^2. The deviation of the luminance between the centres of all panels of a viewing box < ± 15% from the mean value of all panels.
Frequency	Yearly.
Equipment	Luminance meter.

2a.2.4.1.2 Homogeneity

The homogeneity of a single viewing box is measured by multiple readings of luminance over the surface of the illuminator, compared with the luminance in the middle of the viewing panel. Readings very near the edges (e.g. within 5 cm) of the viewing box should be avoided. Gross mismatch between viewing boxes or between viewing conditions used by the radiologist and those used by the radiographer should be avoided. If a colour mismatch exists, check to see that all lamps are of the same brand, type and age. The local personnel has to make sure that all tubes are changed at the same time. To avoid inhomogeneities as a result of dust, clean the light boxes should be regularly cleaned inside and outside.

Limiting value	The luminance across each panel should be within 30% of the luminance in the centre of the panel.
Frequency	Yearly.
Equipment	Luminance meter.

2a.2.4.2 Ambient light

When measuring the ambient light level (illuminance), the viewing box should be switched off. Place the detector against the viewing area and rotate away from the surface to obtain a maximal reading. This value is denoted as the ambient light level.

Limiting value	Ambient light level < 50 lux.
Frequency	Yearly.
Equipment	Illuminance meter.

2a.2.5 System properties

The success of a screening programme is dependent on the proper information transfer and therefore on the image quality of the mammogram. Decreasing the dose per image for reasons of radiation protection is only justified when the information content of the image remains sufficient to achieve the aims of the breast cancer screening programme.

2a.2.5.1 Dosimetry

Image PMMA plates of 20 mm thickness in clinical settings. Record the entrance surface air kerma and the exposure factors chosen by the AEC. Repeat this measurement for 30, 40, 45, 50, 60 and 70 mm PMMA thickness. Calculate the average glandular dose for a breast equivalent to each PMMA thickness. A detailed description of the calculation of the average glandular dose can be found in appendix 5.

Limiting value

A maximum average glandular dose is set per PMMA thickness:

Thickness of PMMA	Equivalent breast thickness	Maximum average glandular dose to equivalent breasts	
		acceptable level	achievable level
[cm]	[cm]	[mGy]	[mGy]
2.0	2.1	< 1.0	< 0.6
3.0	3.2	< 1.5	< 1.0
4.0	4.5	< 2.0	< 1.6
4.5	5.3	< 2.5	< 2.0
5.0	6.0	< 3.0	< 2.4
6.0	7.5	< 4.5	< 3.6
7.0	9.0	< 6.5	< 5.1

Frequency
Every six months.

Equipment
Dose meter, standard test block, densitometer.

2a.2.5.2 Image Quality

The information content of an image may best be defined in terms of just visible contrasts and details, characterised by its contrast-detail curve. The basic conditions for good performance and the constancy of a system can be assessed by measurement of the following: resolution, contrast visibility, threshold contrast and exposure time.

2a.2.5.2.1 Spatial resolution

One of the parameters which determine image quality is the system spatial resolution. It can be adequately measured by imaging two resolution lead bar patterns, up to 20 line pairs per mm (lp/mm) each. They should be placed on top of PMMA plates with a total thickness of 45 mm. Image the patterns at the reference ROI both parallel and perpendicular to the tube axis, and determine these resolutions.

Note: If the resolution is measured at different heights between 25 and 50 mm from the tabletop it can differ by as much as 4 lp/mm. The distance from the chest wall edge is critical, but the position parallel to the chest wall side is not critical within ± 5 cm from the reference ROI. Resolution is generally worse parallel to the tube axis due to the asymmetrical shape of the focal spot.

Limiting value	Acceptable: > 12 lp/mm, achievable: > 15 lp/mm at the reference ROI in both directions.
Frequency	Weekly.
Equipment	PMMA plates 180x240 mm, resolution pattern(s) up to 20 lp/mm, densitometer.

2a.2.5.2.2 Image contrast

Since image contrast is affected by various parameters (like tube voltage, film contrast etc.) this measurement is an effective method to detect a range of system faults. Make a reference exposure of an aluminium or PMMA stepwedge and measure the optical density of each step in the stepwedge. Draw a graph of the readings at each step against the stepnumber. The graph gives an impression of the contrast. Since this graph includes the processing conditions, the film curve has to be excluded to find the radiation contrast, see Appendix 3.

Remark: The value for image contrast is dependent on the whole imaging chain, therefore no absolute limits are given. Ideally the object is part of, or placed on top of, the daily quality control test object.

Limiting value	Acceptable: ± 10%, achievable: ± 5%.
Frequency	Weekly, and when problems occur.
Equipment	PMMA or aluminium stepwedge, densitometer.

2a.2.5.2.3 Threshold contrast visibility

Extensive test: Threshold contrast visibility is determined for circular details with diameters in the range from 0.1 to 2 mm. The details are imaged on a background object with a thickness equivalent (in terms of attenuation) to 50 mm of PMMA. The details must be positioned at a height of 20 to 25 mm above the breast support table[6]. Use the exposure factors that would be selected clinically. Make two images. Three experienced observers should determine the minimal contrast visible on both images. The detail diameter must cover the range from 0.1 to 2 mm. In this range minimal contrast visible for a large number of detail diameter must be determined at acceptance and at least 5 detail diameters in subsequent tests.
The threshold contrast performance specified here relates to the nominal contrast calculated for the details for a 28 kV tube voltage with a molybdenum target and filter materials as explained in appendix 6. This nominal contrast depends on the thickness and materials used to manufacture the test object, and is independent of the actual spectrum used to form the image, which should be that used clinically. It does not include the effects of scatter. The average nominal threshold contrasts should be compared with the limiting values below.
Weekly a simple test should give an indication of the lowest detectable contrast of 'large' objects (diameter > 5 mm). Therefore a selection of low contrast objects have to be embedded in a PMMA test object to mimic clinical exposures. There should be at least two visible and two non-visible objects. Note, that the result is dependent on the mean OD of the image and on noise.
Produce a routine exposure and let two or three observers examine the low contrast objects. The number of visible objects is recorded. Ideally the object is part of, or placed on top of, the daily quality control test object.

Limiting value	Extensive test: results at acceptance are used as reference. Weekly test: minimum detectable contrast for a 5-6 mm detail < 1.5%.
Frequency	Yearly (extensive test), weekly (simple test).
Equipment	Test object with low contrast details plus PMMA plates, to a thickness of 45 mm, densitometer.

2a.2.5.2.4 Exposure time

Long exposure times can give rise to motion unsharpness. Exposure time may be measured by some designs of kVp- and output meters. Otherwise a dedicated exposure timer has to be used. The time for a routine exposure is measured.

Limiting value	Acceptable: < 2 sec.; achievable: < 1.5 sec.
Frequency	Yearly and when problems occur.
Equipment	Exposure time meter, standard test block.

2a.3 Daily and weekly QC tests

There are a number of tests that should be conducted daily or weekly. For this purpose, a dedicated QC-test object or set of test objects are convenient. The actual frequencies recommended for each measurement are specified in section 2a.2.3.2.2 and summarised in Table 2a.4.1. The procedure must facilitate the measurement of some essential physical quantities, and it should be designed to evaluate:

- AEC reproducibility
- Tube output stability
- Reference optical density
- Spatial resolution
- Image contrast
- Threshold contrast visibility
- Homogeneity, artefacts
- Sensitometry (speed, contrast, fog)

Practical considerations:

- Ideally the sensitometric stepwedge should be on the same film as the image of the test object, to be able to correct optimally for the processing conditions.
- To improve the accuracy of the daily measurement, the test object should be designed in such a way that it can be positioned reproducibly on the bucky.
- The shape of the test object does not have to be breast-like. To be able to perform a good homogeneity check, the test object should cover the normally imaged area on the image receptor (180x240 mm).
- For testing the AEC reproducibility, the PMMA test object may comprise several layers of PMMA, 10 or 20 mm thick. It is important to use the same PMMA blocks since variations in thickness of the PMMA plates will influence the tube load (mAs) read-out. Sufficient blocks are required to make up a thickness in the range 20-70 mm to adequately simulate the range of breast thickness found clinically.

2a.4 Tables

Table 2a.4.1 Frequency of quality control, measured and limiting values

2a.2.1 X-ray generation and control	frequency	typical value	limiting value acceptable	limiting value achievable	unit
X-ray source					
- focal spot size	i	0.3	IEC/NEMA	-	-
- source-to-image distance	i	≥ 600	-	-	mm
- alignment of x-ray field/ image receptor	12	-	< 5	< 5	mm
- film/bucky edge	12	-	≤ 5	≤ 5	mm
- radiation leakage	i	-	< 1	< 1	mGy/hr
* output	6	-	> 30% > 70% of baseline	> 40	µGy/mAs
tube voltage					
- reproducibility	6	-	< ± 0.5	< ± 0.5	kV
- accuracy (25 – 31 kV)	6	-	< ± 1.0	< ± 1.0	kV
- HVL	12	-	See appendix 5 table A5.3	See appendix 5 table A5.3	
AEC					
* central opt. dens control setting	6	-	< ± 0.15 of target value	-	OD
- target opt. dens. control setting	6	-	1.4 -1.9		OD
- opt. dens. control step	6	-	0.05 - 0.20	0.05 - 0.10	OD
- adjustable range	6	-	> 1.0	> 1.0	OD
* short term reproducibility	6	-	< ± 5%	< ± 2%	mGy
* long term reproducibility	d	-	< ± 0.20	< ± 0.15	OD
- object thickness	w	-	< ± 0.15	< ± 0.10	OD
and tube voltage compensation	6	-	< ± 0.15	< ± 0.10	OD
- spectra	6	See appendix 4			
- correspondence between AEC sensors	6	-	< 0.20		OD
compression					
- compression force	12	-	130 - 200	-	N
- maintain force for 1 minute	12	-	1	1	min
- compression force indicator	12	-	< ± 20	< ± 20	N
- compression plate alignment, symmetric	12	-	≤ 5	≤ 5	mm

2a.2.2 Bucky and image receptor	frequency	typical value	limiting value acceptable	limiting value achievable	unit
anti scatter grid					
* grid system factor	i	< 3	-	-	-
screen-film					
* inter cassette sensitivity variation (mAs)	12	-	< ± 5%	< ± 5%	mGy
* inter cassette sensitivity variation (OD range)	12	-	< ± 0.10	< ± 0.08	OD
- screen-film contact	12	-	No significant areas of poor contact	-	-

Table 2a.4.1 continued

2a.2.3 Film processing	frequency	typical value	limiting value acceptable	limiting value achievable	unit
processor					
- temperature	i	34 - 36	-	-	°C
- processing time	i	90 - 120	-	-	s
film					
- sensitometry: base and fog	d	0.15 - 0.25[1]	-	-	OD
speed	d	-	-	-	-
Contrast Mgrad:	d	3.0 - 4.0[2]	-	-	-
$Grad_{1,2}$	d	3.5 - 5.0	-	-	-
- daily performance	d	-	See 2a.2.3.2	See 2a.2.3.2	-
- artefacts	d	-	No disturbing artefacts	-	-
darkroom					
- light leakage (extra fog in 2 minutes)	12	-	≤ + 0.02	≤ + 0.02	OD
- safelights (extra fog in 2 minutes)	12	-	≤ + 0.10	≤ + 0.10	OD

2a.2.4 Viewing conditions	frequency	typical value	limiting value acceptable	limiting value achievable	unit
viewing box					
- luminance	12	-	3000 - 6000	3000 - 6000	cd/m^2
- homogeneity	12	-	< ± 30%	< ± 30%	cd/m^2
- luminance difference between panels	12	-	< ± 15%	< ± 15%	cd/m^2
environment					
- ambient light level	12	-	< 50	< 50	lux

2a.2.5 System properties	frequency	typical value	limiting value acceptable	limiting value achievable	unit
dosimetry					
* Glandular dose	6				
- PMMA thickness (cm)					
2.0			< 1.0	< 0.6	mGy
3.0			< 1.5	< 1.0	mGy
4.0			< 2.0	< 1.6	mGy
4.5			< 2.5	< 2.0	mGy
5.0			< 3.0	< 2.4	mGy
6.0			< 4.5	< 3.6	mGy
7.0			< 6.5	< 5.1	mGy
image quality					
* spatial resolution, reference ROI	w	-	> 12	> 15	lp/mm
* threshold contrast visibility	w	-	< 1.5%	< 1.5%	-
* exposure time	12	-	< 2	< 1.5	s

End of table 2a.4.1 i = At acceptance; d = daily; w = weekly; 6 = every 6 months; 12 = every 12 months * standard measurement conditions
1. For standard blue based films only 2. Depend on the film which is used

Table 2a4.2 QC equipment specifications

QC equipment	accuracy	reproducibility	unit
sensitometer	-	± 2%	OD
densitometer	± 2% at 1.0	± 1%	OD
dosemeter	± 5%	± 1%	mGy
thermometer	± 0.3	± 0.1	°C
kVp-meter for mammographic use	± 2%	± 1%	kV
exposure time meter	± 5%	± 1%	s
luminance meter	± 10%	± 5%	$Cd.m^{-2}$
illuminance meter	± 10%	± 5%	klux
test objects, PMMA	± 2%	-	mm
compression force test device	± 10%	± 5%	N

aluminium filters (purity ≥ 99.9%)
aluminium stepwedge
resolution pattern
focal spot test device
stopwatch
film/screen contact test tool
tape measure
rubber foam for compression plate alignment
lead sheet

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2a.6 Completion forms for QC reporting

QC report

based on

The European protocol for the quality control of the physical and technical aspects of mammography screening

Fourth edition

Date: _____

Contact: _____

Institute: _____

Address: _____

Telephone: _____

Conducted by: _____

2a.2.1 X-ray generation and control

2a.2.1.1 X-ray source

2a.2.1.1.1 Focal spot size

Class (large) focal spot: _____ (IEC)

** star pattern method*

diameter star pattern	d_{star}	____ mm
spoke angle θ	θ	____ °
diameter magnified star image	d_{mag}	____ mm
diameter first MTF zero ⊥ AC axis	$d_{blur,\perp}$	____ mm
diameter first MTF zero // AC axis	$d_{blur,//}$	____ mm

$$m_{star} = \frac{d_{mag}}{d_{star}} \; ; \; f = \frac{\pi \times \theta}{180} \times \frac{d_{blur}}{(m-1)}$$

** slit camera method*

width slit		____ mm
distance slit-to-film	$d_{slit\text{-}film}$	____ mm
distance focus-to-slit	$d_{focus\text{-}slit}$	____ mm
width slit image ⊥ AC axis	F⊥	____ mm
width slit image // AC axis	F //	____ mm

$$m_{slit} = \frac{d_{slit-film}}{d_{focus-slit}} \; ; \; f = \frac{F}{m_{slit}}$$

** pinhole method*

diameter pinhole		____ µm
distance pinhole-to-film	$d_{pinhole\text{-}film}$	____ mm
distance focus-to-pinhole	$d_{focus\text{-}pinhole}$	____ mm
diameter pinhole ⊥ AC axis	f⊥	____ mm
diameter pinhole // AC axis	f //	____ mm

$$m_{pinhole} = \frac{d_{pinhole-film}}{d_{focus-pinhole}} \; ; \; f = \frac{F}{m_{pinhole}}$$

Focal spot size f⊥ = _____ mm

f// = _____ mm

Accepted: yes / no

2a.2.1.1.2 Source-to-image distance

Nominal value:	____ mm
Measured value :	
- Focus indication to bucky:	____ mm
- Bucky to cassette:	____ mm
Source-to-image distance:	____ mm

2a.2.1.1.3 Alignment of X-ray field / image receptor

Distance at chest wall side film:	inside/outside image receptor:
position	
- left:	____ mm, in / out
- nipple:	____ mm, in / out
- right :	____ mm, in / out
- chest :	____ mm, in / out
Distance between film edge and bucky edge:	____ mm

Accepted: yes / no

2a.2.1.1.4 Radiation leakage

Description of position of 'hot spots'
1 _____
2 _____
3 _____

detector surface area: ____ mm^2

	measured:	calculated for
distance from tube:	50 mm	1000 mm,
surface area:	____ mm^2	100 cm^2:
nr:		
1. _____	____	____ mGy/hr
2. _____	____	____ mGy/hr
3. _____	____	____ mGy/hr

Accepted: yes / no

2a.2.1.1.5 Tube output

Focus to detector distance:	____ mm
Surface air kerma:	____ mGy
Focal spot charge:	____ mAs
Specific tube output at 1 m	____ µGy/mAs
Output rate at FFD	____ mGy/s

Accepted: yes / no

2a.2.1.2 Tube voltage

2a.2.1.2.1 Reproducibility and accuracy

Pre-set tube load:	____ mAs
Clinically most relevant kV:	____ kV

Accuracy at clinical tube voltage settings

Setting	____	____	____	28	____	____	____	kV
Measured	____	____	____	____	____	____	____	kV
Deviation	____	____	____	____	____	____	____	kV

Accepted: yes / no

Reproducibility at the clinically most relevant tube voltage setting

Set tube voltage ____ kV
Measured value: 1.____ 2.____ 3.____ 4.____ 5.____ kV
Reproducibility (max difference from the mean): ____ kV

Accepted: yes / no

2a.2.1.2.2 Half Value Layer

Target/filter: Mo/Mo
Measured tube voltage: 28 kV
Pre-set tube load: ____ mAs

Filtration:	0.0	0.30	0.40	mm Al
Exposure:	Y_0	Y_1	Y_2	
1.	____	____	____	mGy
2.	____	____	____	mGy
3.	____	____	____	mGy
Average exposure:	____	____	____	mGy

$$HVL = \frac{X_1 \ln(\frac{2Y_2}{Y_0}) - X_2 \ln(\frac{2Y_1}{Y_0})}{\ln(\frac{Y_2}{Y_1})} = \text{____ mm Al}$$

Deviation exposure at 0 mm Al: ____ %

Accepted: yes / no

Half Value Layer for average Glandular Dose calculations

Target/filter: ___ / ___
Measured tube voltage: ____ kV
Pre-set tube load: ____mAs

Filtration:	0.0	____	____	mm Al
Exposure:	Y_0	Y_1	Y_2	
1.	____	____	____	mGy
2.	____	____	____	mGy
3.	____	____	____	mGy
Average exposure:	____	____	____	mGy

HVL: ____ mm Al

Deviation exposure at 0 mm Al : ____ %

2a.2.1.3 AEC-system

2a.2.1.3.1 Optical density control setting: central value and difference per step

Target density value: ____ OD

Setting	Exposure mGy	Tube load mAs	Density OD	Density incr. OD
-3	____	____	____	____
-2	____	____	____	____
-1	____	____	____	____
0	____	____	____	____
1	____	____	____	____
2	____	____	____	____
3	____	____	____	____

Accepted: yes / no

Adjustable range: ____ OD

Accepted: yes / no

Optical density control setting for reference density: ____
Optical density control setting for target density: ____

2a.2.1.3.2 Back-up timer and security cut-off

Exposure terminates by exposure limit : yes/no
Alarm or error code: yes/no
Exposure: ____ mGy
Tube load: ____ mAs

2a.2.1.3.3 Short term reproducibility

Optical density control setting: ____

Exp. #	Exposure (mGy)	Tube load (mAs)
1	____	____
2	____	____
3	____	____
4	____	____
5	____	____
6	____	____
7	____	____
8	____	____
9	____	____
10	____	____

Deviation in tube load: ____ % (= 100 x (max-min)/mean)

Accepted: yes / no

2a.2.1.3.4 Long term reproducibility: Forms should be made to suit the local preferences.

2a.2.1.3.5 Object thickness and tube voltage compensation

Optical density control setting: ____
Mode name: ____

PMMA thickness	Target/ filter	Tube voltage (kV)	Optical Density (OD)	Thickness Indication (mm)
10 mm	____	____	____	____
20 mm	____	____	____	____
30 mm	____	____	____	____
40 mm	____	____	____	____
50 mm	____	____	____	____
60 mm	____	____	____	____
70 mm	____	____	____	____

Variation in optical density: ____ OD

Accepted: yes / no

2a.2.1.3.6 Correspondence between AEC sensors

AEC sensor position	Tube load (mAs)	Optical Density
____	____	____ OD
____	____	____ OD
____	____	____ OD
____	____	____ OD
____	____	____ OD
____	____	____ OD
Difference in Optical Density		____ OD

AEC sensor position	Position extra attenuation	Tube load (mAs)	Chosen AEC sensor position
____	____	____	____
____	____	____	____
____	____	____	____
____	____	____	____
____	____	____	____
____	____	____	____

Accepted: yes / no

2a.2.1.4 Compression

2a.2.1.4.1 Compression force

Force indication: ____ N
Measured compression force: ____ N
Compression force after 1 min: ____ N

Accepted: yes / no

2a.2.1.4.2 Compression plate alignment

Attachment compression plate: in order/out of order

Symmetric load
Thickness indication: ____ cm

Height of compression plate above the bucky at full compression:

	left	right	difference(l/r)	
Rear :	____	____	____	cm
Front :	____	____	____	cm
Difference(r/f)	____	____		cm

Accepted: yes / no

2a.2.2 Bucky and image receptor

2a.2.2.1 Anti scatter grid

2a.2.2.1.1 Grid system factor

	Exposure [mGy]	Tube load [mAs]	Density [OD]
Present:	____	____	____
Absent:	____	____	____
Grid system factor:	____		

Accepted: yes / no

2a.2.2.1.2 Grid imaging

Additional grid images made:

#	Added PMMA	Description of artefacts
1.	yes/no	_____
2.	yes/no	_____
3.	yes/no	_____

Accepted: yes / no

2a.2.2.2 Screen-film

2a.2.2.2.1 Inter cassette sensitivity and attenuation variation and optical density range

AEC setting: ____

Cassette id	Exposure [mGy]	Tube load [mAs]	Density [OD]
1	____	____	____
2	____	____	____
3	____	____	____
4	____	____	____
5	____	____	____
6	____	____	____
7	____	____	____
8	____	____	____
9	____	____	____
10	____	____	____
11	____	____	____
12	____	____	____
Average values:	____	____ mAs	____ OD
Max. deviation:	____ %	____ mAs	____ OD
Reference cassette:	____		

Accepted: yes / no

2a.2.2.2.2 Screen-film contact

Cassette id:	Description of artefacts:
____	_____
____	_____
____	_____
____	_____
____	_____
____	_____
____	_____
____	_____
____	_____
____	_____
____	_____
____	_____

Accepted: yes / no

2a.2.3 Film processing

2a.2.3.1 Baseline performance of the processor

2a.2.3.1.1 Temperature

Point of measurement in bath: _____

	Developer	Fixer
Reference/nominal:	____	____
Thermometer		
Reference:	____	____
Local:	____	____
Console:	____	____

2a.2.3.1.2 Process time

Time from processor signal to film available: ____ s

2a.2.3.2 Film and processor

2a.2.3.2.1 Sensitometry, daily performance, artefacts:

Forms should be made to suit the local preferences

2a.2.3.3 Darkroom

2a.2.3.3.1 Light leakage

Fog (after 2 min.) of a pre-exposed film on the workbench:

point:	1	2	3	4	5	
D(fogged):	____	____	____	____	____	OD
D(background):	____	____	____	____	____	OD
Difference:	____	____	____	____	____	OD

Average difference: ____ OD

Accepted: yes / no

Positions of light sources and leaks in the darkroom:

- _____
- _____

2a.2.3.3.2 Safelights

Type of lighting: direct/indirect
Height : ± ____ meter above workbench
Setting: ____
Filter condition : good / insufficient / absent / not checked

Fog (after 2 min.) of a pre-exposed film on the workbench:

point:	1	2	3	4	5	
D(fogged)	____	____	____	____	____	OD
D(background):	____	____	____	____	____	OD
Difference:	____	____	____	____	____	OD

Average difference: ____ OD

Accepted: yes / no

2a.2.4 Viewing conditions

2a.2.4.1 Viewing box

2a.2.4.1.1 Viewing box luminance and 2a.2.4.1.2 Homogeneity

Viewing panel Luminance (cd/m^2)	1	2	3	4	5
Centre	____	____	____	____	____
Top left	____	____	____	____	____
Top right	____	____	____	____	____
Bottom left	____	____	____	____	____
Bottom right	____	____	____	____	____
Difference in luminance between the centres (%)	____	____	____	____	____
Maximum deviation in luminance compared to the luminance in the centre (%)	____	____	____	____	____

Accepted: yes / no

2a.2.4.2 Ambient light level

Reading from the illuminance meter (detector at the image plane, box is off): ____ lux

Accepted: yes / no

2a.2.5 System properties

2a.2.5.1 Dosimetry

PMMA thickness (mm)	Average glandular dose (mGy)
20	____
30	____
40	____
50	____
60	____
70	____

Accepted: yes / no

2a.2.5.2 Image quality

2a.2.5.2.1 Spatial resolution

Position of the centre of the pattern:

Height above the bucky surface: ____ mm
Distance from thorax side of the bucky: ____ mm
Distance from AC axis: ____ mm

Resolution	R⊥ AC-axis	R//AC-axis
image 1	____	____
image 2	____	____
image 3	____	____
image 4	____	____

Accepted: yes / no

2a.2.5.2.2 Image contrast

image	mAs	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10
1	____	____	____	____	____	____	____	____	____	____	____
2	____	____	____	____	____	____	____	____	____	____	____
3	____	____	____	____	____	____	____	____	____	____	____
4	____	____	____	____	____	____	____	____	____	____	____
5	____	____	____	____	____	____	____	____	____	____	____

Graph(s) attached

2a.2.5.2.3 Threshold contrast visibility

Observer	# objects identified
1	____
2	____
3	____

Accepted: yes / no

Diameter disc (mm)	Threshold contrast (%)
0,1	____
0,2	____
0,5	____
1,0	____
2,0	____

2a.2.5.2.4 Exposure time

AEC setting for a routine image: ____
Tube load obtained: ____ mAs
Exposure time: ____ s

Accepted: yes / no

2b

European protocol for the quality control of the physical and technical aspects of mammography screening

Digital mammography

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Foreword

The 'European guidelines for quality assurance in mammography screening' (European Guidelines, 2001) include as chapter 3 the 'European protocol for the quality control of the physical and technical aspects of mammography screening'. In this protocol the requirements for an adequate screen-film imaging system are defined. In recent years, the image detection technology used in mammography has extended to include the use of digital detector systems. This technology is different in so many ways, that it is necessary to set new quality standards and test procedures specifically for digital systems.

This document is based on the addendum to chapter 3 of the European guidelines (3rd edition), which was released in November 2003 (Addendum, 2003). The approach to quality assessment and control in this protocol is comparable in the sense, that the measurement and evaluation of performance are in principle independent of the type and brand of the system used. The measurements are generally based on parameters that are extracted from the images that are produced when a phantom with known physical properties is exposed under defined conditions. The limiting values are based upon the quality that is achieved by screen-film systems, which fulfil the demands of the European guidelines.
To fulfil the European guidelines in mammography screening, the digital x-ray system must pass all relevant tests at the acceptable level. The achievable level reflects the state of the art for the individual parameter.

This protocol for digital mammography is work-in-progress and subject to improvements as more experience in digital mammography is obtained and new types of digital mammography equipment are developed. Changes in measuring techniques or limiting values will lead to a new version number, changes in wording or added comments will change the sub-number. Updates on the current version will be made available on the EUREF website (www.euref.org). It is recommended that users check the website for updates before testing digital mammography equipment.

In the text some lines are printed in parentheses [like these]. This text is a remark.

Text in a box like this needs further evaluation.

2b.1 Introduction to the measurements

To produce images with adequate quality, each part of the imaging chain must function within the limits of performance given. Experience with some digital systems shows, that non-compliance results in a seriously diminished information transfer to the observer. This can be expected to result in a lower detection rate for microcalcifications and/or for low contrast lesions.
To facilitate the relevant quality control, the user must be able to evaluate the status of the acquisition system including detector, the processing system and the display system (see fig. 1). This protocol follows recommendations according to the DICOM standard (NEMA, Digital Imaging and Communications in Medicine). The equipment therefore must be able to transmit and receive digital mammogram images as IOD's (Information Object Definitions) of modality 'MG' (mammography) or 'CR' (computed radiography), in compliance with parts 3 (IOD definition), 5 (data structures and encoding), 6 (data dictionary) and 7 (message exchange) of the DICOM standard. Modality MG is preferred over modality CR (for example because MG includes exposure parameters and the terms 'for processing' and 'for presentation' are used to distinguish unprocessed and processed images).

The general principles for testing the three main parts of the imaging chain, illustrated in figure 1, are discussed below.

Acquisition system including image receptor
The acquisition system (fig. 1, A) can be evaluated:
- By inspection of a recent 'bad pixel map'. This map (either an image or a table) defines the position of all pixels of which the pixel value is not based on its own del reading (see 2b.2.2.3.2). It must be accessible to the user at any time and be usable independently of a given equipment and manufacturers permission.
- By the assessment of the relation between X-ray exposure parameters, dose to the image receptor and pixel values. An 'unprocessed image' (DICOM defines such an image as 'for processing'), presenting a linear or other known mathematical relationship between del dose and pixel value, must be accessible. This image type must also be available for CAD (computer aided detection) or other processing software.
- By an indication of the nominal sensitivity setting of the system in every image.
  Since image quality increases with dose, the preference for higher system dose can be expected. This leads to a higher mean glandular dose and consequent higher radiation risk to the women screened. In screen-film systems the dose to the image receptor is linked to the mean optical density of each film, given the speed class of the system (speed class 100 corresponds roughly to an air kerma of 10 µGy at the place of the image receptor). An indication, comparable to speed class, must be provided for digital systems to keep the radiologist informed on the average doses delivered. It is recommended that manufacturers provide sufficient information in the header of the file to allow calculation of the average glandular dose for each individual patient. A working group of DICOM is drafting the definitions.
- For the evaluation of the acquisition system this protocol follows some draft procedures of the American Association of Physicists in Medicine (AAPM) Task Group 10 (Samei, 2001) and of preliminary results of the American College of Radiology Imaging Network Dmist trial (ACRIN Dmist).

Processing system
- In future the processing system (fig 1, B) may be evaluated by the inspection and scoring of a test set of images (either mammograms or phantom images), which have been processed in the available standard processing algorithm.
  - These images are to be inserted by the user as 'unprocessed images' (DICOM: 'for processing') and processed by the software of the manufacturer before displaying.
  - The manufacturer must provide information in general terms on the processing applied.
- The processing algorithms are built to enhance the visibility of specific image details. At this moment little experience and literature on the effects is available. These algorithms therefore are not addressed in the present protocol. The observer is urged to convince himself of the value of the algorithms provided.

- Evaluation of processing algorithms and CAD (computer aided detection) will be addressed in a future version of this protocol.

Display system

- The display system (fig 1, C) can be evaluated by the inspection on the display system (printer or monitor) of synthetic test images, produced in DICOM format and independent of the phantom images delivered by the manufacturer. The user must be able to insert these images as 'processed images' (DICOM: 'for presentation'). They are not processed further before displaying. Evaluation of such images is necessary to confirm compliance to quality standards other than those of the manufacturer. It must be possible to load and display these phantom images using the imaging system under evaluation.
- For the evaluation of the display system this protocol follows the advice of AAPM Task Group 18 (Samei, 2004) and of preliminary results of the ACRIN Dmist trial.

The measurements in the protocol are in principle chosen and described to be generally applicable. Where the tests are similar to those required for screen-film mammography, a reference to the relevant part of the European guidelines is given. When necessary, different test procedures are given for CR (computed radiology, i.e. photo-stimulable phosphor type) systems and DR (direct radiology, i.e. solid state type, including scanning slot) systems separately.

Many measurements are performed by an exposure of a test object. All measurements are performed under normal working conditions: no special adjustment of the equipment is necessary. Since the available settings in the different systems vary in spectrum and X-ray quantity for the different breast thicknesses, no common standard exposure can be indicated. Therefore dose calculations for the comparison of systems are based on the AGD (average glandular dose) to the breast (or simulated breast) rather than on entrance surface air kerma.
To evaluate the clinical use of a system, a standard type of exposure is specified: the routine exposure, which is intended to provide information on the system under clinical settings.

For the production of the routine exposure, a test object is exposed using the machine settings as follows (unless stated otherwise):

	Routine exposure:
test object thickness:	45 mm
test object material:	PMMA
tube voltage:	as used clinically
target material:	as used clinically
filter material:	as used clinically
compression device:	in contact with test object
anti scatter grid:	as used clinically
source-to-image distance:	as used clinically
photo timer detector (for CR):	in position closest to chest wall
automatic exposure control:	as used clinically
exposure control step:	as used clinically
exposure-to-read-time (for CR):	1 minute[7]
image processing:	off

Mean pixel values and their standard deviation are measured in a standard region of interest (ROI), which has an area of 4 cm^2 and is positioned 60 mm from the chest wall side and laterally centred.

Limits of acceptable performance for image quality and dose are based on the limits of acceptable performance of screen-film mammography systems. The relation between dose and limits of visibility of details for a certain contrast are based on the performance of a large number of screen-film systems in the UK, the Netherlands, Germany, Belgium and France. These acceptable limits are given, but often a better result is achievable. When applicable the achievable values are also given. Both the acceptable and achievable values are summarised in Appendix 7. Occasionally no limiting value is given, but only a typical value as an indication of what may normally be expected. The measurement frequencies indicated in the protocol (appendix 6) are the minimum required. When the acceptable limiting value is exceeded the measurement should be repeated. If necessary, additional measurements should be performed to determine the origin of the observed problem and appropriate actions that should be taken to solve the problem.
For some tests the limiting values are **provisional,** this means that the limiting value needs further evaluation and may be changed in the future. Check the EUREF website for updates. In some cases further remarks about the limiting values can be found in a box.

Guidance on the specific design and operating criteria of suitable test objects will be given by a separate project group of the European Breast Cancer Network (EBCN). Definition of terms, such as the reference ROI and signal-to-noise-ratio are given in section 2b.1.5. The evaluation of the results of the QC measurements can be simplified by using the forms for QC reporting that are provided on the EUREF homepage (www.euref.org).

2b.1.1 Staff and equipment

The local staff can perform several measurements. The more elaborate measurements should be undertaken by medical physicists who are trained and experienced in diagnostic radiology and specifically trained in mammography QC. Comparability and consistency of the results from different centres is best achieved if data from all measurements, including those performed by local technicians or radiographers, are collected and analysed centrally.

The staff conducting the daily/weekly QC-tests will need the following equipment[8] at the screening site:

- Standard test block[9] (45 mm PMMA[10])
- Reference cassette (CR systems)
- Digital QC test images
- PMMA plates[11]

The medical physics staff conducting the other QC-tests will need the following additional equipment and may need duplicates of some of the above[3]:

- Dose meter
- Tube voltage meter
- Exposure time meter
- Telescopic luminance meter
- Illuminance meter
- QC test objects
- Digital QC test images
- Contrast-detail test object
- Densitometer
- Aluminium sheets
- Focal spot test device + stand
- Screen-film contact test device
- Tape ruler
- Compression force test device
- Rubber foam
- Lead sheet
- Expanded polymer spacers

2b.1.2 System demands

Accessibility
It must be possible to access and insert DICOM images as 'for processing' and 'for presentation' to allow evaluation of the image receptor, image processing and image presentation separately.

AEC
The As Low As Reasonably Achievable (ALARA) principle on dose administered to the patient necessitates the use of an automated exposure control (AEC) system to ensure the optimal exposure of the image receptor compensating for breast thickness and composition. The use of a look up table, only based on the measured thickness of the compressed breast, increases the mean dose to the patients. This is due to the necessary margin in exposure to avoid increased noise by underexposure in dense breasts and to compensate for the incorrect reading of the thickness.

Image receptor
The required physical size of the image receptor and the amount of missed tissue at the short sides and especially at the chest wall side are important for an optimal imaging of the breast tissues. An upper limit is given for the amount of missed tissue at chest wall side, but the acceptance of other margins remains the responsibility of the radiologist.

Display system
Optimal transfer of the information in digital mammograms will be reached, when every pixel in the matrix is projected to at least one pixel on the display system and when the pixel size on the display system is sufficiently small to show details that coincide with the maximum sensitivity of the eye of the observer (1-3 lp/mm at a viewing distance of 30 cm). In screening the monitor should allow for the inspection of the image at full size in full resolution, since the number of images read does not allow time consuming procedures like roaming or zooming. Normally two images are viewed at the same time, and with the current technology it is therefore recommended that diagnostic workstations with two large (45-50 cm diagonal (19-21^{II})) high quality, 5 megapixel monitors are used.
On the acquisition unit it may be acceptable to use a monitor with lower specification, depending on the tasks of the radiographer.
Further research is needed to demonstrate whether cheaper solutions (e.g. 3 megapixel monitors) may be sufficient in clinical situations.

Viewing conditions
Since the maximum intensity on the monitor (300-800 cd/m^2) is much lower than that of a viewing box with unexposed and developed film (3000-6000 cd/m^2) and due to the reflection characteristics of the monitor, the amount of ambient light might seriously diminish the visible dynamic range and the visibility of low contrast lesions. The ambient light level therefore should be low (less than 10 lux) to allow maximal extension to the lower part of the range. Although this level has proven to be acceptable, a short time to adapt to this level might be necessary.

Computed Radiography (CR) system
Measurements should be performed with the same phosphor screen to rule out differences between screens except when testing individual screens as in section 2b.2.2.4 and when testing contrast threshold visibility as in section 2b.2.4.1. The exposure-to-read-time is standardised to minimize differences caused by varying time delays (i.e. fading of the latent image).
The DICOM standard allows both IOD's of 'CR' and 'MG' to be used for CR images. This may lead to improper hanging of the images by different display systems.

Direct Radiography (DR) detector
When measurements are performed for which no image is required (e.g. HVL or tube voltage), the detector should be covered sufficiently to prevent ghost images appearing on subsequent use of the system.
When the absorbers in the QC test object lead to automatic exposure values other than those that would be obtained with homogeneous PMMA, set the system manually to these values.

Printer
The pixel size of the printer should be in the same order of magnitude as (or less than) the pixel size of the image and should be < 100 micron.

2b.1.3 Order of the measurements

It is advisable to perform measurements such as homogeneity, NPS, linearity, MTF first and ghosting last to prevent the influence of possible ghost images. After the ghosting measurement it is advised to make some additional images with a homogeneous block of PMMA covering the whole detector to make sure that ghosts do not appear on clinical images.

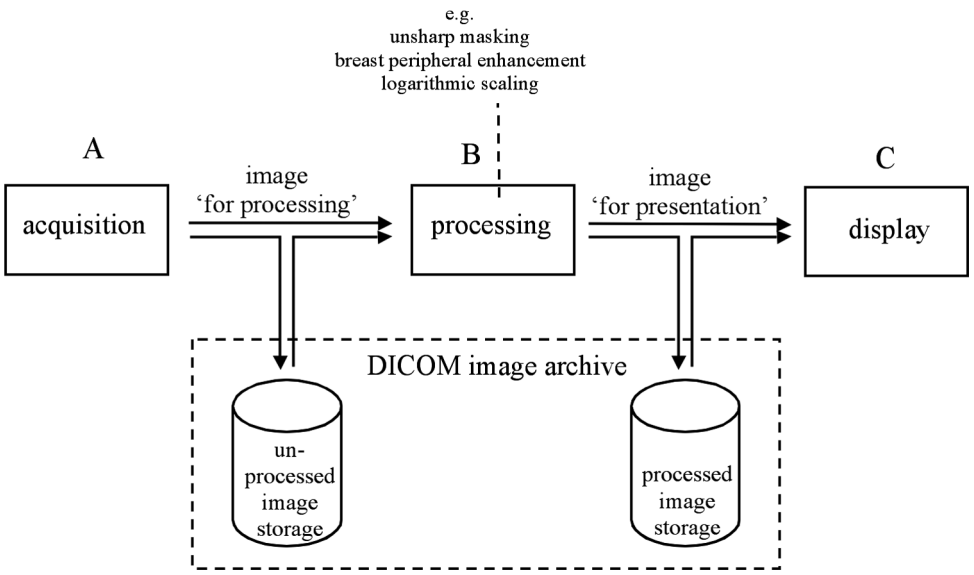


Fig.1

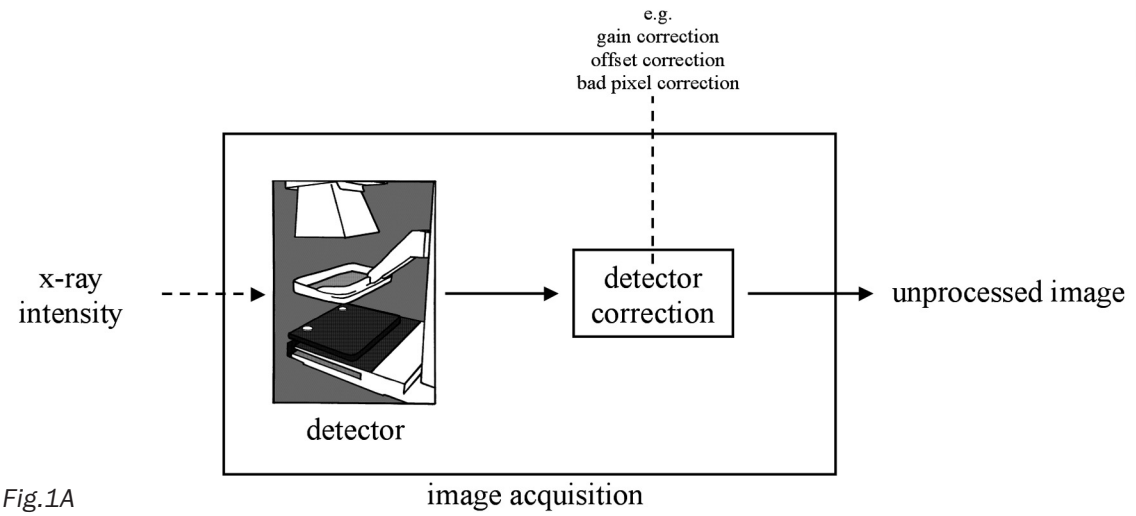


Fig.1A

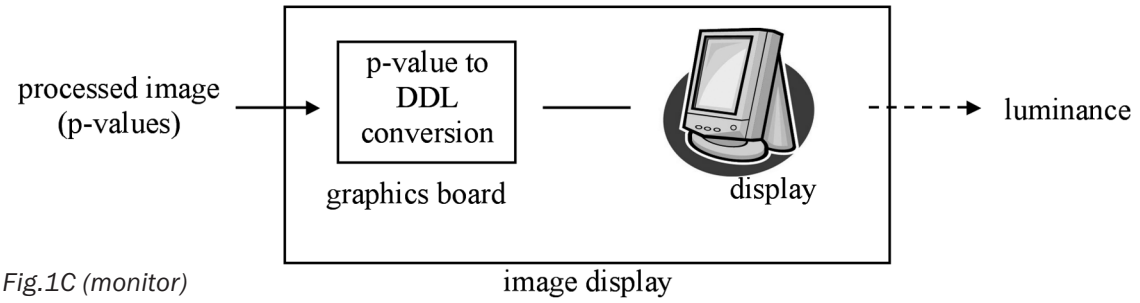


Fig.1C (monitor)

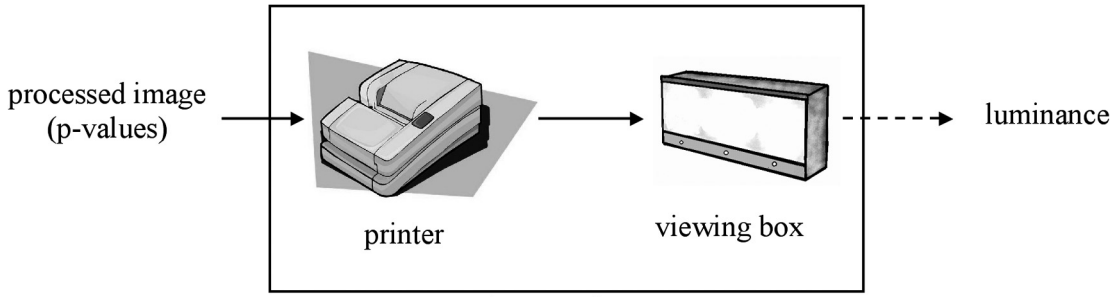


Fig.1C (printer)

2b.1.4 Philosophy

Introduction

The primary scope of this document is setting standards for mammography screening, however similar standards are expected for diagnostic mammography.

The imaging chain in digital mammography can be divided into three independent parts:

1. Image acquisition, which includes the X-ray generation, the image receptor and (for some systems) image receptor corrections.
2. Image processing, which includes the image processing software.
3. Image presentation, including monitor, image presentation software, printer and viewing box.

In the European protocol for the quality control of the physical and technical aspects of mammography screening these parts of the imaging chain are evaluated separately. This is a practical approach because each requires very different evaluation techniques and it allows the use of equipment and software from different vendors. In the present version of the protocol (version 4) only image acquisition and image presentation are considered. Due to the large number of processing techniques and the shortcomings of classical test objects with regard to the evaluation of post processing as histogram and texture based processing, evaluation of the image processing part of the imaging chain has not been addressed (yet). However, manufacturers have to specify in general terms, which image processing techniques are applied and it is advised to evaluate image processing by comparing mammograms to images from the previous screening round by experienced readers.

The digital section of this chapter of the European guidelines should not be considered as a guide for the optimal working point of a particular system or as a guide to optimise image quality. Different research groups are studying these issues and manufacturers are still working on the optimizing of current systems and the development of new techniques. We urge the reader of this document to keep track of all new developments in this rapidly changing technology. Updates of this protocol will be available at www.euref.org.

2b.1.4.1 Methods of testing

The tests as described in the present text on image acquisition are based on the expertise of the different European groups in digital mammography, the American College of Radiology Imaging Network Dmist trial (ACRIN Dmist) QC protocol (and experiences with this protocol which were shared generously by the QC team of the trial), manufacturers QC tests and the publication from American Association of Physicists in Medicine (AAPM) Task Group 10 concerning CR systems.
The tests in the image presentation section are based on the testing methods and test images of AAPM Task Group 18. This includes conformation to the DICOM standard for presentations.

Before publication the test methods have been evaluated using a number of different types of digital systems. For some types of systems only a small number of evaluation tests have been performed due to limited accessibility. Due to the rapidly changing technologies, new methods of testing may be necessary in the future. Check for updates on the EUREF website.

2b.1.4.2 Limiting values

Limiting values have been derived as much as possible from practice using screen-film mammography: it is assumed to be a requirement that digital mammography should perform at least as well as screen-film mammography.
For some test items the limiting values need more evaluation. In these cases, the limiting values have been made provisional. For some requirements, we depend on the provision of additional features by the manufacturers. In these cases, a date is given by which the items should be made available.

To remain up-to-date with the latest insights, the protocol will be updated continuously. Latest versions will be made available on the EUREF website (www.euref.org).
The philosophy of important QC tests and remarks are explained in the following paragraphs.

2b.1.4.3 Image acquisition

The X-ray generation part of the protocol is essentially identical to that of screen-film mammography. Therefore it will not be discussed in this section.

Automatic exposure control
Some digital mammography equipment on the market, are still ‘in development’. One of the features not yet incorporated in some systems, is an automatic exposure control device. This has a number of disadvantages:

1. In the case of completely manual settings, mistakes in exposure settings may occur and lead to under- or overexposure and leading to insufficient image quality or unnecessary patient dose. Contrary to screen-film mammography, in which underexposure is immediately recognized from a change in the optical density of the film, underexposure in digital mammography is not easily recognized by the radiographer or the radiologist. This may lead to insufficient image quality.
2. The system might not be able to handle the high throughput necessary in mammography screening.
3. Due to the unknown breast content, exposure factors must be tuned to dense breasts to guarantee a sufficiently high image quality. This leads, however, to unnecessarily high exposures for other women and does not comply with the As Low As Reasonably Achievable (ALARA) principle. Some manufacturers try to compensate for this by providing exposure tables for several types of breast composition. However, it is not always clear how these tables were set-up and how the categories of breast content are defined or anticipated. The problem comes down to the user who has to choose the right exposure table. This is difficult since breast content may not be known until the breast is imaged.

Therefore, the authors have stated that systems used for mammography screening should incorporate an AEC. Manufacturers of equipment without Automatic Exposure Control (AEC), are

urged to implement such a device in their systems before January 2006. For the time being systems which incorporate an exposure table in the software that account only for compressed breast thickness, will be allowed. We advise against systems in which both spectrum and dose have to be set completely manually.

2b.1.4.4 Image quality evaluation

Image quality is evaluated in terms of threshold contrast visibility at a standard simulated breast thickness. This provides a measure of image quality for an average breast. As this test is rather time consuming, the evaluation is restricted to this standard thickness. The image quality of other thicknesses is related to the image quality at the standard thickness using simpler parameters, which describe the image quality relative to the image quality at the standard thickness.

2b.1.4.4.1 Image quality at standard thickness

Image quality is expressed in terms of threshold contrast visibility using clinical exposure settings. This allows evaluation of the image quality of a digital image receptor in relationship to the spectrum and dose levels, which are used clinically on that particular system.
For the evaluation of threshold contrast visibility 'unprocessed' phantom images must be used. In this way, only the image acquisition part of the system is included and the image quality evaluation cannot be considered as a 'whole-system' test.
It is acknowledged that it is not possible to get 'unprocessed' images from all systems yet. For these systems threshold contrast visibility has to be determined on images with the least possible image processing. This processing may introduce artefacts due to histogram or texture based processing techniques. Therefore care needs to be taken in interpretation of these processed contrast-detail (CD) images.

To increase reliability at least six phantom images are required. To reduce the (in-) visibility of small disks due to the accidental relative position of the disks and the dels of the detector the phantom has to be repositioned slightly after acquisition of each image. Extensive window levelling and zooming must be performed to optimize the visibility of the dots in each section of the phantom image. This prevents the monitor from being the limiting factor for the threshold contrast evaluation instead of the quality of the unprocessed image. At least three readers should score two different images each.
A problem with scoring CD images is the inter- and intra-reader variability. Therefore CDMAM images with scores are available on the EUREF website for reference purposes. In future, the threshold contrast visibility test may be performed using computer readout of the phantom images. This will solve problems with inter- and intra-observer variability Allowance may need to be made for differences between human and machine measurements of threshold contrast.
At this moment image quality is evaluated using a total attenuation equivalent to 50 mm PMMA thickness. This has been chosen because image quality information was available for this thickness. In the future, the image quality evaluation may be performed at the thickness of 45 mm PMMA, which has been chosen as the standard thickness for other tests in the European Guidelines.

Two kinds of limiting values have been set: acceptable and achievable limiting values. The acceptable limiting values have been derived from screen-film mammography, the achievable limiting values have been derived from current full-field digital mammography systems.
The acceptable limiting values have been derived by stating that image quality of digital mammography must be (at least) comparable to screen-film mammography (Young, 2004). For this purpose the image quality of a large number of screen-film mammography systems in different screening programmes has been determined using CD analysis. The CDMAM phantom has been used for these measurements. It was chosen that the image quality limiting values for digital mammography should be such that 97.5% of the screen-film systems in the UK would comply. This means that the image quality limits are not very demanding and it must be realized that a system just complying to the acceptable limits would probably not be considered equivalent to top quality screen-film systems.

The resulting limiting values have been checked with the image quality levels found in the Dutch screening and in some of the German screening projects (of which data was available) and were found to be realistic.
Furthermore the limiting values have been checked with the CD curves from some hospitals in which it was established (by radiologists) that image quality of the digital system was too low for mammography. (The visibility of microcalcifications was regarded insufficient). Threshold contrast visibility for small diameters did not meet the acceptable limiting values in these hospitals. The image quality of a system is only acceptable if contrast threshold values for all diameters comply with the limiting values.
The achievable limiting values have been derived as averages from a number of established digital mammography systems. At the EUREF website CDMAM images with scores can be found for reference purposes.

2b.1.4.4.2 Image quality at other PMMA thicknesses

In version 1.0 of the protocol for digital mammography image quality at thicknesses other than standard thickness is related to the image quality at the standard thickness using Signal-to-Noise Ratio (SNR) and Contrast-to-Noise Ratio (CNR) requirements. The absolute values of SNR and CNR are system dependent (they are dependent on for example pixel size), therefore limiting values need to be expressed in terms of variation in SNR over the whole range of simulated breast thicknesses and percentage of CNR at standard thickness respectively.
However there are difficulties with this measurement. At this moment three kinds of parameters are used by manufacturers to control image quality in AEC systems: dose to the detector (pixel value), SNR and CNR.
Screen-film mammography systems and some digital systems keep dose to the AEC detector constant over the whole range of breast thicknesses (for digital systems this means that pixel value is kept constant), some other systems keep SNR constant and recently a system has been introduced which tries to keep CNR constant.

In the view of the authors CNR would be the right measure to quantify image quality at thicknesses other than standard thickness. CNR should not necessarily be equal across the whole range of breast thicknesses. However, problems arise when setting the CNR value at standard thickness as reference for other thicknesses using the method described in version 1.0 of the Protocol for digital mammography. If the CNR at standard thickness is high, CNR at other thicknesses may fail, not because image quality is too low, but because image quality at standard thickness is relatively high. So the method of testing and limiting values needed to be revised.
In this fourth edition of the guidelines the value of CNR at standard thickness is estimated which would be obtained on a system if this system just complied with the acceptable limiting values of threshold contrast visibility. In the calculation of this minimum CNR level it is assumed that quantum noise is the main source of noise in the system. The calculation is based on the Rose theory, from which can be derived that threshold contrast visibility is inversely related to CNR. The calculated CNR at the acceptable limiting value of threshold contrast is the lower limit of CNR at standard thickness. Lower limits of CNR at other thickness are related to this value providing sufficient CNR for the whole range of breast thickness.

2b.1.4.5 Glandular dose

It is assumed that average glandular dose levels in digital mammography systems should be no more than for screen-film systems. To ensure this, the limiting dose values have been changed compared to the third edition of the European guidelines for quality assurance in mammography screening in three aspects:
In the present version of the protocol the clinical spectrum is used for dose measurements instead of a standard spectrum, the dose limits have been made independent of optical density and a limiting dose value per PMMA thickness is introduced. The reasons for these changes will be explained in the next paragraphs.

In the third edition of the protocol for screen-film systems, limiting dose values were measured using a standard spectrum. This requirement of the third edition cannot be fulfilled by some digital mammography systems due to the available spectra. For example: scanning slot systems use tungsten instead of molybdenum targets due to the required tube loading. Furthermore using clinical spectra in dose measurements is closer to clinical practice.
In the third edition, Entrance Surface Air Kerma (ESAK) limits at standard thickness have to be measured for a given optical density. Practical ESAK values are found to be far below the limiting value, even at the clinically used optical density. In digital mammography the link between limiting dose values and OD is non-existent. Therefore a choice had to be made what limiting dose value would be appropriate for digital mammography. In the view of the authors, inspired by the ALARA principle, dose should not increase substantially when changing to digital mammography. Data from the Dutch (Beckers 2003), Swedish (Leitz 2001), Norwegian (Pedersen 2000) and UK (NHSBSP 2000, 2003) screening programmes show that average glandular dose levels in screen-film mammography systems are between 0.8 and 2.5 mGy for 4.5 cm PMMA in clinical settings (corrected for difference in standard PMMA thickness in the UK and the Netherlands). Therefore an average glandular dose limit of 2.5 mGy at standard thickness in clinical settings has been chosen to ensure that dose levels in digital mammography will not exceed those of screen-film mammography. This limiting value is comparable to the objective of the NHSBSP in the UK to have average glandular dose levels of 2 mGy or less (for 4.0 cm PMMA) and the limiting average glandular dose value for the Dutch screening programme (3 mGy for 5.0 cm PMMA). In the present version of the protocol limiting dose values for a range of PMMA thickness have been introduced. This has been done because in some non-AEC systems it was noticed that manufacturers decreased dose at standard thicknesses to comply with the limiting value at standard thickness while dose levels at other thickness were found to be (much) higher than found in screen-film mammography. Besides this it has been found that some systems did use much lower tube voltages than in screen-film mammography (thus increasing patient dose substantially). In measurements performed by some of the authors, these very low values proved unnecessary for image quality, therefore the use of these tube voltages does not comply with the ALARA principle. Setting limiting dose levels per PMMA thickness prevents this situation. The limiting values for PMMA thicknesses other than standard thickness have been obtained by averaging all measured glandular dose levels per PMMA thickness from all X-ray units of the Dutch screening programme and some German screening trials. The resulting average glandular dose against PMMA thickness curve has been scaled to the limiting value at standard thickness. The results have been compared with the dose values per PMMA thickness found in the UK and some of the German screening projects (screen-film mammography). The limiting values were found to be reasonable.

2b.1.4.6 Exposure time

The exposure time should be sufficiently short to avoid motion unsharpness. For scanning slot systems a distinction has to be made between the time in which each individual part of the breast is exposed and the total scanning time. The first is important for motion unsharpness, the latter for the time during which the breast of a woman is compressed.
For most systems exposure time increases rapidly with breast thickness and content. Depending on the screen-film combination and the clinically used spectra this range may vary from 0.2 to 3 seconds. For some scanning slot systems however, scanning time and exposure time are fairly constant for the whole range of breast thickness and content. Due to this design, these systems may not comply with the limiting value of 2 seconds at standard thickness. Ideally exposure time should be below a certain limiting value even for very thick and dense breasts, so the limiting value at standard thickness may not be the right measure to prevent motion unsharpness for all breasts. Because this worst case liming value has not been determined yet, the value of 2 seconds at standard thickness is maintained, with the exception that scanning slot systems for which exposure time is only slightly dependent on breast thickness and content do not have to comply. For these systems clinical results will have to show that motion unsharpness is not a problem.

2b.1.4.7 Image receptor

2b.1.4.7.1 Response function

The response function should comply with a specification. The response function may be linear or logarithmic or fulfil some other mathematical relationship. The response function should be monotonous increasing (or decreasing). In some systems manufacturers certain value is added to the pixel value of all pixels to prevent negative values. When calculating SNR this offset must be taken into account. The response function of current CR systems is not linear but may be logarithmic. For these systems the response function needs to be linearised before SNR and CNR calculations are performed.

2b.1.4.7.2 Noise evaluation

Noise is evaluated by plotting SNR squared against entrance surface air kerma (ESAK) for systems with a linear response (such as current DR systems) and Standard Deviation squared against one over ESAK for systems with a logarithmic response (such as current CR systems). The non-linearity and the offset of the curve are indications of the presence of additional noise. At acceptance a reference curve is measured. At subsequent QC tests the results should be compared to the reference curve.

2b.1.4.7.3 Missed tissue at chest wall side

The limiting value on the amount of missed tissue at chest wall side is based on characteristic values found in screen-film mammography systems. In November 2003 (date of publication of version 1.0 of the protocol for digital mammography), some specific designs of digital mammography system did not comply with the limiting value of 5 mm. Because it is stated that digital mammography should be at least equal to screen-film mammography, the manufacturers of systems, that do not comply with the limiting value, have been urged to reduce the amount of missed tissue at chest wall side for their system(s). A number of responding manufacturers have stated that they will comply.

2b.1.4.7.4 Detector element failure (DR)

It is very important to check the number and position of defective detector elements (dels). At this moment manufacturers are reluctant to provide this kind of information to users, but buyers of equipment have the right to know the extent to which the images on their systems are reconstructed. Therefore this information should be made available to the user.
It is demanded that a bad pixel map (either an image or a table with the position of all pixels of which the pixel value is not based on its own del reading) is incorporated and that this map is accessible to the user at any time and in such a format that it can be used independent of the equipment of the manufacturer.
Limiting values on detector element failure should firstly (and most importantly) be based on clinical relevance. At this moment there is not much information available on this subject. It is expected that the loss of individual microcalcifications will not influence diagnostic decisions, so (reconstructed) individual defective dels can be allowed. If a large number of dels are defective within a certain area, this might influence diagnostic decisions. The difficulty is where to draw the line.
Secondly, the correction algorithm, which is used on a particular X-ray unit, must be considered. If an algorithm cannot handle the reconstruction of certain defective del values, this might lead to unwanted artefacts on the image, even if the area is sufficiently small not to influence diagnostics. For both reasons it is currently advisable to refer to the specifications of the manufacturer for the number of defective detector elements, which can be allowed on a particular detector.

2b.1.4.7.5 Image receptor homogeneity

For DR detectors, detector corrections are applied. In this correction the pixel value of defective dels is reconstructed from the readout of neighbouring dels and corrections for differences in electronic gain of the read-out and individual detector element sensitivity variations are

performed. For some systems, the latter correction has to be performed by the user. If the user has to perform this calibration, sufficient time must have passed since the last images were made to prevent the influence of possible ghost images on the calibration. These corrections can be checked in a homogeneity test.
Strictly speaking the correction for differences in sensitivity is only valid at the spectrum and simulated breast thickness at which calibration is performed. Therefore it is advised to perform the homogeneity test at several clinically relevant spectra and thickness at acceptance. At acceptance, a baseline is established for the homogeneity test. For some types of DR detectors homogeneity changes relatively quickly over time. Therefore it is advised to check image homogeneity regularly (weekly) and check the results with the baseline. The frequency may change in future and may be dependent on the type of digital system. For CR systems the usefulness of the homogeneity test needs to be established. For the moment it is also recommended to perform this test on CR systems.
Problems may occur if the Heel effect and geometric effects are relatively large. These effects might influence the results of the image receptor homogeneity measurement. If a specific system does not comply with the provisional limiting values it is advised to check whether geometry or the Heel effect causes this deviation or any malfunction in the system. It is recommended that the images are checked visually for artefacts.

2b.1.4.7.6 Fading of latent image (CR)
At acceptance it is advised that the fading of the latent image on the phosphor screens is measured. With the results of this test the importance of using the same exposure-to-processing time (in clinical practice and during quality control tests) can be determined.

2b.1.4.7.7 Ghosting
Several reports on ghosting in DR systems have been published (for example: Siewerdsen, 1999). In CR systems ghosts may occur if the erasure of the screens is not performed optimally. This ghosting is quantified by comparing the pixel value of an induced ghost image to a known contrast in the image (contrast of an aluminium sheet). After the ghosting measurement it is advised to make some additional images with a homogeneous block of PMMA covering the whole detector to make sure that ghosts will not appear on clinical images.
For scanning slot systems ghosts will not show with the proposed method of testing, but any ghosting is included in MTF measurements.

2b.1.4.8 Image presentation

The whole image presentation section of this protocol is based on the work of AAPM Task Group 18. Only measurements which differ from the recommendations of Task Group 18 and limiting values for which systems do not comply are mentioned below.

2b.1.4.8.1 Monitors

2b.1.4.8.1.1 Ambient light
AAPM Task Group 18 does not have specific limiting values on ambient light. In fact maximum ambient light levels are dependent on the minimum luminance and reflection characteristics of the monitor. For reasons of simplicity a single ambient light limiting value has been set.

2b.1.4.8.1.2 Grayscale display function
The grayscale display function of the monitor is checked against the DICOM Greyscale Standard Display Function (GSDF). It is noticed that a number of display systems do not comply to the GSDF. Manufacturers are urged to comply with this part of the DICOM standard. Test image TG18-QC seems to be a good and quick (daily) test for the display on the monitor.

2b.1.4.3.2 Printers

2b.1.4.3.2.1 Greyscale display function

The suggestions for QC made by AAPM Task Group 18 have been adapted slightly. Task Group 18 measurements are based on measuring luminances of a printed test pattern on a viewing box. These measurements should be performed for all combinations of printers and viewing boxes. From a quality control point of view this is impractical, therefore a standard viewing box has been defined (luminance of the viewing box without film: 4000 cd/m^2, luminance contribution due to ambient illuminance reflecting of the printout: 1 cd/m^2. The optical densities of the test pattern should be such that the printout in combination with this virtual viewing box would comply with the GSDF. The luminance of the viewing boxes is controlled by the tests described in the screen-film section of the European guidelines.

2b.1.4.3.2.2 Pixel size

To be able to print images with sufficient resolution, the pixel size of the printer should be in the same order of magnitude as (or less than) the pixel size of the image and should always be < 100 micron.

2b.1.5 Definition of terms

The definitions given here specify the meaning of the terms used in this document.

Active display area — The part of the display used for displaying images, applications and the desktop.

Bad pixel map — A map (either an image or a table) which defines the position of all pixels of which the pixel value is not based on its own del reading.

Bit-depth — Number of values which can be assigned to a pixel in a certain digital system, expressed in bits.

Computer Aided Detection (CAD) — Software to aid the radiologists' detection of suspect areas in the breast image.

Computed Radiography (CR) — Digital radiology technology using photostimulable phosphor plates.

Contrast to Noise Ratio (CNR) — The CNR is calculated as follows for a specific test object (e.g. 0.2 mm Al thickness on 45 mm PMMA).

$$CNR = \frac{\text{mean pixel value (signal)} - \text{mean pixel value (background)}}{\sqrt{\frac{\text{Standard deviation (signal)}^2 + \text{Standard deviation (background)}^2}{2}}}$$

Del — Discrete element in a DR detector.

Detective Quantum Efficiency (DQE) — Function which describes the transfer of SNR as function of spatial frequency when recording an X-ray image. The DQE gives the efficiency with which the device uses the available quanta.

Detector corrections — Correction in DR systems whereby the pixel value of defective detector elements are reconstructed and pixel values are corrected for individual detector element sensitivity variations and electronic gain of the read-out.

Direct Radiography (DR)	Digital radiology technology using sealed units mounted on a radiography system, which captures X-rays and produces a digital image by sampling the X-ray image.
Digital Driving Level (DDL)	Digital value which is the input for a display system.
Exposure indicator	Number ascribed to an image related to the exposure.
Exposure time	The time between the first and last moment that primary X-rays reach an individual part of an imaged object.
Ghost image	Residuals of previous images visible on the current image.
Modulation Transfer Function (MTF)	Function, which describes how the contrast of image components is transmitted as a function of their spatial frequency content.
Noise	Fluctuations in pixel values which are unrelated to the imaged object. The standard deviation in a ROI in the output image is taken as measure of noise.
Noise power spectrum (NPS)	Function which describes image noise as a function of spatial frequency.
P-value	See presentation value.
Pixel	Picture element, the smallest unit in the image.
Pixel pitch	Physical distance between the centres of adjacent pixels. In the DICOM tags pixel pitch is called imager pixel spacing and is generally equal to detector element spacing.
Pixel value	Discrete value assigned to a pixel, in mammography systems the number of pixel values range from 1024 (10-bits) to 16384 (14 bits), depending on the detector.
Pixel value offset	Constant value that is added to the values of all pixels.
Presentation value	Pixel value after Value Of Interest Look-Up-Table (VOI LUT) or window width and window level settings have been applied.
Primary class display device	A display device used for the interpretation of medical images (also referred to in the text as ‘diagnostic display device’).
Processed image	The image after image processing, ready for presentation on the monitor or print-out. In the DICOM file the value of tag Pixel Intensity Relationship (0028,1040) is ‘for presentation’.
Raw image	See unprocessed image.
Reference region-of-interest (ROI)	The region-of-interest (≈ 4 cm^2, either circular or square) in which mean pixel values and standard deviation are measured. The centre of the region-of-interest is positioned 60 mm perpendicular to the chest wall edge of the table and centred laterally.
Secondary class display device	A display device used for viewing the images, but not for diagnosis.

(Nominal) sensitivity setting

Indication of the sensitivity setting of the system, comparable to the speed class in screen-film systems. The practical method to implement a (nominal) sensitivity setting will be discussed with manufacturers.

Screen processing

Image processing applied in a CR system during read-out of the imaging plate.

Signal to Noise Ratio (SNR)

The SNR is calculated as follows for a specific ROI:

$$SNR = \frac{\text{mean pixel value - pixel value offset}}{\text{standard deviation in pixel value}}$$

Standard test block

PMMA test object to represent approximately the average breast (although not an exact tissue-substitute) so that the X-ray machine operates correctly under automatic exposure control and the dose meter readings may be converted into dose to glandular tissue. The thickness is 45 ± 0.5 mm. The standard test block covers the whole detector.

Threshold contrast

The smallest detectable contrast for a given detail size that can be shown by the imaging system with different intensity (density) over the whole dynamic range. The threshold contrast is a measure for imaging of low-contrast structures.

Uncorrected image

The image in a DR system before any image processing, including detector corrections and flat-fielding, is performed.

Unprocessed image

The image of a DR system after flat-fielding and detector corrections but before other image processing has been applied. In the unprocessed image the pixel value is in general linear to pixel exposure. In the DICOM file the value of tag Pixel Intensity Relationship (0028,1040) is 'for processing'. International Electrotechnical Commission (IEC) Maintenance Team (MT) 31 refers to the unprocessed image as 'raw data'.

Variation

$$\text{Variation} = \frac{\text{maximum value - minmum value}}{\text{mean value}} \times 100\%$$

VOI LUT

Value of interest lookup table, defines the (non-linear) transformation of pixel values into values meaningful for presentation (presentation values).

Window centre

Setting defining (together with window width) a linear relationship between modality pixel values and pixel values meaningful for presentation (presentation values).

Window width

Setting defining (together with window centre) a linear relationship between modality pixel values and pixel values meaningful for presentation (presentation values).

2b.2 Image acquisition

2b.2.1 X-ray generation

2b.2.1.1 X-ray source

The measurements to determine the focal spot size, source-to-image distance, alignment of X-ray field and image receptor, radiation leakage and tube output are described in this section.

> To prevent ghosting artefacts, it is advised to cover the detector with a lead sheet during all tests for which no image is required and use the non-imaging mode (if available) on the X-ray unit.

2b.2.1.1.1 Focal spot size

Use the methods and limiting values described in section 2a.2.1.1.1 of the screen-film part of the European guidelines. Either film or the digital detector may be used, but beware of detector saturation.

2b.2.1.1.2 Source-to-image distance

Use the method and limiting values described in section 2a.2.1.1.2 of the screen-film part of the European guidelines. The distance on the digital images may be obtained by multiplying distance in number of pixels with the pixel pitch.

2b.2.1.1.3 Alignment of X-ray field/image area

For CR systems use the method and limiting values described in section 2a.2.1.1.3 of the screen-film part of the European guidelines. (Currently the most convenient method for DR systems is with screen-film cassettes or CR cassettes. In future these facilities might not be available. If cassettes and film processor are unavailable at the test site, use cassettes that can be read-out or processed elsewhere or use self developing such as Polaroid Type 57 or Gafchromic XR Type T film[12]).

2b.2.1.1.4 Radiation leakage

For CR systems use the method and limiting values described in section 2a.2.1.1.4 of the screen-film part of the European guidelines. (Currently the most convenient method for DR systems is with screen-film or CR cassettes. In future this might be a problem. If cassettes and film processor are unavailable at the test site, use cassettes that can be read-out or processed elsewhere or use self developing such as Polaroid Type 57 or Gafchromic XR Type T film[12]).

2b.2.1.1.5 Tube output

Use the measurement method described in section 2a.2.1.1.5 of the screen-film part of the European guidelines. Tube output measurements should be performed at all clinically used target-filter combinations for dose calculations (if necessary). Measurements should be performed with compression paddle in place. To calculate the transmission factor of the compression paddle, which may be needed for glandular dose estimates, tube output measurements should also be performed without compression paddle. The transmission factor should be calculated as the measured air kerma in presence of the compression paddle, divided by the measured air kerma in absence of the compression paddle.

2b.2.1.2 Tube voltage and beam quality

The beam quality of the emitted X-ray beam is determined by tube voltage, anode material and filtration. Tube voltage and beam quality can be assessed by the measurements described below.

2b.2.1.2.1 Tube voltage

Both the accuracy and reproducibility of the tube voltage are measured. Use the method and limiting values described in section 2a.2.1.2.1 of the screen-film part of the European guidelines.

2b.2.1.2.2 Half Value Layer (HVL)

Use the method described in section 2a.2.1.2.2 of the screen-film part of the European guidelines.

2b.2.1.3 AEC-system

It is generally recommended that systems used for mammography screening incorporate an AEC. The performance of the AEC system should be tested in terms of reproducibility and accuracy under varying conditions (object thickness and beam quality). The AEC system should adjust target, filter and tube voltage such that image quality is sufficient and dose is within an acceptable range. Semi-automated systems that start from a user defined target, filter and tube voltage but adapt dose according to breast transparency, are also acceptable.
The use of a look-up-table (LUT) for the determination of target, filter, tube voltage and dose based on compressed breast thickness can only be allowed if this LUT is programmed into the X-ray unit. However, it must be realized that these systems do not take breast composition into account and therefore cannot be fully optimized with respect to image quality and dose. For this kind of system some guidance for QC measurements is given in appendix 8.
For dose measurements it is essential that the dosimeter is positioned outside the region in which the exposure settings are determined. Alternatively, dose can be calculated using tube loading (mAs) and tube output.

> Manufacturers of equipment, which do not incorporate an AEC, are urged to implement an AEC in their mammography X-ray units before January 2006.
> The authors advise against the use of mammography X-ray units on which the exposure settings have to be set completely manually.

2b.2.1.3.1 Exposure control steps: central value and difference per step (if applicable)

This test item only applies to mammography units with exposure control steps. Image the standard test block at the different exposure control steps (or a relevant subset). Record entrance dose (or tube loading). Calculate exposure steps in entrance dose (or tube loading).

Remark: If it is noticed that the system switches between two spectra, release the compression paddle and compress again or use another PMMA thickness (add for example 0.5 cm PMMA) to force the choice of one single spectrum and repeat the measurement.

The central setting is the standard setting. In this setting image quality must be sufficient, this is determined by contrast threshold visibility measurements, see section 2b.2.4.1.

Typical value	5 - 15% increase in exposure per step[13].
Frequency	Every six months.
Equipment	Standard test block, dose meter.

2b.2.1.3.2 Back-up timer and security cut-off

Use the method and limiting values described in section 2a.2.1.3.2 of the screen-film part of the European guidelines. Make sure that the detector is completely covered, or tape some lead plates to the tube window.

Warning: An incorrect functioning of the back-up timer could damage the tube. To avoid excessive tube load, consult the manual for maximum permitted exposure time.

2b.2.1.3.3 Short term reproducibility

Use the method and limiting values described in section 2a.2.1.3.3 of the screen-film section of the European guidelines.

Remark: If it is noticed that the system switches between two spectra, release the compression paddle and compress again or use another PMMA thickness (add for example 0.5 cm PMMA) to force the choice of one single spectrum and repeat the measurement.

2b.2.1.3.4 Long term reproducibility

Use the weekly homogeneity check (see section 2b.2.2.3.1) for long term reproducibility.

Limiting value	The variation of SNR in the reference ROI and dose < ± 10%.
Frequency	Weekly.
Equipment	Standard test block.

2b.2.1.3.5 Object thickness and tube voltage compensation

Compensation for object thickness should be measured by exposures of PMMA plates in the thickness range from 20 to 70 mm (steps of 10 mm), using the clinical AEC settings (tube voltage, target, filter and mode). The compression paddle must be in contact with the PMMA plates.

Image PMMA plates of 20 mm thickness, with an aluminium object of 0.2 mm thickness on top, if necessary in manual mode and with settings as close as possible to the clinical AEC settings (if manual mode is used, substract the pre-exposure from the settings). Position the aluminium object as shown in figure 2.1. Measure the mean pixel value and standard deviation in a ROI (4 cm^2) with (position 2) and without (position 1) aluminium object. Calculate CNR. Repeat this measurement for 30, 40, 45, 50, 60 and 70 mm PMMA thickness.

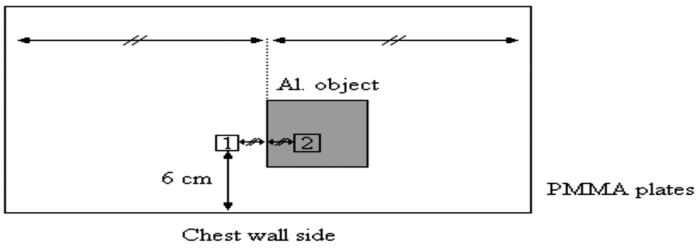


Fig. 2.1 Position of the aluminium filter for the CNR measurement

Image quality is evaluated for one thickness (at the equivalent of 5.0 cm PMMA) using contrast threshold measurements (section 2.4.1). At other PMMA thicknesses $CNR_{limiting\ value}$ is related to the $CNR_{limiting\ value}$ at 5.0 cm PMMA to ensure image quality at other thicknesses[14].

The following formula is used to calculate the limiting value of CNR at standard thickness:

$$\text{Threshold contrast}_{measured} * CNR_{measured} = \text{Threshold contrast}_{limiting\ value} * CNR_{limiting\ value}$$

The value of CNR at 5.0 cm thickness is related to the measured threshold contrast visibility in section 2b.2.4.1. Using the formula above the limiting value of CNR at standard thickness can be estimated using the measured threshold contrast in section 2b.2.4.1 and the (acceptable) limiting value of value of the 0.1 mm diameter disc. The calculated $CNR_{limiting\ value}$ should be used as the 100% level mentioned in the limiting values below.

Limiting value

CNR per PMMA thickness, see table for **provisional** limiting values; Compare CNR values with results at acceptance

PMMA Thickness	CNR[15] (relative to 5.0 cm PMMA)
[cm]	[%]
2.0	> 115
3.0	> 110
4.0	> 105
4.5	> 103
5.0	> 100
6.0	> 95
7.0	> 90

Frequency
Every six months.

Equipment
PMMA: a set of 10 mm thick PMMA plates covering the complete detector area, 0.2 mm thick Al object (for example: the filters which are used for the HVL measurement).

2b.2.1.4 Compression

Use the method and limiting values described in section 2a.2.1.4 of the screen-film part of the European guidelines.

2b.2.1.5 Anti scatter grid

The anti scatter grid is designed to absorb scattered photons. The tests in this section only apply to mammography units with (removable) grid. Some digital mammography systems do not incorporate anti scatter grids (e.g. scanning systems).

2b.2.1.5.1 Grid system factor

Image the standard test block in clinical setting with grid. Record entrance dose and measure the mean pixel value in the reference ROI. Expose two images without grid with mean pixel values respectively below and above the value of the image with grid. Interpolate the pixel values to obtain the entrance dose for which the pixel value is similar to the image with grid. Calculate the grid system factor by dividing the entrance dose with grid by the entrance dose without grid.

Limiting value
Manufacturers specification, typical value < 3.

Frequency
At acceptance.

Equipment
Standard test block, dose meter.

2b.2.1.5.2 Grid imaging

Use the method and limiting values described in section 2a.2.2.1.2 of the screen-film part of the European guidelines. The imaging of the grid is not possible for some grids due to minimum required exposure times.

2b.2.2 Image receptor

This section describes measurements applicable to both DR and CR systems i.e. the image receptor response and missed tissue at chest wall side. Other measurements apply to DR or CR systems only. For a DR system detector element failure is determined. The performance of the imaging plates of a CR system can be described by the CR plate sensitivity and the sensitivity to other sources of radiation.

2b.2.2.1 Image receptor response

The measurement of the response is performed to check compliance with manufacturers specifications, pixel value offset and the presence of additional noise sources beside quantum noise.

2b.2.2.1.1 Response function

The response function of the detector can be assessed by imaging a standard test block with different entrance doses (tube loading) at the clinically used beam quality. Use the manual mode for this measurement. Use at least 10 different tube loadings (mAs values). The range of mAs values should be chosen such that the linearity measurement includes a wide range of entrance surface air kerma (for example: 1/10 to 5 times[16] the entrance surface air kerma for a routine exposure).
For systems with a linear response, such as currently available DR systems, measure the mean pixel value and standard deviation in the reference ROI on the unprocessed image. Plot the mean pixel value against entrance surface air kerma. Determine linearity by plotting a best fit through all measured points and determine the zero crossing to check presence of a pixel value offset. Calculate the square of the correlation coefficient (R^2). Compare the results to previous measurements.

For systems with a non-linear response, such as currently available CR systems, plot mean pixel value against . log relative entrance surface air kerma. Refer to the information provided by the manufacturer whether pixel value should be linear or logarithmic versus entrance surface air kerma at the applied screen processing. Post processing should be turned off. The screen processing should be turned off as much as possible (see appendix 7). Determine linearity by plotting a best fit through all measured points. Calculate the square of the correlation coefficient (R^2). Compare the results to previous measurements.

Appendix 7 provides information about the relation between entrance surface air kerma and exposure indicator for some CR systems and screen processing modes.

Limiting value	R^2 > 0.99, results at acceptance are used as reference.
Frequency	Every six months. At acceptance: additional measurements at minimum and maximum tube voltage used in clinical practice at every target-filter combination.
Equipment	Standard test block, dose meter.

2b.2.2.1.2 Noise evaluation

Measure the mean pixel value and standard deviation in the reference ROI on the unprocessed images of the response function measurement (2b.2.2.1.1). For systems with a linear response, calculate the SNR and plot SNR^2 against entrance surface air kerma. Determine linearity by plotting a best fit through all measured points. Calculate the square of the correlation coefficient (R^2). Repeat this measurement for all available target-filter combinations used in clinical practice. Non-linearity is an indication for the presence of additional noise sources besides quantum noise. (At acceptance: additional measurements at minimum and maximum tube voltage used in clinical practice for each target-filter combination). Compare the results to previous measurements.
For systems with a logarithmic response plot standard deviation squared against 1/entrance surface air kerma. Determine linearity by plotting a best fit through all measured points. Calculate the square of the correlation coefficient (R^2). The offset is an indication for the presence of additional noise sources besides quantum noise. Compare the results to previous measurements.

For CR systems: No post processing should be applied, the screen processing should be turned off as much as possible (see appendix 7).

Limiting value	Results at acceptance are used as reference
Frequency	Every six months. At acceptance: additional measurements at minimum and maximum tube voltage used in clinical practice at every target-filter combination
Equipment	Standard test block, dose meter

2b.2.2.2 Missed tissue at chest wall side

Determine the width of tissue not imaged between the edge of the breast support table and the imaged area. This can be done by several methods. In some phantoms markers at a fixed distance from chest wall side are incorporated. The position of these markers on the image can be used to determine the missed tissue at chest wall side. For CR systems, this measurement should be repeated 5 times to check whether the insertion of the plate in the cassette is reproducible.

Limiting value	Width of missed tissue at chest wall side ≤ 5 mm.
Frequency	At acceptance.
Equipment	Phantom with markers positioned close to the bucky surface.

2b.2.2.3 Image receptor homogeneity and stability

2b.2.2.3.1 Image receptor homogeneity

The homogeneity of the image receptor can be obtained by exposing at clinical settings a standard test block covering the complete detector. Record the exposure settings and tube loading. Evaluate the unprocessed image by calculating the mean pixel value and standard deviation in a ROI (a square with an area of 1 cm^2). Move the ROI over the whole image. Determine the mean pixel value in the whole image and the mean SNR in all ROI's. Compare the mean pixel value and the SNR of each ROI to the overall mean pixel value and the mean SNR. Compare the SNR to previous homogeneity tests. Software for determining detector homogeneity is available on: www.euref.org.
To exclude failure due to inhomogeneities in the standard block, rotate the standard test block 180° and repeat the measurement.
Check the homogeneity visually. The window width should be set at 10% of the mean pixel value.

Perform this measurement at acceptance also at other PMMA thickness (for example with PMMA blocks of 20 and 70 mm thickness). For all measurements clinical settings should be used.

For CR systems: No post processing should be applied, the screen processing should be turned off as much as possible (see appendix 7).

It is acknowledged that the Heel effect and geometry effects influences the results of the homogeneity measurement. If a specific system does not comply with the provisional limiting values it is advised to check whether geometry or the Heel effect causes this deviation or some malfunction in the system. For CR systems an additional homogeneity image can be obtained by exposing a cassette using half dose under normal conditions and half dose with the cassette rotated 180° in the bucky to minimize the Heel effect and geometric effects.

Limiting value	**(provisional)** Maximum deviation in mean pixel value < ± 15% of mean pixel value in whole image, maximum deviation in SNR < ± 15% of mean SNR in all ROI's, maximum variation of the mean SNR between weekly images < ± 10%, entrance surface air kerma (or tube loading) between weekly images < ± 10%.
Frequency	Weekly and after maintenance, at acceptance also at 20 and 70 mm PMMA thickness.
Equipment	Standard test block covering the complete detector, at acceptance also PMMA blocks of 20 and 70 mm thickness covering the complete detector, software for determining detector homogeneity.

2b.2.2.3.2 Detector element failure (DR systems)

Inspect the most recent 'bad pixel map' of the manufacturer. This map (either an image or a table) defines the position of all pixels of which the pixel value is not based on its own del reading. This bad pixel map must be accessible by the user at any time and must be usable independent of the equipment of that manufacturer.
Evaluate the up to date information on bad columns and bad dels from the manufacturer and compare the position and number of defective dels to previous maps. Large clusters of defective dels and dels from which the reading is influenced by neighbouring defective dels may become visible in the image of a screen-film contact tool.

Limiting value	At this moment no limits have been established. In future versions of this protocol limits will be set and probably the number of defective dels/columns will (also) be limited by the percentage of a certain area, which is defective. At this moment it is advised to refer to the limits of the manufacturer.
Frequency	Every six months.
Equipment	Bad pixel map.

2b.2.2.3.3 Uncorrected defective detector elements (DR systems)

To determine the number and position of defective detector elements not corrected by the manufacturer, an image of the standard test block made at clinical settings should be evaluated by calculating the mean pixel value in ROIs (squares with an area of 1 cm^2). Move the ROI over the whole image. Determine the pixels deviating more than 20% from the mean pixel value in a ROI. To increase reliability deviating pixels can be determined on four images. Pixels, which deviate more than 20% on several images, are potentially bad pixels. If the deviating pixels are in one column, it is likely to be a bad column. Software for determining the number of uncorrected defective detector elements is available on: www.euref.org.

Limiting value	No limits have been set yet on the number of uncorrected defective detector elements.
Frequency	Weekly.
Equipment	Standard test block covering the complete detector, at acceptance also PMMA blocks of 20 and 70 mm thickness covering the complete detector.

2b.2.2.4 Inter plate sensitivity variations (CR systems)

Image the standard test block using the AEC exposure setting that is normally used clinically. Record the entrance surface air kerma (or tube loading). Process the plate. The screen processing should be turned off as much as possible (see appendix 7). No post processing should be applied. Measure the mean pixel value and standard deviation in the reference ROI. Calculate SNR. Repeat this measurement for all imaging plates. Evaluate the homogeneity of each image.

Limiting values	SNR variation in the reference ROI between all imaging plates < ± 15%, variation in entrance surface air kerma (or tube loading) < ± 10%, no major inhomogeneities on the images.
Frequency	Yearly and after introducing new imaging plates.
Equipment	Standard test block.

2b.2.2.5 Influence of other sources of radiation (CR systems)

Erase a single imaging plate. Tape two different coins, one on each side of the cassette. Store the imaging plate in the storage area during a maximal time period, for example during the complete acceptance test. Process the plate. The screen processing should be turned off as much as possible (see appendix 7). No post processing should be applied. Evaluate the visibility of the coins on the resulting image.

Limiting value	The coins should not be visible.
Frequency	At acceptance and when changes in storage of the cassettes have occurred.
Equipment	Two coins of different size (for example a one and a two Euro coin).

2b.2.2.6 Fading of latent image (CR systems)

Image the standard test block using one fixed exposure that is normally used clinically. Process the plate after 1 minute. Measure the mean pixel value in the reference ROI. Repeat the measurement with different time periods before read-out (2, 5, 10, 30 minutes).

Limiting value	Results at acceptance are used as reference.
Frequency	At acceptance and when image quality problems are suspected.
Equipment	Standard test block.

2b.2.3 Dosimetry

Use the method and limiting values described in paragraph 2.5.1 of the screen-film part of the European guidelines. The PMMA plates should cover the whole detector. For dose measurements it is essential that the dose probe is positioned outside the region in which the exposure settings are determined. Alternatively, dose can be calculated using tube loading (mAs) and tube output.

2b.2.4 Image Quality

2b.2.4.1 Threshold contrast visibility

Threshold contrast visibility is determined for circular details with diameters in the range from 0.1 to 2 mm. The details are imaged on a background object with a thickness equivalent (in terms of attenuation) to 50 mm of PMMA. The details must be positioned at a height of 20 to 25 mm above the breast support table[17]. Use the exposure factors that would be selected clinically. Make six images of the details and move the details slightly between the images to obtain

images with different relative position of the details and the detector elements. Three experienced observers should determine the minimal contrast visible on two images. Every observer must score two different images. The whole detail diameter range specified in the table below must be covered. In this range minimal contrast visible for a large number of detail diameter must be determined at acceptance and at least 5 detail diameters in subsequent tests. This evaluation should be done on unprocessed images. The window width and level and zoom facilities must be adjusted to maximise the visibility of the details on the displayed images.

> It is acknowledged that at present it is not possible to get unprocessed images from some systems. For these systems threshold contrast visibility evaluation should be done on processed images. The image processing may introduce artefacts on phantom images and may be different from image processing for mammograms due to histogram or local texture based processing techniques. Therefore care needs to be taken in interpretation of these processed images.

The threshold contrast performance specified here relates to the nominal contrast calculated for the details for a 28 kV tube voltage with molybdenum target and filter materials as explained in appendix 6. This nominal contrast depends on the thickness and materials used to manufacture the test object, and is independent of the actual spectrum used to form the image, which should be that used clinically. It does not include the effects of scatter. The average nominal threshold contrasts should be compared with the limiting values below.
For CR systems: No post processing should be applied, the screen processing should be turned off as much as possible (see appendix 7). If the screens comply with the limiting values of section 2b.2.2.4 inter plate sensitivity variations, it is not necessary to use the same screen in the threshold contrast visibility measurement.

Limiting value See table

	Threshold contrast			
	Acceptable value		Achievable value	
Diameter of detail [mm]	Radiation contrast using Mo/Mo 28 kV [%]	Equivalent gold thickness[18] [µm]	Radiation contrast using Mo/Mo 28 kV [%]	Equivalent gold thickness[11] [µm]
5*	< 0.85	0.056	< 0.45	0.032
2	< 1.05	0.069	< 0.55	0.038
1	< 1.40	0.091	< 0.85	0.056
0.5	< 2.35	0.150	< 1.60	0.103
0.25	< 5.45	0.352	< 3.80	0.244
0.1	< 23.0	1.68	< 15.8	1.10

* This diameter size is optional

Frequency Yearly.
Equipment Contrast detail phantom.

The threshold contrast standards defined in the table above are chosen to ensure that digital mammography systems perform at least as well as screen-film systems (Young, 2004). They have been derived from measurements on screen-film and digital mammography systems using the Nijmegen CDMAM contrast detail phantom version 3.4 (see section 2b.1.4). However it is intended that they are sufficiently flexible to allow testing by other designs and makes of test

objects. The values quoted form a smooth curve and may be interpolated for other detail diameters. It is expected that a new design of test object will be developed that will simplify the testing against these standards on a routine basis.
On the EUREF website (www.euref.org) CDMAM images and scores are available for reference purposes.

2b.2.4.2 Modulation Transfer Function (MTF) and Noise Power Spectrum (NPS) [optional]

Image an MTF test tool. Determine the MTF of the detector by using appropriate software tools. Image a NPS phantom, or the standard test block. Determine the NPS of the detector by using appropriate software. Use the resulting MTF and NPS of the acceptance test as reference. The measurement can be repeated when in doubt about the quality of the detector.

Limiting value	Results at acceptance are used as reference.
Frequency	At acceptance and when image quality problems are suspected.
Equipment	MTF test tool, software to calculate MTF, NPS phantom [standard test block], software to calculate NPS.

2b.2.4.3 Exposure time

Long exposure times can give rise to motion unsharpness. Exposure time is defined as the time during which primary X-rays reach each individual part of an imaged object. Exposure time may be measured by some designs of tube voltage and output meters. Otherwise a dedicated exposure timer has to be used. The time for a routine exposure in all clinical AEC modes is measured at standard PMMA thickness. For scanning slot systems, also measure the scanning time.

Remark: For most systems exposure time increases rapidly with breast thickness and content. Depending on the screen-film combination and the clinically used spectra this range may vary from 0.2 to 3 seconds. For some scanning slot systems however, scanning time and exposure time are fairly constant for the whole range of breast thickness and content. Due to this design, these systems may not comply with the limiting value of 2 seconds at standard thickness. Ideally exposure time should be below a certain limiting value even for very thick and dense breasts, so the limiting value at standard thickness may not be the right measure to prevent motion unsharpness for all breasts. Because this worst case liming value has not been determined yet, the value of 2 seconds at standard thickness is maintained, with the exception that scanning slot systems for which exposure time is only slightly dependent on breast thickness and content do not have to comply. For these systems clinical results will have to show that motion unsharpness is not a problem.

Limiting value	Exposure time: acceptable: < 2 s[19]; achievable: <1.5 s; scanning time: values at acceptance are used as reference, typical value: 5 - 8 s.
Frequency	Yearly.
Equipment	Exposure time meter, standard test block.

2b.2.4.4 Geometric distortion and artefact evaluation

Evaluate geometric distortion by measuring distances (with digital distance measuring tools) on an image of a phantom with straight lines (CDMAM, Toronto geometric distortion phantom etc.). Image a wire mesh (e.g. mammography screen-film contact test device) at the standard AEC setting. For CR systems: process the plate. The screen processing should be turned off as much as possible (see appendix 7). No post processing should be applied. Evaluate the grid pattern on the resulting image.

For the different digital systems, different types of artefacts can occur. Inspect all test images for artefacts.

Limiting value	No disturbing artefacts, no visible distortion.
Frequency	Every six months.
Equipment	Test object with horizontal, vertical and diagonal lines, wire mesh.

2b.2.4.5 Ghost image/erasure thoroughness

A ghost image is the residue of a previous image on the present image. In this measurement an induced ghost image is related to the contrast of 0.1 mm Al at clinical setting.

In manual mode an image of the standard test block is made using clinical settings. The block is positioned such that half of the detector is covered and half of the detector is not covered. For the second image (at clinical settings) the standard test block covers the whole detector and the aluminium object is placed exactly centred on top of the standard block (see figure 2.2). The time between both images should be approximately one minute.

Repeat the ghost image measurement a number of times during testing.

For CR systems: No post processing should be applied, the screen processing should be turned off as much as possible (see appendix 7).

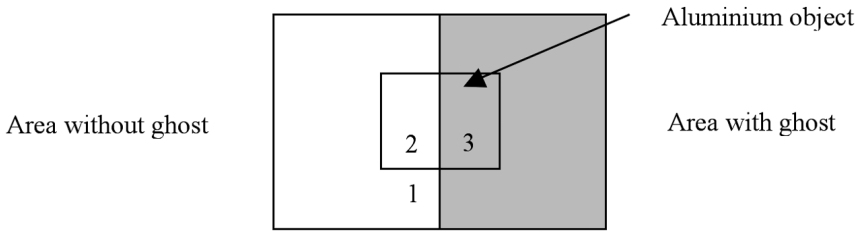


Fig. 2.2 Ghost image / erasure thoroughness measurement

Measure the mean pixel value (PV) in the ROI (area: 4 cm^2) on the locations shown in the figure above (on the second image) and calculate the 'ghost image'-factor.

$$\text{Ghost image factor} = \frac{\text{mean pixel value (region 3) - mean pixel value (region 2)}}{\text{mean pixel value (region 1) - mean pixel value (region 2)}}$$

If the system fails to meet the limiting value, check the homogeneity of the image. If the Heel effect is large regions 1 to 3 should be chosen on a line parallel to chest wall side.

> If the ghost image test is performed last, it is advised to make a number of images of a homogeneous block PMMA covering the whole detector afterwards to get rid of possible ghosts.

Limiting value	'Ghost image'-factor < 0.3 **(provisional)**.
Frequency	Yearly.
Equipment	Standard test block, aluminium object of 0.1 mm thickness (for example: the filters which are used for the HVL measurement).

2b.3 Image processing

Image processing will not be considered in this version of the protocol. Manufacturers have to specify in general terms which image processing is applied. It is advised that image processing is evaluated clinically by comparing the image quality of mammograms (for example: a set of 50 mammograms) to mammograms of previous screening rounds by experienced readers. Special attention should be given to the visualization of microcalcifications and subtle structures.

2b.4 Image presentation

The tests in this section are based upon the work of AAPM TG18 (American Association of Physicists in Medicine, Task Group 18). The TG18 test patterns described in this section should be obtained independently from the manufacturer, and can be downloaded from the TG18 website (2k versions should be used when available): http://deckard.mc.duke.edu/~samei/tg18. Some mammography display systems need adjusted versions of the test patterns, these will be available from the EUREF website.

Some general remarks:
- The test patterns have to be displayed at full resolution (exactly one display pixel for each pixel in the digital image) or printed at full size, contrast and brightness of the images may not be adjusted.
- For the tests in this chapter, the use of the display (primary class (diagnostic) or secondary class display device) often determines the limiting values.
- Some of the tests in this chapter are for Cathode Ray Tube (CRT) displays or Liquid Crystal Displays (LCDs) only.
- A magnifying glass may be used in the evaluation of printed images.
- The monitors should be tested as used clinically (e.g. third monitor on, viewing boxes on covered with films).

2b.4.1 Monitors

2b.4.1.1 Ambient light

Most of the quality tests in this chapter are highly sensitive to ambient light, therefore all of them should be performed under clinical conditions (room lights, light boxes and other display devices should be at the same luminance level as under clinical conditions). The ambient light should be measured at the centre of the display with the light detector facing outwards and the display switched off.

Limiting value	Ambient light should be less than 10 lux for primary display devices. [The maximum ambient light actually depends on the reflection characteristics and minimum luminance of the monitor, but for reasons of simplicity this is ignored here.]
Frequency	Every six months. (Every time the system is used, it has to be made sure that ambient light conditions have not changed.)
Equipment	Illuminance meter.

2b.4.1.2 Geometrical distortion (CRT displays)

Visually check whether the TG18-QC image (fig. 4.1) is displayed without geometrical distortion. To do so, inspect the lines and borders of the test pattern.

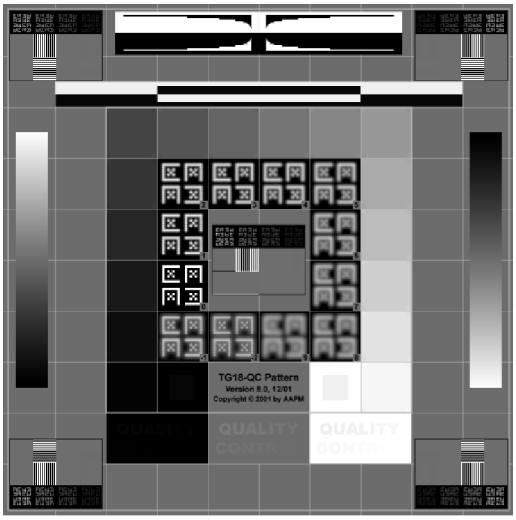


Fig. 4.1 TG18-QC test pattern

Limiting value	Borders should be completely visible, lines should be straight, the active display area should be centred on the screen.
Frequency	Daily.
Equipment	TG18-QC test pattern.

2b.4.1.3 Contrast visibility

The TG18-QC test pattern contains several items for evaluating the contrast visibility of a display. Each of the sixteen luminance patches located approximately equidistant from the centre of the image, contains four corner squares at equal low contrast steps to the patch (fig 4.2). The two patches in the bottom with minimum and maximum pixel value, surrounding the test pattern name, contain a centre square with a pixel value of 5% and 95% of the maximal grey level respectively. The letters 'QUALITY CONTROL' in the three rectangles below these patches are displayed with decreasing contrast to the background. The visible part of the letters should be written down and checked with the visibility at acceptance, in order to keep track of contrast degradation. If contrast visibility is not sufficient, it may help to dim the room lights. If this is done however, the lights should also be dimmed while using the displaying system clinically. The appearance of the TG18-QC test pattern also depends on the mapping of pixel values to luminance. Therefore if this test has failed, the tests in sections 2b.4.1.6 and 2b.4.1.7 should be performed.

Remark: It should be kept in mind that the luminance of LCD monitors depends on the viewing angle. When large viewing angles are used, contrast visibility may not comply with the limiting values.

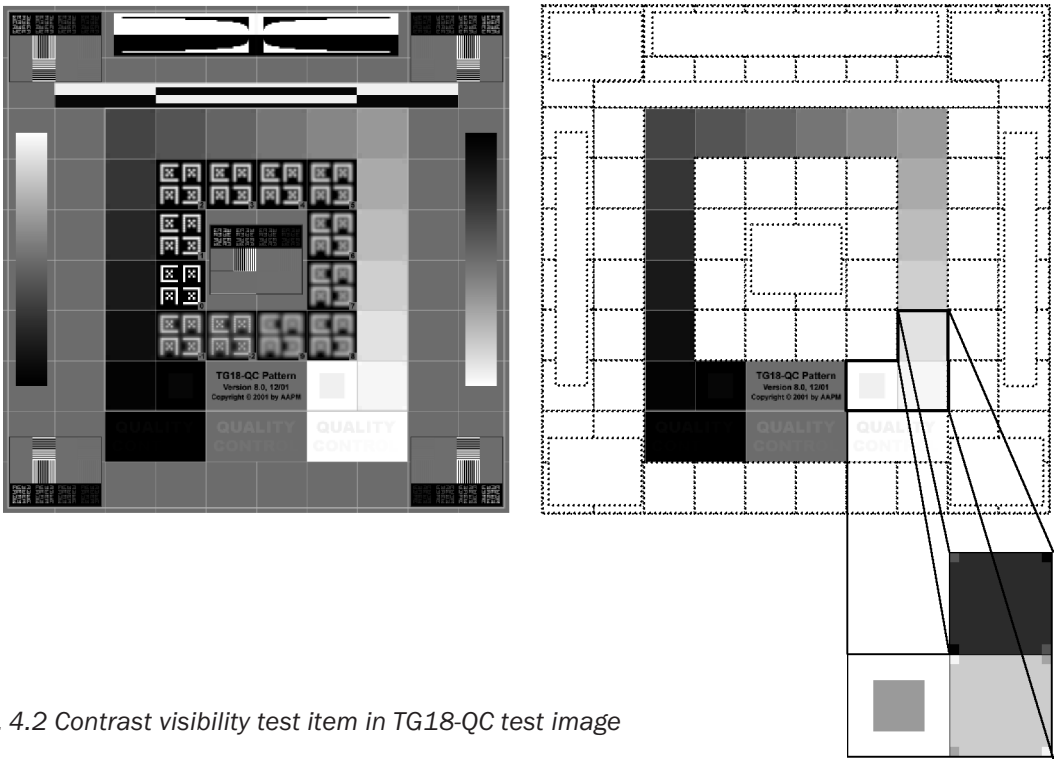


Fig. 4.2 Contrast visibility test item in TG18-QC test image

Limiting value	All corner patches should be visible, the 5% and 95% pixel value squares should be clearly visible.
Frequency	Daily.
Equipment	TG18-QC test pattern.

2b.4.1.4 Resolution

Evaluate horizontal and vertical line patterns to check display resolution visually.
AAPM Task Group 18 provides 6 line patterns at different background luminance levels. (Horizontal line patterns TG18-LPH10, -LPH50 and -LPH89; Vertical line patterns TG18-LPV10, -LPV50 and -LPV89.)

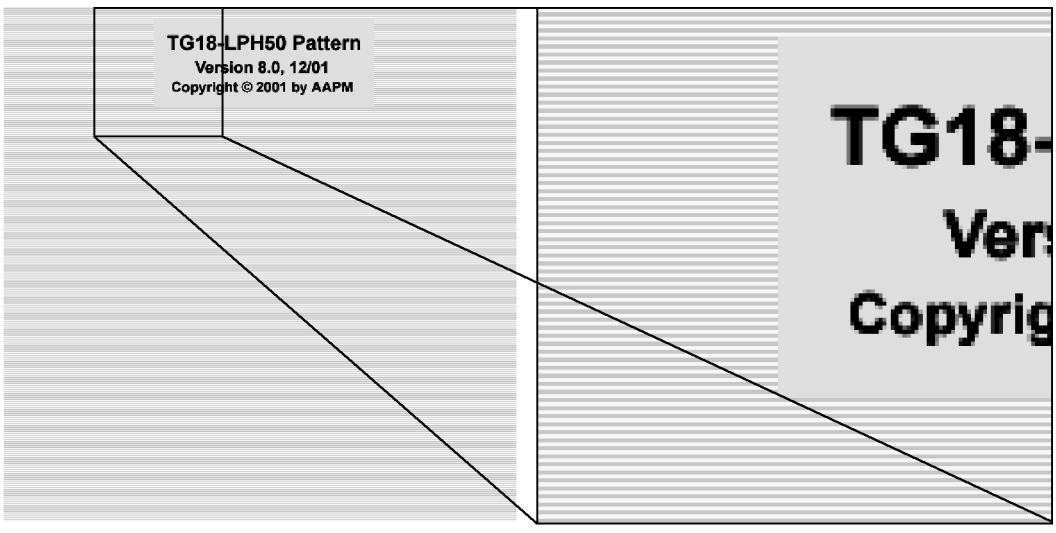


Fig. 4.3 Zoomed versions of the TG18-LPH50 pattern

Limiting value	All line patterns should be discernible.
Frequency	Every 6 months.
Equipment	2kx2k TG18-LPH10, TG18-LPH50, TG18-LPH89, TG18-LPV10, TG18-LPV50 and TG18-LPV89 test patterns.

2b.4.1.5 Display artefacts

The TG18-QC test pattern also contains some elements, which can be used for recognising display artefacts. The image should be carefully checked for defect pixels (LCD only), steps in the black-to-white and white-to-black ramp bars (this can reveal an insufficient bit depth), and artefacts near the black-to-white and white-to-black transitions (video card). Also pay attention to temporal instability (flicker) and spatial instability (jitter).

Limiting Values	No disturbing artefacts should be visible.
Frequency	Daily.
Equipment	2kx2k TG18-QC test pattern.

2b.4.1.6 Luminance range

Measure the maximum and minimum luminance of the display device. Test patterns TG18-LN12-01 and TG18-LN12-18 can be used.
The ratio of maximum and minimum display luminance, in the presence of ambient light, is an indicator of luminance contrast response capabilities of the monitor (under the current environmental conditions). Both luminances should be measured using a telescopic luminance meter, to include the influence of ambient light.
The ratio can be increased by reducing ambient light or by display adjustments. DICOM GSDF conformance (section 2b.4.1.7) makes sure the available contrast is spread out in an appropriate and standard manner over the full greyscale range of the monitor.

Remark: It should be kept in mind that the luminance of LCD monitors depends on the viewing angle. When large viewing angles are used, the luminance range may not comply with the limiting values.

Limiting Values	The maximum to minimum luminance ratio should be at least 250 for primary display devices, or 100 for secondary display devices. The difference of maximum luminances between displays belonging to one displaying station should not exceed 5% of the lowest.
Frequency	Every six months or when contrast visibility has changed.
Equipment	Telescopic luminance meter, TG18-LN12-01 and TG18-LN12-18 test patterns.

2b.4.1.7 Greyscale Display Function

To make sure a mammogram will appear similarly on different viewing stations and on printed film, the mapping of greyscale values to display luminance or optical density should be consistent. In this measurement it is determined whether a display conforms to the DICOM Greyscale Standard Display Function (GSDF).

The greyscale display function (GDF) can be determined by measuring the luminance of the 18 AAPM luminance test patterns (TG18-LN12-01 through TG18-LN12-18). The test patterns should be displayed full screen and the luminance has to be measured at the centre of the screen. The shape of the GDF depends on the ambient light in the room. Therefore room lights, light boxes and other display devices should be at the same luminance level as when the system is used clinically. A telescopic luminance meter should be used to include the influence of ambient light.

The measured values can be inserted into a spreadsheet (available on the EUREF website: www.euref.org) to automatically determine GSDF conformance.

After doing this measurement, the amount of ambient light may not be increased anymore, otherwise the contrast response has to be measured again!

Remark: This test only applies to primary and secondary display systems. The acquisition workstation monitor is excluded from this test. Due to the required ambient light levels in the mammography room the acquisition workstation monitor will not comply with the limiting values of primary and secondary displays. Therefore this monitor should only be used to check positioning techniques, not for diagnosis and image quality checks.

It is acknowledged that some displaying systems do not comply with the DICOM Greyscale Standard Function. Manufacturers are urged to comply with this standard.

Remark: It should be kept in mind that the luminance of LCD monitors depends on the viewing angle. When large viewing angles are used, the display on a monitor may not comply with the GSDF.

Limiting value	The calculated contrast response should fall within ± 10% of the GSDF contrast response for primary class displays (± 20% for secondary class displays).
Frequency	Every six months and when contrast visibility has changed.
Equipment	Telescopic luminance meter, TG18-LN12-01 through TG18-LN12-18 test patterns.

2b.4.1.8 Luminance uniformity

When the display has been tested for DICOM conformance at the centre of the monitor, this does not mean contrast visibility is optimal at every position on the monitor. One could test the GDF for several locations on the monitor, but it is more convenient to check display uniformity. Measure the display luminance at five locations for each monitor. The test patterns TG18-UNL10 and TG18-UNL80 can be used (fig. 4.4).

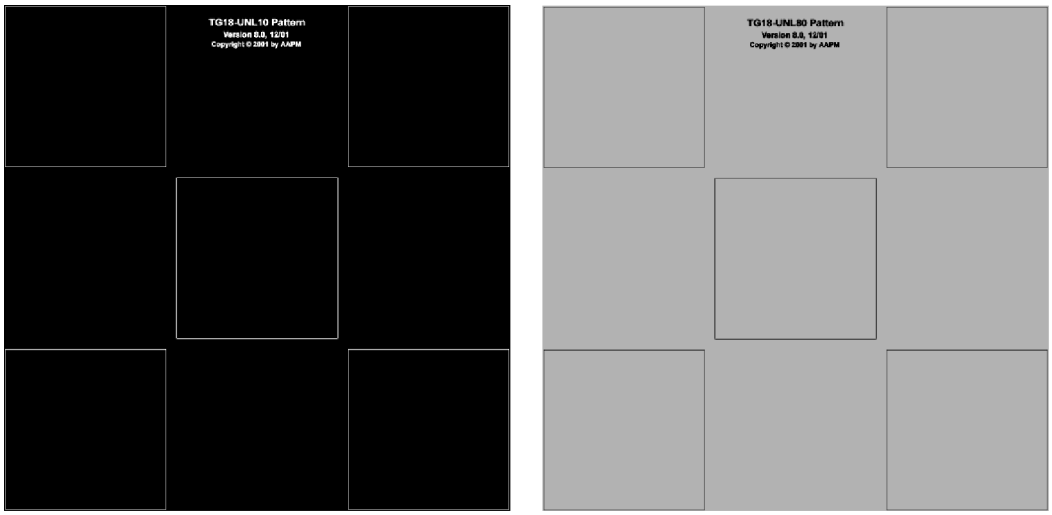


Fig. 4.4 TG18-UNL10 an TG18-UNL80 test pattern

Limiting value	Maximum luminance deviation of a display device should be less than 30% for CRT displays and LCD displays ((Lmax-Lmin)/ Lcentre < 0.3).
Frequency	Every six months and when contrast visibility has changed.
Equipment	Luminance meter (telescopic luminance meters should be equipped with a cone or baffle for this measurement), TG18-UNL10 and TG18-UNL80 test patterns.

2b.4.2 Printers

2b.4.2.1 Geometrical distortion

Print the TG18-QC test pattern (fig. 4.1) and check visually if the image is printed without geometrical distortion. Only the lines and borders of the test pattern are used to do this.

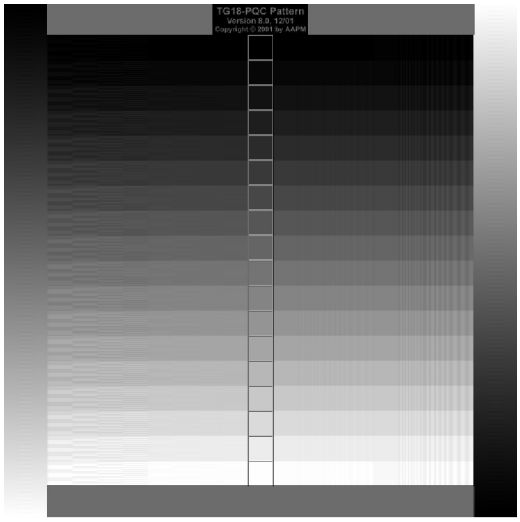
Limiting value	Borders should be completely visible, lines should be straight.
Frequency	Daily.
Equipment	TG18-QC test pattern.

2b.4.2.2 Contrast visibility

Print the TG18-QC test pattern (see fig. 4.1). Check the visibility of the several items for evaluating the contrast visibility (see fig. 4.2). Be sure that the viewing box, on which the test pattern is checked, has sufficient luminance.
If contrast visibility is not sufficient, it may help to use diaphragms (if clinically used) or dim the room lights. If this is done however, the lights should also be dimmed while using the displaying system clinically. The appearance of the TG18-QC test pattern also depends on the mapping of pixel values to densities. Therefore if this test has failed, the tests in sections 2b.4.2.5 and 2b.4.2.6 should be performed.

Limiting value	All corner patches should be visible, the 5% and 95% pixel value squares should be clearly visible.
Frequency	Daily.
Equipment	TG18-QC test pattern.

2b.4.2.3 Resolution



Evaluate horizontal and vertical line patterns to check the resolution of a print-out.
The fine detail horizontal and vertical line patterns in the TG18-PQC test pattern (fig 4.5) can be used.

Limiting value	All line patterns should be discernible[20].
Frequency	At acceptance and when decreased resolution is suspected.
Equipment	TG18-PQC test pattern.

Fig. 4.5 TG18-PQC test pattern

2b.4.2.4 Printer artefacts

Print the TG18-QC, -PQC, -UN80 and -UN10 test patterns. Check the image for printer artefacts, for example banding and streaking artefacts, pick-off artefacts, etc.

Limiting Values	No disturbing artefacts should be visible.
Frequency	Daily.
Equipment	TG18-QC, TG18-PQC, TG18-UN10 and TG18-UN80 test patterns.

2b.4.2.5 Optical Density Range (optional)

Print the TG18-QC test pattern. Measure D_{min} and D_{max} on this image.

Limiting value	$D_{min} < 0.25$ OD, $D_{max} > 3.40$ OD[21] (provisional).
Frequency	Every six months.
Equipment	Densitometer, TG18-QC test pattern.

2b.4.2.6 Greyscale Display Function

To make sure a mammogram will appear similarly on different viewing stations and on printed film, the mapping of greyscale values to display luminance or optical density should be consistent. In this measurement it is determined whether a printer conforms to the DICOM Greyscale Standard Display Function (GSDF).

The greyscale display function (GDF) can be determined by printing the TG18-PQC test pattern and measuring the optical density of marked regions of the 18 bars. The GDF is determined by the luminance corresponding with the optical density. The relationship between the luminance (L) and the optical density (D) of the printed bars is:

$L = L_a + L_0 * 10^{-D}$
where: L_a is the luminance contribution due to ambient illuminance reflected off the film, and
L_0 is the luminance of the light box with no film present

Printed mammograms may be viewed on different viewing boxes and under a variety of viewing conditions. It is not desirable to repeat this measurement for each viewing box. Assuming each viewing box, on which printed mammograms will be diagnosed, complies with the limiting values, a standard viewing box is defined. For this standard viewing box L_a is 1 cd/m^2 and L_0 is 4000 cd/m^2.

The measured values can be inserted into an spreadsheet (available on the EUREF website: www.euref.org) to automatically determine GSDF conformance.

Limiting value	The calculated contrast response should fall within ± 10% of the GSDF contrast response.
Frequency	Every six months and when contrast visibility has changed.
Equipment	Densitometer, TG18-PQC test pattern.

2b.4.2.7 Density uniformity

Print the test patterns TG18-UNL10 and TG18-UNL80. Measure the optical density at the five marked locations.

Limiting value	Maximum optical density deviation should be less than 10% ((Dmax-Dmin)/Dcentre < 0.1).
Frequency	Every six months and when contrast visibility has changed.
Equipment	Densitometer, TG18-UNL10 and TG18-UNL80 test patterns.

2b.4.3 Viewing boxes

If mammograms are read on printed images, check the viewing boxes using the method and limiting values described in the European guidelines for quality assurance in mammography screening, third edition (page 87).

2b.5 CAD software

May be considered in future versions of this protocol.

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Table 2b.1: Frequencies of Quality Control

This protocol is work-in-progress and subject to improvements as more experience in digital mammography is obtained and new types of digital mammography equipment are developed. Therefore the frequencies of quality control may change in future. Updates will be made available on the EUREF website (www.euref.org). It is recommended that users check the website for updates before testing digital mammography equipment.

Table 2b.1.1 Frequencies of Quality Control

2b.2	**Image acquisition**					
test-item		**acceptance and on indication**	**yearly**	**six monthly**	**weekly**	**daily**
2b.2.1	X-ray generation					
2b.1.1	X-ray source					
2b.1.1.1	Focal spot size	X				
2b.1.1.2	Source-to–image distance	X		if adjustable		
2b.2.1.1.3	Alignment of X-ray field/image area	X	X			
2b.2.1.1.4	Radiation leakage	X				
2b.2.1.1.5	Radiation output	X		X		
2b.2.1.2	Tube voltage and beam quality					
2b.2.1.2.1	Tube voltage	X		X		
2b.2.1.2.2	Half Value Layer	X				
2b.2.1.3	AEC-system					
2b.2.1.3.1	Exposure control steps	X		X		
2b.2.1.3.2	Back-up timer and security cut-off	X	X			
2b.2.1.3.3	Short term reproducibility	X		X		
2b.2.1.3.4	Long term reproducibility	X			X	
2b.2.1.3.5	Object thickness and tube voltage compensation	X		X		

O: optional test, X: required test

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Table 2b.1.1 continued

test-item		acceptance and on indication	yearly	six monthly	weekly	daily
2b.2.1.4	Compression	X	X			
2b.2.1.5	Anti scatter grid					
2b.2.1.5.1	Grid system factor (if present)	X				
2b.2.1.5.2	Grid imaging	O	O			
2b.2.2	Image receptor					
2b.2.2.1	Image receptor response					
2b.2.2.1.1	Response function	X		X		
2b.2.2.1.2	Noise evaluation	X		X		
2b.2.2.2	Missed tissue at chest wall side	X				
2b.2.2.3	Detector homogeneity and stability					
2b.2.2.3.1	Detector homogeneity	X			X	
2b.2.2.3.2	Detector element failure (DR)	X		X		
2b.2.2.3.3	Uncorrected defective DELs (DR)	X			X	
2b.2.2.4	Inter plate sensitivity variations (CR)	X	X			
2b.2.2.5	Influence of other sources of radiation (CR)	X				
2b.2.2.6	Fading of latent image (CR)	X				
2b.2.3	Dosimetry	X		X		
2b.2.4	Image quality					
2b.2.4.1	Threshold contrast visibility	X	X			
2b.2.4.2	MTF and NPS	O				
2b.2.4.3	Exposure time	X	X			

O: optional test, X: required test

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Table 2b.1.1 continued

test-item		acceptance and on indication	yearly	six monthly	weekly	daily
2b.2.4.4	Geometric distortion and artefact evaluation	X		X		
2b.2.4.5	Ghost image / erasure thoroughness	X	X			
2b.4	**Image presentation**					
2b.4.1	Monitors					
2b.4.1.1	Ambient light	X		X		
2b.4.1.2	Geometrical distortion (CRT)	X				X
2b.4.1.3	Contrast visibility	X				X
2b.4.1.4	Resolution	X		X		
2b.4.1.5	Displaying artefacts	X				X
2b.4.1.6	Luminance range	X		X		
2b.4.1.7	DICOM Greyscale Standard Display Function	X		X		
2b.4.1.8	Luminance uniformity	X		X		
2b.4.2	Printers					
2b.4.2.1	Geometrical distortion	X				X
2b.4.2.2	Contrast visibility	X				X
2b.4.2.3	Resolution	X				
2b.4.2.4	Printer artefacts	X				X
2b.4.2.5	Optical Density range	O		O		
2b.4.2.6	DICOM GSDF	X		X		
2b.4.2.7	Density uniformity	X		X		
2b.4.3	Viewing boxes	X	X			

O: optional test, X: required test

Table 2b.2 Limiting values

Table 2b.2.1 Limiting values

2b.2. Image acquisition	typical value	limiting value acceptable	limiting value achievable	unit
2b.2.1 X-ray generation				
X-ray source				
See European Guidelines, part A, table 4.1.				
tube voltage				
See European Guidelines, part A, table 4.1.				
AEC				
- exposure contol steps	5 - 15%			mGy or mAs
- back-up timer and security cut-off	-	function properly		
- short-term reproducibility	-	< ± 5%	< ± 2%	mGy
- long-term reproducibility				
variation in SNR	-	< ± 10%		mGy
variation in dose	-	< ± 10%		mGy
- object thickness and tube voltage compensation				
CNR per PMMA thickness				
2.0 cm	-	> 115%		
3.0 cm	-	> 110%		
4.0 cm	-	> 105%		
4.5 cm	-	> 103%		
5.0 cm	-	> 100%		
6.0 cm	-	> 95%		
7.0 cm	-	> 90%		
compression				
See European Guidelines, part A, table 4.1.				
anti scatter grid				
See European Guidelines, part A, table 4.1.				

2b.2.2 Image receptor	typical value	limiting value acceptable	limiting value achievable	unit
response function				
- linearity	-	$R^2 > 0.99$	-	-
- noise evaluation	-	-	-	-
missed tissue at chest wall side				
detector homogeneity	-	≤ 5	-	mm
- variation in mean pixel value (on image)	-	< ± 15%	-	-
- variation in SNR (on image)	-	< ± 15%	-	-
- variation in mean SNR (between images)	-	< ± 15%	-	-
- variation in dose (between images)	-	< ± 10%	-	mGy
detector element failure				
- number of defective dels	-	not yet established	not yet established	-
- position of defective dels	-	not yet established	not yet established	-

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Table 2b.2.1 continued

2b.2.2 Image receptor	typical value	limiting value acceptable	limiting value achievable	unit
uncorrected dels				
- number of uncorrected defective dels	-	not yet established	not yet established	-
- position of uncorrected defective dels	-	not yet established	not yet established	-
inter plate sensitivity variations				
- variation in SNR	-	< ± 15%	-	-
- variation in dose	-	< ± 10%	-	-
influence of other sources of radiation	-	coin not visible	-	-
fading of latent image	-	-	-	-

2b.2.3 Dosimetry	typical value	limiting value acceptable	limiting value achievable	unit
- glandular dose per PMMA thickness				
2.0 cm	-	< 1.0	< 0.6	mGy
3.0 cm	-	< 1.5	< 1.0	mGy
4.0 cm	-	< 2.0	< 1.6	mGy
4.5 cm	-	< 2.5	< 2.0	mGy
5.0 cm	-	< 3.0	< 2.4	mGy
6.0 cm	-	< 4.5	< 3.6	mGy
7.0 cm	-	< 6.5	< 5.1	mGy

2b.2.4 Image quality	typical value	limiting value acceptable	limiting value achievable	unit
threshold contrast visibility				
- detail				
5.0 mm (optional)	-	< 0.85%	< 0.45%	-
2.0 mm	-	< 1.05%	< 0.55%	-
1.0 mm	-	< 1.40%	< 0.85%	-
0.5 mm	-	< 2.35%	< 1.60%	-
0.25 mm	-	< 5.45%	< 3.80%	-
0.10 mm	-	< 23.0%	< 15.8%	-
MTF and NPS				
- MTF (optional)	-	-	-	-
- NPS (optional)	-	-	-	-
exposure time	-	< 2.0	< 1.5	s
scanning time	5 to 8			s
geometric distortion and artefact evaluation				
- geometric distortion	-	no distortions	-	-
- artefact evaluation	-	no disturbing artefacts	-	-
ghost image factor	-	0.3	-	-

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Table 2b.2.1 continued

2b.4 Image presentation	**typical value**	**limiting value** acceptable	achievable	**unit**
2b.4.1 monitors				
- ambient light	-	< 10	-	lux
- geometrical distortion	-	straight lines		
- contrast visibility	-	corner patches visible	-	
		squares visible	-	
- resolution	-	line pattern discernible	-	
- display artefacts	-	no disturbing artefacts	-	
- luminance range				
* ratio maximum/minimum luminance	-	250	-	
* difference in luminance left and right monitor	-	5%	-	Cd/m^2
- DICOM greyscale standard display function	-	± 10% of GSDF	-	
- luminance uniformity				
* deviation in luminance (CRT display)	-	30%	-	Cd/m^2
2b.4.2 printers				
- geometrical distortion	-	straight lines	-	
- contrast visibility	-	corner patches visible	-	
		squares visible		
- resolution	-	line pattern discernible	-	
- printer artefacts	-	no disturbing artefacts	-	
- optical density range (optional)	-	$D_{min} < 0.25$[1], $D_{max} > 3.4$[1]	-	OD
- DICOM greyscale standard display function	-	± 10% of GSDF	-	
- density uniformity				
* deviation in optical density	-	< 10%	-	OD
2b.4.3 viewing boxes				
See European Guidelines, part A, table 4.1.				

[1] Provisional limiting values

European protocol for the quality control of the physical and technical aspects of mammography screening

Appendices

Appendix 1: Mechanical and electrical safety checks

Introduction

Basic mechanical and electrical safety tests should be performed according to local regulations. If such regulations do not exist this appendix gives an example of such tests based on the UK protocol.

Mechanical Function and Safety checks

The following features of the equipment should be checked:

- All movements should operate smoothly and be free running. The force needed to move any part should be less than 30 N.
- All mechanical/electromechanical brakes should function properly.
- All scales/indications on linear/rotational movements and focus film distance (FFD) (if adjustable) should be clearly marked.
- All beam limiting diaphragms should be marked with their field sizes at the relevant FFD.
- Power driven vertical movement of the U-arm should be possible with the patient leaning against the breast support platform (without compression applied).
- Vertical and rotational movement of the U-arm should be prevented when compression is applied.
- All foot switches should operate correctly.
- All attachments should locate correctly and their locks should function properly.
- It should be possible to move the AEC detector properly into the pre-set positions.
- The bucky assembly should provide firm retention of the cassette (with the U-arm both vertical and horizontal) but allow easy insertion and removal.
- The interlock to prevent exposure when the cassette is not correctly positioned should operate correctly.
- The light intensity from the x-ray field light should be adequate.
- The movement of the compression device should be smooth.
- When compression is applied, it should not be possible to move the U-arm.
- The automatic release of the compression plate after an exposure should function correctly. The override of this automatic release should also function correctly.
- An emergency release of compression should be available and function properly.
- The compression paddle and breast support platform should be smooth and must not have any sharp edges or surfaces, etc. which may injure the patient.
- The edges of the radiation protection screen should be clearly defined so that the operator is aware of the outline.
- The restraining devices use (for X-ray unit, radiation protective screen, etc.) provided on mobile units should be effective in use.

Markings and labelling

The following should be clearly marked or indicated:

- The focal spot size and position.
- The amount of inherent, added and total filtration (usually in mm of aluminium) including that of alterable or removable filters.
- The position of AEC detectors.
- The function of all controls.

Radiation safety

The following checks relate to the safe operation of the x-ray unit:

- A mains isolator, accessible from the normal operating position should be provided.
- A visible indication must be provided on the control panel to show that the mains are switched on.
- The visible exposure warning indication must function correctly.
- The total filtration must be equivalent to at least 0.5 mm Al or 0.03 mm Mo.
- If the added filtration is removable or interchangeable, an interlock must be provided to prevent exposure if the filter is removed or incorrectly inserted.
- If the field-limiting diaphragm can be removed, an interlock should be provided to prevent exposure unless the diaphragm is properly aligned.
- The exposure must terminate if the exposure control is released prematurely.
- The location of the exposure control should confine the operator to the protected area during exposure.
- The exposure control should be designed to prevent inadvertent production of x-rays.
- The design of the exposure control should prevent further exposure unless pressure on the control is first released.

Integral radiation protection screen

A radiation protection screen should be provided to afford protection equivalent to at least 0.1 mm of lead at 50 kV and should allow good visibility of the patient by the operator and vice versa. The lead equivalence of the radiation protection screen should be marked (on both the glass and the panel where appropriate) at a specified voltage. If the lead equivalence is not marked and is not shown in the accompanying documentation, it will need to be measured.

X-ray room

- Room warning lights should be provided at all entrances to the x-ray room. These should indicate when x-rays are being or are about to be generated.
- A check on the room shielding, either visually, against the local requirements at the planning stage, or by transmission measurements, should be undertaken at or prior to installation.

Appendix 2: Film-parameters

The film curve can be characterised by a few parameters. Most important items are contrast, sensitivity and base and fog. There are different methods to calculate the film parameters. Existing normalisation's differ so much that the following method is suggested, derived from the Dutch protocol (1991), which is based on the ANSI (1983) norm.
Very high contrast can be a problem because of an associated reduction in dynamic range which may result in dense breast tissue being imaged in relatively low film densities where the film performance is relatively poor. To some extent this can be compensated for by setting relatively high average film densities, but even then a lower film contrast may better image local areas of dense tissue. Conversely a very low overall film contrast may indicate an inadequately processed film and subtle details may be missed by the radiologist.
Research has shown that film gradient measured by light sensitometry correlates well with film gradient measured by x-ray sensitometry using a fixed kV and target filter combination. One must bear in mind that film emulsions may respond slightly differently to the light from a sensitometer as opposed to the light from the screen used for imaging.

D_{min} — Base and fog; the optical density of a non exposed film after developing. The minimum optical density can be visualised by fixation only of an unexposed film. The extra fog is a result of developing the (unexposed) emulsion.

D_{max} — The maximum density achievable with an exposed film; i.e. the highest density step.

MGrad — Mean Gradient; the property which expresses the filmcontrast in the diagnostic range. MGrad is calculated as the slope of the line through the points $D_1=D_{min}+0.25$ OD and $D_2=D_{min}+2.00$ OD. Since the film curve is constructed from a limited number of points, D_1 and D_2 must be interpolated. Linear interpolation of the construction points of the film curve will result in sufficient accuracy.

$Grad_{1,2}$ — Middle Gradient; the property which expresses the filmcontrast in the diagnostic range. $Grad_{1,2}$ is calculated as the slope of the line through the points $D_1=D_{min}+1.00$ OD and $D_2=D_{min}+2.00$ OD. Since the film curve is constructed from a limited number of points, D_1 and D_2 must be interpolated. Linear interpolation of the construction points of the film curve will result in sufficient accuracy.

$Grad_{gland}$ — The glandular tissue gradient can be defined as an alternatively. This is the gradient at glandular densities 0.8 – 1.2 OD. This gradient is used in combination with the $Grad_{fat}$.

$Grad_{fat}$ — The alternative fat gradient is defined between densities of 2.0 and 2.4 OD. This gradient is used in combination with the $Grad_{fat}$.

Speed — Sensitivity; the property of the film emulsion directly related to the dose. The Speed is calculated as the x-axis cut-off at optical density $1.00+D_{min}$, also called 'Speedpoint'. The higher the figure for Speed, the more dose is needed to obtain the right optical density. Since the film curve is constructed from a limited number of points, the Speed must be interpolated. Linear interpolation will result in sufficient accuracy.
Since these parameters are derived from the characteristic curve by interpolation they are not very practical if a computer is not available. A simpler procedure is to use the parameters below which are based on density measurements of particular sensitometric steps.

Speed Index	The density of the step near to the speedpoint density 1.0 OD, base and fog excluded. Usually this is the density of step 11 of the sensitometric stepwedge.
Contrast Index 1	The difference in density found between the step nearest to the speedpoint density (1.0 OD, base and fog excluded) and the one with a 0.6 log E (factor 4) higher light exposure (normally 4 density steps) (ACR).
Contrast Index 2	The difference in density steps found between the step nearest to the speedpoint and the step nearest to a density at 2.0 OD, base and fog excluded (IPSM, see bibliography).

Appendix 3: A method to discriminate between processing and exposure variations by correction for the film-curve

The optical density of a film is the result of X-ray exposure and processing. The film is mainly exposed by light emitted by the intensifying screen. The light-emission of the screen is proportional with the incident X-ray exposure. Primary X-rays only contribute up to 5% of the total exposure. The developing process determines the optical density of the exposed area.
When an optical density in any given film is measured, the corresponding exposure is unknown. However, the film curve (measured with light-sensitometry) describes the relation between light-exposure and optical density. Any measured optical density can be converted into a relative log (light-exposure) or log (I') by interpolation of the film curve. This figure log (I') is a relative value and strongly depends on the sensitometer used. But still it is a useful value, closely related with the radiation dose applied and is therefore suitable to calculate the mass attenuation coefficient of an arbitrary X-ray step wedge.
Note that recently available films, using a different type of sensitizing and grains, in some cases show a discrepancy between the gradient as a result of light and by X-rays.

When the optical density of several images, taken under identical conditions, are measured, there will be a range of optical densities. This can either be the result of a change in exposure or a change in developing conditions. By calculating the relative figure log (I') we are able to distinguish between processor faults and tube malfunctions.

Approximation of X-ray contrast

To assess the X-ray contrast, correct the OD-readings of an Al-stepwedge for the processing conditions by converting the optical densities into a fictional 'exposure', log (I'), according the film curve. Now, a graph of the stepwedge number against 'exposure' will result in an almost straight line. The slope of this line is a measure for the X-ray contrast.

Appendix 4: Typical spectra per PMMA thickness in screen-film mammography

Changing X-ray spectrum influences both glandular dose and image quality. The choice of spectrum should be based on the optimization between both effects. In general the X-ray spectrum should be harder when (simulated) breast thickness is increased. In the table below some typical spectra, which are used in mammography, and which do not reduce contrast by more than 10% compared to an image made with Mo-Mo 28 kV are given. The results should be taken as typical values, not limiting values. When using the newly introduced high contrast films (like the Kodak EV film), the values in the table below may need adaptation.

A4.1: Typical spectra per PMMA thickness

	Spectrum			
PMMA thickness (cm)	Mo-Mo	Mo-Rh	Rh-Rh	W-Rh
2	25, 26 kV			
3	25-27 kV			
4	26-28 kV	26, 27 kV		
5	27-29 kV	26, 27 kV		
6	28-30 kV	27-30 kV	27-30 kV	
7	30, 31 kV	29-31 kV	29-31 kV	27-29 kV

Appendix 5: Procedure for determination of average glandular dose

A5.1 Dose to typical breasts simulated with PMMA

The doses to a range of typical breasts can be assessed using blocks of PMMA as breast substitutes. This method relies on the equivalence in attenuation between different thicknesses of PMMA and typical breasts [Dance et al, 2000] as listed in tables A5.1 and A5.2. It should be noted that since PMMA is generally denser than breast tissue any automatic selection of kV, target or filter may be slightly different from real breasts. This can be corrected by adding expanded polystyrene blocks to the PMMA as a spacer to make up a total thickness equal to the equivalent breast. On systems that determine the exposure factors primarily on attenuation such as the GE 2000D this should not be necessary. The average glandular dose (D) to a typical breast of thickness and composition equivalent to the thickness of PMMA tested is calculated by applying the following formula.

$$D = Kgcs \qquad (A5.1)$$

where K is the entrance surface air kerma (without backscatter) calculated at the upper surface of the PMMA. The factor g, corresponds to a glandularity of 50%, and is derived from the values calculated by Dance et al 2000 and is shown in table A5.1 for a range of HVL. The c-factor corrects for the difference in composition of typical breasts from 50% glandularity [Dance et al 2000] and is given here for typical breasts in the age range 50 to 64 in table A5.2. Note that the c and g-factors applied are those for the corresponding thickness of typical breast rather than the thickness of PMMA block used. Where necessary interpolation may be made for different values of HVL. Typical values of HVL for various spectra are given in table A5.3. The factor s shown in table A5.4 corrects for differences due to the choice of X-ray spectrum (Dance et al 2000).
The dose should be determined using the usual clinically selected exposure factors including any automatic selection of kV and target/filter combination.

A5.2 Clinical breast doses

It is also possible to measure the average glandular doses for a series of breast examinations on each mammography system. To do this, the breast thickness under compression is measured, and the tube voltage, and tube loading delivered are recorded.
From a knowledge of the output of the X-ray set for the kV and target and filter material used, this tube loading may be used to estimate average glandular dose using the following formula:

$$D = Kgcs \qquad (A5.2)$$

where K is the entrance surface air kerma calculated (in the absence of scatter) at the upper surface of the breast. The factor g, corresponds to a glandularity of 50%, and is shown in table A5.5 (Dance et al 2000). The factor c corrects for any difference in breast composition from 50% glandularity. C-factors for typical breast compositions in the age range 50 to 64 and 40 to 49 are shown in tables A5.6 and A5.7. The factor s corrects for differences due to the choice of X-ray spectrum as noted earlier. Measurement of compressed breast thickness for this purpose is performed by the radiographer, by reading the displayed compressed thickness on the X-ray set. The accuracy of the displayed thickness should be verified by applying a typical force (e.g. 100 N) to rigid material of known thickness. It may be necessary to apply correction factors if the displayed values are in error. An accuracy of better than ± 2 mm is required. Software for making such dose calculations has been published by the UK Breast Screening Programme (Young, 2001).

Table A5.1: g-factors for breasts simulated with PMMA

PMMA thickness (mm)	Equivalent breast thickness (mm)	g-factors (mGy/mGy) HVL (mm Al)							
		0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60
20	21	0.329	0.378	0.421	0.460	0.496	0.529	0.559	0.585
30	32	0.222	0.261	0.294	0.326	0.357	0.388	0.419	0.448
40	45	0.155	0.183	0.208	0.232	0.258	0.285	0.311	0.339
45	53	0.130	0.155	0.177	0.198	0.220	0.245	0.272	0.295
50	60	0.112	0.135	0.154	0.172	0.192	0.214	0.236	0.261
60	75	0.088	0.106	0.121	0.136	0.152	0.166	0.189	0.210
70	90		0.086	0.098	0.111	0.123	0.136	0.154	0.172
80	103		0.074	0.085	0.096	0.106	0.117	0.133	0.149

Table A5.2: c-factors for breasts simulated with PMMA

PMMA thickness (mm)	Equivalent breast thickness (mm)	Glandularity of equivalent breast	c-factors HVL (mm Al)						
			0.30	0.35	0.40	0.45	0.50	0.55	0.60
20	21	97	0.889	0.895	0.903	0.908	0.912	0.917	0.921
30	32	67	0.940	0.943	0.945	0.946	0.949	0.952	0.953
40	45	41	1.043	1.041	1.040	1.039	1.037	1.035	1.034
45	53	29	1.109	1.105	1.102	1.099	1.096	1.091	1.088
50	60	20	1.164	1.160	1.151	1.150	1.144	1.139	1.134
60	75	9	1.254	1.245	1.235	1.231	1.225	1.217	1.207
70	90	4	1.299	1.292	1.282	1.275	1.270	1.260	1.249
80	103	3	1.307	1.299	1.292	1.287	1.283	1.273	1.262

Table A5.3: Typical HVL measurements for different tube voltage and target filter combinations. (Data includes the effect on measured HVL of attenuation by a PMMA compression plate*.)

	HVL (mm Al) for target filter combination				
kV	Mo + 30 µm Mo	Mo +25 µm Rh	Rh +25 µm Rh	W +50 µm Rh	W +0.45 µm Al[22]
25	0.33 ± .02	0.40 ± .02	0.38 ± .02	0.52 ± .03	0.31 ± .03
28	0.36 ± .02	0.42 ± .02	0.43 ± .02	0.54 ± .03	0.37 ± .03
31	0.39 ± .02	0.44 ± .02	0.48 ± .02	0.56 ± .03	0.42 ± .03
34		0.47 ± .02		0.59 ± .03	0.47 ± .03
37		0.50 ± .02			0.51 ± .03

* Some compression paddles are made of Lexan, the HVL values with this type of compression plate are 0.01 mm Al lower compared with the values in the table.

Table A5.4: s-factors for clinically used spectra [Dance et al. 2000]

Spectrum	s-factor
Mo/Mo	1.000
Mo/Rh	1.017
Rh/Rh	1.061
Rh/Al	1.044
W/Rh	1.042
W/Al	1.05*

* This value is not given in the paper of Dance et al. The value in the table has been estimated using the S-values of other spectra.

Table A5.5: g-factors (mGy/mGy) for breast thicknesses of 2-11 cm and the HVL range 0.30-0.60 mm Al. The g-factors for breast thicknesses of 2-8 cm are taken from Dance (1990), and for 9-11 cm from Dance et al. (2000)

Breast Thickness (cm)	g-factors (mGy/mGy) HVL (mm Al)						
	0.30	0.35	0.40	0.45	0.50	0.55	0.60
2	0.390	0.433	0.473	0.509	0.543	0.573	0.587
3	0.274	0.309	0.342	0.374	0.406	0.437	0.466
4	0.207	0.235	0.261	0.289	0.318	0.346	0.374
4.5	0.183	0.208	0.232	0.258	0.285	0.311	0.339
5	0.164	0.187	0.209	0.232	0.258	0.287	0.310
6	0.135	0.154	0.172	0.192	0.214	0.236	0.261
7	0.114	0.130	0.145	0.163	0.177	0.202	0.224
8	0.098	0.112	0.126	0.140	0.154	0.175	0.195
9	0.0859	0.0981	0.1106	0.1233	0.1357	0.1543	0.1723
10	0.0763	0.0873	0.0986	0.1096	0.1207	0.1375	0.1540
11	0.0687	0.0786	0.0887	0.0988	0.1088	0.1240	0.1385

Table A5.6: c-factors for average breasts for women in age group 50 to 64 (Dance et al. 2000)

Breast Thickness (cm)	c-factors HVL (mm Al)						
	0.30	0.35	0.40	0.45	0.50	0.55	0.60
2	0.885	0.891	0.900	0.905	0.910	0.914	0.919
3	0.925	0.929	0.931	0.933	0.937	0.940	0.941
4	1.000	1.000	1.000	1.000	1.000	1.000	1.000
5	1.086	1.082	1.081	1.078	1.075	1.071	1.069
6	1.164	1.160	1.151	1.150	1.144	1.139	1.134
7	1.232	1.225	1.214	1.208	1.204	1.196	1.188
8	1.275	1.265	1.257	1.254	1.247	1.237	1.227
9	1.299	1.292	1.282	1.275	1.270	1.260	1.249
10	1.307	1.298	1.290	1.286	1.283	1.272	1.261
11	1.306	1.301	1.294	1.291	1.283	1.274	1.266

Table A5.7: c-factors for average breasts for women in age group 40 to 49 (Dance et al. 2000)

Breast Thickness (cm)	c-factors HVL (mm Al)						
	0.30	0.35	0.40	0.45	0.50	0.55	0.60
2	0.885	0.891	0.900	0.905	0.910	0.914	0.919
3	0.894	0.898	0.903	0.906	0.911	0.915	0.918
4	0.940	0.943	0.945	0.947	0.948	0.952	0.955
5	1.005	1.005	1.005	1.004	1.004	1.004	1.004
6	1.080	1.078	1.074	1.074	1.071	1.068	1.066
7	1.152	1.147	1.141	1.138	1.135	1.130	1.127
8	1.220	1.213	1.206	1.205	1.199	1.190	1.183
9	1.270	1.264	1.254	1.248	1.244	1.235	1.225
10	1.295	1.287	1.279	1.275	1.272	1.262	1.251
11	1.294	1.290	1.283	1.281	1.273	1.264	1.256

Appendix 6: Calculation of contrast for details in a contrast-detail test object

The minimum and achievable standards in section 2b.2.4.1 depend on the calculation of nominal contrast for the details involved. To allow different designs of test object the standard is specified in terms of radiation contrast for a typical spectrum using a tube voltage of 28 kV, a molybdenum target material and a 30 mm thick molybdenum filter. (The spectrum was derived from IPEM Report 78). The contrast of the discs and the threshold limiting values have been determined using the CDMAM phantom with a 2 cm thickness of PMMA above and 2 cm thickness below the test object. The CDMAM phantom includes an aluminium base which is approximately equivalent to 1cm of PMMA in terms of attenuation. In the European guidelines third edition however 4.5 cm has been chosen as the standard thickness of PMMA. Therefore in future threshold contrast might be determined at a total thickness equivalent to 4.5 cm PMMA. Calculated contrast for various thicknesses of gold are shown in Table A6.1. The corresponding contrast calculated for the use of a CDMAM phantom with 4 cm of PMMA and for gold details on 4.5 cm PMMA is shown. In both cases the effect of scatter is not included in the calculation.

Table A6.1: Calculated radiation contrast for various gold thickness on the standard test object

Thickness of gold (µm)	Radiation contrast (%) for gold disc on 4.5 cm PMMA	Radiation contrast (%) for CDMAM with 4 cm PMMA
0.1	1.63	1.57
0.5	7.83	7.60
1.0	15.02	14.55
1.5	21.57	20.92
2.0	27.56	26.76

Appendix 7: Computed Radiography screen processing modes

For all test-items the following screen processing settings must be chosen except for the test-items listed below. If a specific system or screen processing mode is not mentioned below, it is advised to refer to the manual of the manufacturer:

Fuji systems	Use FIXED EDR screen processing, suggested: S = 120, L = 2
Kodak systems	Use Pattern screen processing
Agfa systems	Use System diagnostics/flat field screen processing

Remark: For all measurements on the Fuji system an L-value of 2 is advised (which resembles the L-value in clinical practice). If clipping occurs with an S-value of 120, another S-value should be chosen.

2b.2.2.1.1 Response function

The following relations between pixel value (sensitivity/exposure index) and entrance surface air kerma should be linear (If a screen processing mode is not mentioned below, it is advised to refer to the manual of the manufacturer):

Fuji systems: Fixed EDR screen processingsuggested: S = 120, L = 2	Linear relations: Plot the mean pixel value in the reference ROI versus log entrance surface air kerma
Semi EDR screen processing	Plot sensitivity index versus inverse entrance surface air kerma
Kodak systems: Pattern screen processing	Plot the mean pixel value in the reference ROI versus log entrance surface air kerma
Agfa systems: System diagnostics/flat field screen processing	Plot the mean pixel value in the reference ROI versus log entrance surface air kerma

2b.2.2.1.2 Noise evaluation

Fuji systems	FIXED EDR screen processing, suggested: S = 120, L = 2
Kodak systems	Use Pattern screen processing
Agfa systems	Use System diagnostics/flat field screen processing

2b.2.4.1 Threshold contrast visibility

Fuji systems	Use FIXED EDR screen processing. The S and L value must be chosen such that they are typical for the clinical situation. These values may differ from site to site. Typical values (according to Fuji): S = 40 to 100, L = 1.8 to 2.6.
Kodak systems	Use Pattern screen processing
Agfa systems	Use System diagnostics/flat field screen processing

2b.2.4.5 Ghost image / erasure thoroughness

Fuji systems	Use FIXED EDR screen processing. The S and L value must be chosen such that they are typical for the clinical situation. These values may differ from site to site. Typical values (according to Fuji): S = 40 to 100, L = 1.8 to 2.6.
Kodak systems	Use Pattern screen processing
Agfa systems	Use System diagnostics/flat field screen processing

Notes

1. This is the PMMA thickness most commonly used, but others may be specified in parts of this protocol.
2. The specifications of the listed equipment are given, where appropriate, in section 4, table 2.
3. The standard test block may be composed of several PMMA plates.
4. PMMA (polymethylmethacrylate) is commercially available under several brandnames, e.g. Lucite, Plexiglas and perspex.
5. 150 X 100 mm or semi-circular with a radius of ≥µ100 mm, and covering a total thickness range from 20 to 70 mm PMMA.
6. In future the PMMA thickness may change to the 'standard thickness' of 45 mm with the details positioned at a height of 40 to 45 mm above the breast support table. This may mean that the limiting values need slight adjustment.
7. If the exposure-to-read-time other than one minute is more relevant for practical reasons, that other time should be chosen.
8. The specifications of the listed equipment are given, where appropriate, in chapter 3.5, table 2 of the European Guidelines, third edition.
9. The standard test block, covering the whole imaging area, may be composed of several PMMA plates.
10. PMMA (polymethylmethacrylate) is commercially available under several brand names, e.g. Lucite, Plexiglas and Perspex.
11. Covering the whole imaging area, and covering a total thickness range from 20 to 70 mm PMMA (Normally PMMA of 180 X 240mm is available).
12. These films have been reported as suitable for use in collimation assessment by Beideck and Gingold at the AAPM 2004 annual meeting.
13. These values are derived from screen-film mammography. At this moment no limiting values on exposure increase per step for digital mammography have been set, but they should be approximately uniform.
14. In future the contrast threshold visibility may be determined at the standard PMMA thickness of 45 mm, so CNR limits will also be relative to 45 mm in future.
15. These values are provisional, it is advised to check the EUREF website for alterations
16. For some scanning slot systems only a limited range of mA or mAs settings are available, for these systems images should be made at all settings.
17. In future the PMMA thickness may change to the 'standard thickness' of 45 mm with the details positioned at a height of 40 to 45 mm above the breast support table. This may mean that the limiting values need slight adjustment.
18. CDMAM phantom with a 4 cm thickness of PMMA, see appendix 6.
19. For some scanning slot systems, see the remark above.
20. Aliasing problems may occur due to the difference in pixel size of the printer and test pattern.
21. Further research is necessary to investigate whether the Dmin and Dmax limiting values are appropriate.
22. Data partly based on: Bengt Hemdal, Lars Herrnsdorf, Ingvar Andersson, Gert Bengtsson, Boel Heddson and Magnus Olsson, Average glandular dose in routine mammography screening with Sectra MicroDose Mammography, MDM, poster at: Medicinska Riksstämman, Göteborg, Sweden 2004.