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"QC Measurements in Mammography"

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QC Measurements in Mammography

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The European Protocol for the

Quality Control of the Physical and Technical Aspects

of Mammography Screening

EUROPEAN COMMISSION

• DG V F.2 Europe Against Cancer •
• DG XI C.1 Radiation Protection Actions •
• DG XII F.6 Radiation Protection Actions •

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This document is the first revision of chapter 4, "Technical Aspects" in the "European Guidelines for Quality Assurance in Mammography Screening", published in 1993 (EUR 14821, ISSN 1018-5593). Original authors: Johan M. Lindeijer, NL †. Remko Bijkerk, NL Martin A. O. Thijssen, NL

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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, organizational and technical aspects. This section is specifically concerned with the quality control of physical and technical aspects 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 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 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 diagnostic 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 analyzed 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 control system;
- Bucky and image receptor;
- Film processing;
- System properties (including dose);
- 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 basic and desirable limiting values for some QC parameters. The basic values indicate the minimal performance limits. The desirable values indicate the limits that are achievable. New equipment must meet the desirable limits. Limiting values are only indicated when consensus on the measurement method and parameter values has been obtained.
The necessary QC equipment for both the basic and desirable level of QC is listed also, together with the appropriate tolerances.

Methods of dosimetry are described in the "European Protocol on Dosimetry in Mammography" (EUR16263). It provides accepted indicators for breast dose, both by measurements on a group of women and by phantom measurements. The summary of this document is listed in annex.

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. This revised (1996) version is based on a critical review of recent QA and QC literature and includes the experience gained by users of the document and comments from manufacturers of equipment and film-screen systems (see literature and reference list, Chapter 6, bibliography). Communication on this protocol can be directed to the EUREF Coordinating Office, National Expert and Training Centre for Breast Cancer Screening, PO-box 9101, NL-6500 HB Nijmegen, The Netherlands, Tel: +31-(0)24-3617515.

1 Introduction to the measurements

This protocol is intended to provide the basic techniques for the quality control (QC) of the physical and technical aspects of mammography screening. It is based on other existing protocols (see chapter 6, 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 needs to be updated regularly.

Many measurements are performed using an exposure of a test object or phantom. All measurements are performed under normal working conditions: no special adjustments of the equipment are necessary.
Two types of exposures need to be mentioned:

- The **reference exposure** is intended to provide the information of the system under ***defined*** conditions, independent of the clinical settings.
- The **routine exposure** is intended to provide the information of the system under ***clinical*** conditions, dependent on the settings that are clinically used.

For the production of the reference or routine exposure, a plexiglass phantom is exposed and the machine settings are as follows (unless otherwise mentioned):

		Reference exposure:	***Routine exposure:***
- tube voltage	:	28 kV	clinical setting
- compression device	:	in contact with phantom	in contact with phantom
- plexiglass phantom	:	45 mm	45 mm
- 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	clinical setting
- automatic exposure control	:	on, central density step	on
- optical density control	:	central position	clinical setting

The optical density (OD) of the processed image is measured at the ***reference point***, which lies 60 mm from the chest wall side and laterally centred. The ***reference optical density*** is 1.0 OD, base and fog *excluded*. Therefore the aim of the measured OD value in the reference point is: 1.0 ± 0.1 + base + fog (OD). The routine OD may be different.
All measurements should be performed with the same cassette to rule out differences between screens and cassettes.

Limits of acceptable performance are given, but often a better result would be desirable. Both the acceptable and desirable limits are given in chapter 5, table 1. Occasionally no limiting value is given, but only a typical value as an indication.
The measurement frequencies indicated in the table are the minimum required. When problems occur, 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 Objects (see chapter 6, Bibliography). The definition of terms, like the reference point and the reference density are given in chapter 4. The evaluation of the results of the QC measurements can be simplified by using the completion forms provided in appendix 4.

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 analyzed centrally.

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

- Sensitometer
- Densitometer
- Thermometer
- PMMA plates**
- Daily QC test object
- Reference cassette

The medical physics staff conducting the other QC-tests will need the following additional equipment*:

- 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

* The specifications of the listed equipment are given, where appropriate, in chapter 5, table 2.

** PMMA (polymethylmethacrylate) is commercially available under several brandnames, e.g. Lucite, plexiglass and perspex.

2 Description of the measurements

2.1 X-ray generation and control

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.

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. 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 three 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)

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) 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 point 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 a optical density of the starpattern image: 0.8<OD<1.4.
According the IEC/NEMA norm, an 0.3 focal spot is limited to a width of 0.45 mm and a length of 0.65 mm. An 0.4 focal spot is limited to 0.60 and 0.85 mm respectively. No specific limiting value is given here: the measurement of imaging performance of the focal spot is incorporated in the limits for spatial resolution at high contrast. (see 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.

$$f = \frac{\pi \times \theta}{180} \times \frac{D_{blur}}{(M_{star}-1)} \qquad (2.1)$$

where θ 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:

$$M_{star}=D_{image}/D_{star} \quad (2.2)$$

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 µm slit is used. Produce two magnified images (magnification 2.5 to 3 times) of the slit, perpendicular and parallel to the tube axis. Remove the compression device and use the test stand to support the slit.
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:

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

Note: $M_{slit} = M_{image} - 1$

Remark: The method requires a higher exposure than the star pattern and slit camera methods.

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 30 µm 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:

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

Remark: 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.*

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.

Limiting value	*The source-to-image distance should conform to the manufacturers' specification and typically is ≥ 600 mm.*
Frequency	*Only initially.*
Equipment	*Tape measure.*

Alignment of X-ray field/image receptor

The alignment of the X-ray field and image receptor at the chest wall side can be measured 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 misalignment between film and X-ray field can be measured.
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 focal distance is used, the measurement should be repeated for each diaphragm or distance.

Limiting value	*Thorax-side: X-rays must cover the film by no more than 5 mm outside the film.* *Lateral sides: X-rays must cover the film to the edges*
Frequency	*Yearly.*
Equipment	*X-ray absorbers -e.g. coins. tape measure.*

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 tubehousing with loaded cassettes and expose to the maximum kilovoltage and a high mAs (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 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 cm², and according to local regulations.*
Frequency	*Initially and after intervention on the tube housing.*
Equipment	*Dose meter and appropriate detector.*

Tube output

The specific tube output (µGy/mAs) and the output rate (mGy/s) should both be measured on an axis passing through the reference point, in the absence of scatter material and attenuation (e.g. due to the compression plate). An 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).

Limiting values *acceptable: >30 µGy/mAs; desirable: 40-75 µGy/mAs at 1 metre*
acceptable: > 7.5 mGy/s; desirable: 10-30 mGy/s at a distance equal to the FFD
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 present back-up time. In addition any marked changes in output require investigation.

2.1.2 Tube voltage

The radiation quality of the emitted X-ray spectrum 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.

Reproducibility and accuracy

A tube voltage check over the whole used kV-range at 1 kV intervals should be performed. The reproducibility is measured by repeated exposures at one fixed tube voltage that is normally used clinically (e.g. 28 kV). A digital kVp-meter (specially designed for mammography) is presently the most suitable for this purpose.

Note: consult the manufacturers' instruction manual for the correct positioning.

Limiting value *Accuracy for 25-31 kV: < ± 1 kV, reproducibility < ± 0.5 kV.*
Frequency *Every six months.*
Equipment *Digital kVp-meter*

Half Value Layer

The Half Value Layer (HVL) 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 point (since the HVL is position dependent) on top of the bucky. Place the compression device halfway between focal spot and detector. Select 28 kV tube voltage and an adequate focal spot charge (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 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 the protocol on dosimetry).
The HVL is calculated by applying formula 2.5.

$$HVL = \frac{X_1 \times \ln(\frac{2Y_2}{Y_0}) - X_2 \times \ln(\frac{2Y_1}{Y_0})}{\ln(\frac{Y_2}{Y_1})} \qquad (2.5)$$

The direct exposure reading is denoted as Y_0; Y_1 and Y_2 are the exposure readings with added

aluminium thicknesses of X_1 and X_2 respectively.

Note 1: The purity of the aluminium ≥ 99.0% is required. The thicknesses 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) energies and other target materials and filters may also be measured for assessment of the mean glandular dose (see appendix 1 and the protocol on dosimetry).

Note 4: Alternatively a digital HVL-meter can be used, but correct these readings under extra filtration following to the manufacturers' manual.

Limiting value *For 28 kV Mo/Mo the HVL must be over 0.30 mm Al equivalent. Typically readings are< 0.40 mmAl. For typical readings for other kV's, targets and filters, see appendix 3.*

Frequency *Yearly.*

Equipment *Dosemeter, aluminium sheets 0.30 and 0.40 mm.*

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 thicknesses and tube voltages. An essential prerequisite for these measurements is a stable operating film-processor and the use of the reference cassette.

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 with a 45 mm PMMA phantom with varying positions of the optical density control selector.
A target value for the mean optical density should be established according to local preference. Once the target is agreed, any deviations must be monitored.

Limiting value *The optical density (base and fog included) at the reference point should remain within ± 0.15 OD to the target value. Target value is typical in the range: 1.3 - 1.8 OD, base and fog included.*
The desirable quantity for the smallest optical density control step-size is 0.10 OD; ≤ 0.20 OD per step is acceptable. Adjustable range > 1.0 OD.

Frequency *Stepsize: every six months*
Central density or mAs-value: daily

Equipment *PMMA 45 mm thick block, densitometer*

Guard timer

The AEC system should also be equipped with a guard timer which will terminate the exposure in case of malfunctioning of the AEC system. Measure the mAs at which the system terminates the exposure.

Warning: ***since an incorrect functioning of the guard timer could seriously damage the tube, this measurement should be performed under the responsibility of the manufacturer.***

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).

Limiting value *The deviation of the mean value of exposures must be < ± 5%, desirable would be < ± 2%.*
Frequency *Every six months.*
Equipment *PMMA 45 mm thick block, dosemeter.*

Note: For the assessment of the reproducibility, also compare the results from the short term reproducibility with those from the thickness and tube voltage compensation and the optical density control setting at 45 mm PMMA and 28 kV. Any problem will be indicated by a mismatch between those figures.

Long term reproducibility

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

Limiting value *< ± 0.20 OD acceptable; < ± 0.15 OD desirable from the target OD.*
Frequency *Daily*
Equipment *PMMA 45 mm thick block or QC phantom, densitometer*

Object thickness compensation

Compensation for object thickness is measured by exposures of PMMA plates in the thickness range 20 to 70 mm, using the clinical setting for the AEC.

Limiting value *All optical density variations must be within the range ± 0.15 OD, with respect to the target optical density. Desirable: ± 0.10 OD.*
Frequency *Weekly.*
Equipment *PMMA: plates 10x180x240 mm^3, densitometer.*

Tube voltage compensation

Compensation for tube voltage is measured over the clinical range of kV, filters and target materials used.

Limiting value *All optical density variations must be within the range ± 0.15 OD, with respect to the target optical density. Desirable: ± 0.10 OD.*
Frequency *Every six months.*
Equipment *PMMA 45mm, densitometer.*

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.

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 tennisball to protect the bucky and compression device). When compression force is indicated on the console, it should be verified whether the figure corresponds with the measured value.

Limiting value	*Maximum automatically applied force: 130 - 200 N. (~ 13-20 kg)*
Frequency	*Yearly.*
Equipment	*Compression force test device.*

Compression plate alignment

The alignment of the compression device at maximum force can be visualized and measured when a piece of foam-rubber is compressed. Measure the distance between bucky surface and compression device on each corner. Ideally, those four distances should be equal. Misalignment normal to the chest wall side is less disturbing than in the parallel direction. The upright edge of the device must be imaged outside the receptor area and optimally within the chestwall side of the bucky.

Limiting value	*Minimal misalignment is allowed, < 15 mm is acceptable for asymmetrical load and in the direction towards the nipple, < 5 mm for symmetrical load.*
Frequency	*Annually.*
Equipment	*Foam rubber, tape measure.*

2.2 Bucky and image receptor

2.2.1 Anti scatter grid

The anti scatter grid is composed of alternating strips of lead and cotton fibre interspace material mainly and is designed to absorb scattered photons. The grid system is composed of a cassette holder, breast support table and a mechanism for moving the grid, to prevent grid lines on the image.

Grid system factor

The grid system factor can be measured with a dosemeter. Produce two images, one with and one without the grid system. Use manual exposure control to obtain images of about unit optical density. The first image is made with the cassette in the bucky tray (with grid system) and PMMA on top of the bucky, and the second with the cassette on top of the bucky (without grid system) and PMMA on top of the cassette. The grid system factor is calculated by dividing the exposures, corrected for the inverse square law and optical density differences.

Limiting value *Grid system factor ≤ 3.*
Frequency *Initially and when dose or exposure time increases suddenly.*
Equipment *Dosemeter, PMMA 45 mm thick block and densitometer.*

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.

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 a stock of cassettes is described by the inter cassette sensitivity variation and screen-film contact.

Inter cassette sensitivity and attenuation variation and optical density range

The relative sensitivity of the screens can be assessed with the reference exposure (chapter 1). Select an AEC setting (should be the normal position) 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 point.

Limiting value *The exposure, in terms of mGy (or mAs), must be within ±5% for all cassettes.*
The maximum difference in optical density between all cassettes: ≤0.20 OD is acceptable, ≤ 0.15 OD is desirable.
Frequency *Initially (including manual exposures), yearly, and after introducing new screens.*
Equipment *PMMA 45 mm* or phantom, dosemeter, densitometer.

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 (mesh: about 40 wires/inch,

1.5 wires/mm) on top of the cassette and expose to produce a film optical density of about 2 OD at the reference point. Regions of poor contact will be blurred and appear as dark spots in the image. Reject cassettes only when they repeatedly show the same spots.

Limiting value	*No significant areas of poor contact are allowed in the diagnostically relevant part of the film.*
Frequency	*Initially, yearly and after introducing new screens.*
Equipment	*Mammography screen-film contact test device and densitometer.*

2.3 Film processing

2.3.1 Base line performance processor

The performance of the processor greatly affects image quality. The best way to measure its performance is by sensitometry. Measurements like temperature and processing time are performed to establish a base-line performance. No limiting values are given, since temperature and processing time are set to adapt to the requirements of the sensitometry.

Temperature

To establish a base-line 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.

Limiting value	*None.*
Frequency	*Initially and when problems occur.*
Equipment	*Thermometer (digital or alcohol, no mercury allowed)*

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	*None.*
Frequency	*Initially and when problems occur.*
Equipment	*Stopwatch.*

2.3.2 Film and processor

The films used in mammography should be specially designed for that purpose and should comply with the given figures under "Limiting value". Light sensitometry is a suitable method to measure the performance. Disturbing processor artifacts should be absent on the processed image.

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 exposure by light) the values of base and fog, maximum density, speed and mean gradient can be derived. These parameters characterize the processing performance. A detailed description of these ANSI-parameters can be found in appendix 1, calculation of film parameters.

Limiting value	*The required values for these parameters are:* *base and fog: ≤ 0.20 OD* *contrast: MGrad: 2.8 - 3.2*
Frequency	*Daily.*

Equipment *Sensitometer, densitometer.*

Note: There is no clear evidence for the optimal value of MGrad; the range is based on theory and current experience. A higher value of MGrad might lead to under- and over exposure of parts of the image and therefore reduce the information content. Only in stable conditions with very low variability of the parameters could it further improve image quality.

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 1).

Limiting value *Variability for all parameters acceptable: < ±10%, desirable < ±5%.*
Frequency *Daily and more often when problems occur.*
Equipment *Sensitometer, densitometer.*

Note: A more practical approach to the assessment of variations can be found in the use of the following table, where the limiting percentages are expressed as a **range** of limiting values (Max value - Min value):

	acceptable:	*desirable*
base+fog:	*< 0.03*	*< 0.02*
max. density:	*< 0.30*	*< 0.20*
speed:	*< 0.05*	*< 0.03*
mean gradient:	*< 0.20*	*< 0.10*

Artifacts

The image of the PMMA block obtained daily, should be inspected. This should show a homogeneous density, without scratches, shades or other marks indicating artifacts.

Limiting value *No artifacts.*
Frequency *Daily.*
Equipment *PMMA block 45 mm or plates 40-60 mm, viewing box*

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. Cassettes and film hopper should also be light tight. Extra fogging by the safelights must be within given limits.

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 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 four minutes. Position the cover also perpendicular to the heel effect. to avoid the influence of this inhomogeneity in the measurements. Measure the optical density difference of the background (D_{bg}) and the fogged area (D_{fogged}). The extra fog (ΔD) equals:

$$\Delta D = D_{fogged} - D_{bg} \qquad (2.6)$$

Limiting value *Extra fog: $\Delta D \leq 0.02$ OD in 4 minutes.*
Frequency *Initially, every six months and when light leakage is suspected.*
Equipment *Film cover, densitometer.*

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 4 minutes.*
Frequency *Initially, every six months and every time the darkroom environment has changed.*
Equipment *Film cover, densitometer.*

Film hopper

Fogged edges on unexposed (clear) films may indicate that the film hopper is no longer light tight. Place one fresh sheet of film in the hopper. Leave it there for several hours with full white light illumination in the darkroom. Inspect the processed film for light leakage of the hopper.

Limiting value *No extra fogging.*
Frequency *This test should be performed initially and when light leakage is suspected.*

Cassettes

Dark edges on radiographs indicate a need to perform light leak tests on individual cassettes. Reload the suspect cassette with a fresh sheet of film and place it in front of a viewing box for several hours. Making sure that each side of the cassette is exposed to bright light by turning it over. Inspect the processed film for dark edges due to light leakage of the cassette.

Limiting value *No extra fogging.*
Frequency *This test should be performed initially and when light leakage is suspected.*

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 the film should be masked to minimise stray light.

As regards light levels 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 readers 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. This approach makes assumptions about the collection geometry, therefore 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 have recommended 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 seem a reasonable compromise until clearer evidence is available.

2.4.1. Viewing box

Luminance

Measure the luminance close to the centre of the illuminated area 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 2000-6000 cd/m^2.*
Frequency *Yearly.*
Equipment *Luminance meter.*

Homogeneity

The homogeneity of a single viewing box is measured by multiple readings of luminance over the surface of the illuminator, compared with the mean value of readings in the middle of the viewing area. 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. To avoid inhomogeneities as a result of dust, clean the light boxes regularly inside and out.

Limiting value *The uniformity of luminance across a single light box is typically within ± 30%. The intensity of different light boxes at one department is suggested to be within 15% (measured in the middle of the viewing area).*
Frequency *Yearly.*
Equipment *Luminance meter.*

2.4.2. Ambient light

Level

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*

2.5 System properties

The quality of any X-ray image is defined by its ability to transfer the information, necessary to make the right diagnosis, from the tissues examined to the radiologist. This information is proffered by X-ray quanta that are not absorbed by the tissues and reach the detector. The differences in absorption by the different tissues make them discernable. The better the differences are defined, the better the information can be visualised, be it by blackening of the processed film or intensities on a monitor of a digital system. A better separation of the imaged tissues can be achieved by a larger difference between the OD's representing those tissues, and/or by a better definition of the differences in absorption.

- The first improvement is achieved by manipulating the X-ray spectrum, either by the choice of a lower kV or of appropriate target and filter materials. It increases the difference in mean value of the OD's of the imaged tissues at the film and by that, the contrast between the tissues.
- The second improvement is achieved by increasing the system dose. Without affecting the mean values it improves the definition of those values by lowering the standard deviation of their distributions and by that, giving less noise in the imaged tissues.

Both ways to improve image quality are at the cost of a higher patient dose either by more absorption due to the lower energies or by more irradiation to compensate for a less sensitive imaging system.
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 aim.

2.5.1 Dosimetry

The measurement of exposure and the calculation of the mean glandular dose in mammography are described in detail in the *European Protocol on Dosimetry in Mammography*.(see chapter 6, Bibliography) Only the measurement of entrance surface air kerma is described here for convenience.

Entrance surface air kerma

This measurement is performed under reference conditions either with AEC or manual exposure. Produce two exposures of a PMMA block with an optical density under and over 1.0 OD respectively. The corresponding entrance surface dose should be measured as close to the reference point as possible. The value for the entrance surface air kerma at 1.0 OD (base and fog excluded) can be interpolated linearly from these data.

Limiting value	*≤10 mGy for 40 mm PMMA,* *≤12 mGy for 45 mm PMMA,* *≤20 mGy for 50 mm PMMA.*	*(Limiting values for other OD's: see appendix 3)*
Frequency	*Yearly.*	
Equipment	*Dose meter, PMMA block 150x240 mm², densitometer.*	

2.5.2 Image Quality

Although 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 some physical measurements.

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/mm each. They are placed either between PMMA plates to measure the resolution in the tissue, or on top of

PMMA plates with a total thickness of 45 mm, to measure worst-case resolution. Image the patterns at the reference point both parallel and perpendicular to the tube axis, and measure these resolutions.
Note: The resolution measured at different heights between 25 and 50 mm from the tabletop does not differ much, since geometric blur is largely compensated by magnification for small focal spot sizes. The distance from the chest wall edge is critical, but the position parallel to the thorax side is not critical within ± 5 cm from the reference point. Resolution is generally worse parallel to the tube axis due to the asymmetrical shape of the focal spot.

Limiting value *> 12 lp/mm acceptable, > 15 lp/mm desirable at the reference point*
Frequency *Weekly.*
Equipment *PMMA plates 150x240 mm, resolution pattern(s) up to 20 lp/mm, densitometer.*

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 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 2.
Remark: The value for image contrast is dependent on the whole imaging chain, therefore no absolute limits are given.

Limiting value *10% to baseline is suggested.*
Frequency *Weekly.*
Equipment *PMMA or aluminium stepwedge, densitometer.*

Threshold contrast visibility

This measurement 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 phantom 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.
Produce a routine exposure and let two or three observers examine the low contrast objects. The number of visible objects is recorded.

Limiting value *<1.3% contrast for a 6 mm detail is suggested.*
Frequency *Weekly.*
Equipment *Test object with low contrast details plus PMMA plates, to a thickness of 45 mm, densitometer.*

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.; desirable: <1.5 sec.*
Frequency *Yearly and when problems occur.*
Equipment *Exposure time meter, PMMA 45x150x240 mm.*

3 Daily and weekly QC tests.

There is a number of items that should be checked daily or weekly. For this purpose, a dedicated QC-phantom or set of test objects must be available. 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, artifacts
- sensitometry (speed, contrast, gross fog)

Note: The reproducibility of the AEC system should be tested daily, using a 40 - 50 mm PMMA block phantom. Its constancy of response to thin and to thick compressed breasts should be tested weekly using PMMA plates covering the range 20 - 70 mm thick.

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 phantom should be designed in such a way that it can be positioned reproducibly on the bucky.
- The shape of the phantom does not have to be breast-like. To be able to perform a good homogeneity check, the phantom should at least cover the normally imaged area (150x240 mm) on the image receptor (180x240 mm).
- For testing the AEC reproducibility, the PMMA phantom may comprise several layers of PMMA, 10- or 20-mm thick. It is important that the correct thicknesses are known, since commercially available plates are neither identical nor correct in thickness.

4 Definition of terms

Note that the definitions given here may not be universally applicable but do express the meaning of the terms as used in this document.

Accuracy represents unbiased and precise results. It is the closeness of an observed value of a quantity to the true value. Its value is: the percentage of difference between measured value (m) and true value (t) according: (m/t -1) x 100%

Air kerma: The quotient of dE_{tr} by dm, measured in Gray, where dE_{tr} 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)

Automatic exposure control (AEC) system: A mode of operation of an X-ray machine by which the tube loading is automatically controlled and terminated when a pre-set radiation exposure to the image receptor is reached. Also the tube potential (kV) may or may not be automatically controlled.

Average glandular dose: Reference term (ICRP 1987) for radiation dose estimation from X-ray mammography i.e. the average absorbed dose in the glandular tissue (excluding skin) in a uniformly compressed breast of, e.g., 50% adipose, 50% glandular tissue composition. The reference breast thickness and composition should be specified.

Baseline value: The value that is used for comparison when no absolute limiting value is present.

Breast compression: The application of pressure to the breast during mammography so as to immobilize the breast and to present a lower and more uniform breast thickness to the X-ray beam.

Compression paddle: An approximately rectangular plate, positioned parallel to and above the breast table of a mammography X-ray machine, which is used to compress the breast.

Deviation (± %): The percentage of difference between measured value (m) and prescribed value (p) according: (m/p -1) x 100% .

Dmin, Dmax: see appendix 1: "Calculation of film-parameters"

Entrance surface air kerma (ESAK): The air kerma measured free-in-air (without backscatter) at a point in a plane corresponding to the entrance surface of a specified object e.g., a patient's breast or a standard phantom.

Entrance surface dose (ESD): The absorbed dose in air, including the contribution from backscatter, measured at a point on the entrance surface of a specified object e.g., a patient's breast or a standard phantom.

Grid: A device which is positioned close to the entrance surface of an image receptor to reduce the quantity of scattered radiation reaching the receptor.

Half-value layer (HVL): The thickness of aluminium absorber which attenuates the air kerma of a collimated X-ray beam by half.

Heel effect: The non-uniform distribution of air kerma rate in an X-ray beam in a direction parallel to the cathode-anode axis.

Inverse square law: The physical law which states that the X-ray beam intensity reduces in inverse proportion to the square of the distance from the point of measurement to the X-ray tube focus.

Image Quality: Information content of the image in terms of just visible contrasts and details.

Laterally centred: Centred on a line perpendicular to the kathode-anode axis, not necessarily in the middle of the image.

Limiting value: A value of a parameter which, if exceeded, indicates that corrective action is required, although the equipment may continue to be used clinically. Limiting values for dose or air kerma are derived differently from reference values, i.e., reference ESD is based on third quartile values derived during surveys whereas limiting values of other parameters are derived from standard good practice.

Mammography: The X-ray examination of the female breast. This may be undertaken for health screening of a population (mammography screening) or to investigate symptoms of breast disease (symptomatic diagnosis).

MGrad: see appendix 1: "Calculation of film-parameters"

Net optical density: Optical density excluding base and fog.

Optical density (OD): The logarithm of the ratio of the intensity of perpendicularly incident light (Io) on a film to the light intensity (I) transmitted by the film: OD=log(Io/I). Optical density differences are always measured in a line perpendicular to the tube axis to avoid influences by the heel-effect.

Patient: Any woman attending a facility for mammography whether for screening or for symptomatic diagnosis.

Patient dose: A generic term for a variety of radiation dose quantities applied to a (group of) patient(s).

Phantom: Test object, often a series of PMMA-plates or a PMMA-block with various embedded measuring devices.

PMMA: The synthetic material polymethylmethacrylate. Trade names include Lucite, Perspex and Plexiglass.

Precision: The variation (usually relative standard deviation) in observed values.

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."

Radiation detector: An instrument indicating the presence and amount of radiation.

Radiation dose: A generic term for a variety of radiation quantities.

Radiation dosemeter: A radiation detector, connected to a measuring and display unit, which has a geometry, size, energy response and sensitivity suitable for measurements of the radiation generated by an X-ray machine.

Radiation output: The air kerma measured free-in-air (without backscatter) per unit of tube loading at a specified distance from the X-ray tube focus and at stated radiographic exposure factors.

Radiation quality: A measure of the penetrating power of an X-ray beam, usually characterised by a statement of the tube potential and the half-value layer (HVL).

Range: The absolute or relative difference of minimum and maximum values of measured quantities.

Reference cassette: The identified cassette that is used for the QC tests.

Reference exposure: The exposure of the phantom to provide an image at the reference optical density.

Reference optical density: The optical density of 1.0 OD, base and fog excluded, measured in the reference point.

Reference phantom: A phantom similar to the standard phantom, but of a specifically stated thickness.

Reference point: A measurement position in the plane occupied by the entrance surface of a 45 mm thick phantom, 60 mm perpendicular to the chest wall edge of the table and centred laterally.

Reference value (for dose): The value of a quantity obtained for patients which may be used as a guide to the acceptability of a result. In the 1996 version of the "European Guidelines on Quality Criteria for Diagnostic Radiographic Images" it is stated that the reference value can be taken as a ceiling from which progress should be pursued to lower dose values in line with the ALARA principle. This objective is also in line with the recommendations of ICRP Publication 60 (1991) that consideration be given to the use of "dose constraints and reference or investigation levels" for application in some common diagnostic procedures.

Reproducibility indicates the reliability of a measuring method or tested equipment. The results under identical conditions should be constant.

Resolution (at high or low contrast) describes the smallest detectable detail at high or low contrast to a given background.

Routine exposure: The exposure of the phantom under the conditions that would normally be used to produce a mammogram. It is used to determine image quality and dose under clinical conditions.

Speed: see appendix 1: "Calculation of film-parameters"

Standard breast: A model used for calculations of glandular dose consisting of a 40 mm thick central region comprising a 50% : 50% mixture by weight of adipose tissue and glandular tissue surrounded by a 5 mm thick superficial layer of adipose tissue. The standard breast is semicircular with a radius ≥80 mm and has a total thickness of 50 mm. (see: Standard phantom)

Standard phantom: A PMMA phantom 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 dosemeter readings may be converted into dose to glandular tissue. The thickness is 45 ± 0.5 mm and the remaining dimensions are either rectangular ≥ 150 mm x 100 mm or semi-circular with a radius of ≥ 100 mm.

Target OD: The optical density (OD) at the reference point of a routine exposure, choosen by the local staff as the optimal value, typically in the range 1.3 - 1.8 OD, base and fog included.

Test object: see phantom

Threshold contrast: The contrast that produces a just visible difference between two optical densities.

Tube-current exposure-time product (mAs): The product of the X-ray tube current (milliampere, mA) and the radiographic exposure time (second, s)

Tube loading: The tube-current exposure-time product (mAs) that applies during a particular exposure.

Tube potential: The potential difference (kilovolt, kV) applied across the anode and cathode of the X-ray tube during a radiographic exposure.

Typical value: The value of a parameter that is found in most facilities in comparable measurements. The statement of such a value is an indication of what to expect, without any limits attached to that.

X-ray spectrum: The distribution of photon energies in an X-ray beam.

5 Tables

TABLE 1. Radiographic technique parameters
frequency of Quality Control, measured and limiting values.

2.1 X-ray generation and control		freq.	typical	acceptable	desirable	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
	- radiation leakage	i	-	< 1	-	mGy/hr
	* output	6	40 - 75	> 30	> 40	µGy/mAs
	* output rate	6	10 - 30	> 7.5	> 10	mGy/s
tube voltage	- reproducibility	6	-	< ± 0.5	< ± 0.5	kV
	- accuracy (26 - 30 kV)	6	-	< ± 1.0	< ± 1.0	kV
	- HVL	12	0.3-0.4	> 0.3	system dep.	mm Al
AEC	* central opt. dens control setting (1)	6	1.3-1.8	< ± 0.15	< ± 0.15	OD
	- opt. dens. control step	6	0.15	< 0.20	< 0.10	OD
	* short term reproducibility	6	-	< ± 5 %	< ± 2 %	mGy
	* long term reproducibility	6	-	< ± 0.20	< ± 0.15	OD
	- object thickness compensation	w	-	< ± 0.15	< ± 0.10	OD
	- tube voltage compensation	6		< ± 0.15	<± 0.10	OD
compression	- compression force	12	130-200	-	-	N
	- compression plate alignment, asymm.	12	-	< 15	< 15	mm
	- compression plate alignment, symm.	12	-	< 5	< 5	mm
2.2 Bucky and image receptor						
anti scatter grid	* grid system factor	i	-	< 3	< 3	-
screen-film	* inter cassette sensitivity variation (mAs)	12	-	< ±5%	< ±5%	mGy
	* inter cassette sensitivity variation (OD range)	12	-	< 0.20	< 0.15	OD
	- screen-film contact	12	-	-	-	-

i = initially; d = daily; w = weekly; 6 = every 6 months; 12 = every 12 months
* standard measurement conditions
(1) total optical density is indicated, base and fog are included.
=> *This table is continued on next page.*

TABLE 1, continued. Radiographic technique parameters frequency and limiting values.

		freq	typical	acceptable	desirable	unit
2.3 film processing						
processor	- temperature	i	34-36	-	-	°C
	- processing time	i	90	-	-	s
film	- sensitometry: base and fog	d	> 0.15	< 0.20 (1)	< 0.20 (1)	OD
	speed	d	-	-	-	-
	contrast	d	-	> 2.6	2.8 - 3.2	-
	- daily performance	d	-	< 10 %	< 5 %	
	- artifacts	d	-	-	-	-
darkroom	- light leakage (extra fog in 4 minutes)	12	-	< +0.02 (2)	< +0.02 (2)	OD
	- safelights (extra fog in 4 minutes)	12	-	< +0.10 (2)	< +0.10 (2)	OD
	- film hopper	i	-	-	-	-
	- cassettes	i	-	-	-	-
2.4 viewing conditions						
viewing box	- brightness	12	-	2000 - 6000	2000 - 6000	cd/m²
	- homogeneity	12	-	< ± 30 %	< ± 30 %	cd/m²
	- difference	12	-	-	< ± 15 %	cd/m²
environment	- ambient light level	12	-	< 50	< 50	lux
2.5 system properties						
reference dose	* entrance surface dose; 45 mm phantom	12	-	< 12	< 10	mGy
image quality	* spatial resolution, reference point	w	-	> 12	> 15	lp/mm
	* image contrast variation	w	-	< 10%	< 10%	-
	* threshold contrast visibility	w	-	-	-	-
	* exposure time	12	-	< 2	< 1.5	s

i = initially; d = daily; w = weekly; 6 = every 6 months; 12 = every 12 months
* standard measurement conditions

(1) for standard blue based films only
(2) at net optical density 1.00 OD

=> End of table 1.

TABLE 2. QC equipment and calibration requirements

QC equipment	accuracy	reproducibility	unit
sensitometer	-	± 2%	OD
densitometer	± 2% at 1.0 OD	± 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
light meter	± 10%	± 5%	klux
phantoms, PMMA	± 2%	-	mm
compression force test device	± 10%	± 5%	N
aluminum filters (purity ≥ 99,5%)			
focal spot test device			
stopwatch			
film/screen contact test tool			
tape measure			
rubber foam for compression plate alignment			
(lead sheet)			

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Appendix 1: Calculation of film-parameters

The film curve can be characterized by a few parameters. Most important items are contrast, sensitivity and base and fog. There are different methods to calculate the film parameters. Existing normalizations differ so much that the following method is suggested, derived from the Dutch protocol (1991), which is based on the ANSI (1983) norm.

Dmin Base and fog; the optical density of a non exposed film after developing. The minimum optical density can be visualized by fixation only of an unexposed film. The extra fog is a result of developing the (unexposed) emulsion.

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=Dmin+0.25 OD and D_2=Dmin+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.

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+Dmin, also called 'Speedpoint'. The higher the figure 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.

Two other methods are available for the determination of film contrast, both less precise and less reproducible but easier.

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 logIt (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 2: 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 step wedge.

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 3: Typical values for other spectra and densities

Other spectra

The techniques used to produce a mammographic image are constantly optimized. New anode materials, in combination with filters of different composition and thicknesses, may be explored to improve image quality or to reduce patient dose. Some of these new techniques are used in mammography screening. The typical values of the HVL of some of these combinations are listed below (IEC).

Anode and filter materials	HVL at 25 kVp mmAl	HVL at 28 kVp mmAl
Mo + 30 µm Mo	0.28	0.32
Mo + 25 µm Rh	0.36	0.40
W + 60 µm Mo	0.35	0.37
W + 50 µm Rh	0.48	0.51
W + 40 µm Pd	0.44	0.48
Rh + 25 µm Rh	0.34	0.39

Other densities

The mean optical density of a mammogram affects the dose imparted in the tissue. Applying a different mean OD in the mammogram changes the exposure and the glandular dose. An indication of the changes expected in respect to the reference exposure (28 kV) are listed below as adaptation of the limiting value for the Entrance Surface Air Kerma (ESAK) and standard Average Glandular Dose (sAGD). The film is expected to fulfill the limiting value by having a MGrad of 3.0 (see the European Protocol on Dosimetry in Mammography, 1996).

net film density (OD)	0.8	1.0	1.2	1.4	1.6	1.8
ESAK (mGy)	9.8	12.0	14.2	16.5	18.7	20.9
standard AGD (mGy)	1.6	2.0	2.4	2.8	3.1	3.5

Appendix 4: Sample data sheets for QC reporting

QC report

based on

The European Protocol for the Quality Control of the Physical and Technical Aspects of Mammography Screening

Version: June 1996

Date:

Contact:

Institute:

Address:

Telephone:

Conducted by:

2.2 X-ray generation and control

2.1.1 X-ray source

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} ⊥	___ mm
diameter first MTF zero // AC axis	D_{blur} //	___ mm

$$M_{star} = \frac{D_{mag}}{D_{star}} \quad ; \quad f = \frac{\pi \times \theta}{180} \times \frac{D_{blur}}{(M_{star}-1)} =$$

* *slit camera method*

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

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

* *pinhole method*

diameter pinhole		___ µm
distance pinhole-to-film	$d_{pinhole\text{-}to\text{-}film}$:	___ mm
distance focus-to-pinhole	$d_{focus\text{-}to\text{-}pinhole}$:	___ mm
diameter pinhole ⊥ AC axis	F⊥:	___ mm ⊥
diameter pinhole // AC axis	F//:	___ mm//

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

Focal spot size $f_{\perp}$ = ___ mm
f// = ___ mm

Accepted: yes / no

Source-to-image distance

Nominal value : ___ mm

Measured value :

- Focus indication to bucky : ___ mm
- Bucky to cassette : ___ mm

Total focus-film distance : ___ mm

Alignment of X-ray field / image receptor

Deviation at chest wall side film:

inside/outside image receptor: left : ___ mm, in / out

middle: ___ mm, in / out

right : ___ mm, in / out

Accepted: yes / no

Deviation at the short edges of film:

beam reaches at the left hand side onto the film edge: yes/no

beam reaches at the right hand side onto the film edge: yes/no

Accepted: yes / no

Radiation leakage

Description of position of 'hot spots'

1 _____

2 _____

3 _____

detector surface area : ___ mm^2

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

Accepted: yes / no

Tube output

focus 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

2.1.2 Tube voltage

Reproducibility and accuracy

Preset mAs: ____ mAs
Clinically most relevant kV: ____ kV

Accuracy

Setting	25	26	27	28	29	30	31	kV
Measured	____	____	____	____	____	____	____	kV
Deviation	____	____	____	____	____	____	____	kV

Accepted: yes / no

Reproducibility at the clinically most relevant value

Measured value: 1.____ 2.____ 3.____ 4.____ 5.____ kV

Reproducibility (max deviation from the mean): ____ kV

Accepted: yes / no

Half Value Layer

Measured tube voltage: ____kV

Preset mAs value: ____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

$$HVL = \frac{0.3 \times \ln(\frac{2Y_2}{Y_0}) - 0.4 \times \ln(\frac{2Y_1}{Y_0})}{\ln(\frac{Y_2}{Y_1})} = \text{____ } mmAl$$

HVL: ____ mm Al
Variation exposure at 0 mm Al : ____ %

Accepted: yes / no

2.1.3 AEC-system

Optical density control setting: central value and difference per step

Target density value: ____ OD

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

Accepted: yes / no

Density range: ____ OD

Accepted: yes / no

Optical density control setting for D = 1.0 - 1.2 OD : ____
Optical density control setting for target density: ____

Guard timer

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

Short term reproducibility

Optical density control setting: ____

Exp. #	Exposure	mAs
1	____	____
2	____	____
3	____	____
4	____	____
5	____	____
6	____	____
7	____	____
8	____	____
9	____	____
10	____	____

Variation in mAs: ____ % (= 100 x (max-min)/mean)

Accepted: yes / no

Long term reproducibility

Object thickness compensation

Optical density control setting: ____

Thickness [cm]	Exposure [mGy]	mAs [mAs]	Density [OD]
2.0	____	____	____
3.0	____	____	____
4.0	____	____	____
5.0	____	____	____
6.0	____	____	____
7.0	____	____	____

Variation in optical density: ____ OD

Accepted: yes / no

Tube voltage compensation

Optical density control setting: ____

Tube volt. [kV]	Exposure [mGy]	mAs [mAs]	Density [OD]
25	____	____	____
26	____	____	____
27	____	____	____
28	____	____	____
29	____	____	____
30	____	____	____
31	____	____	____

Variation in optical density: ____ OD

Accepted: yes / no

2.1.4 Compression

Compression force

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

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)
Front :	____	____	____ cm
Rear :	____	____	____ cm
Difference(f/r)	____	____	cm

Accepted: yes / no

A-symmetric load left-right

Height of compression plate above the bucky at full compression:

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

Accepted: yes / no

A-symmetric load front-rear

Height of compression plate above the bucky at full compression:

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

Accepted: yes / no

2.2 Bucky and image receptor

2.2.1. Anti scatter grid

Grid system factor

Bucky	exposure [mGy]	deliv.mAs [mAs]	density [OD]
Present:	____	____	____
Absent:	____	____	____
Bucky factor:	____		

Accepted: yes / no

Grid imaging

Additional grid images made:

#	added PMMA	description of artefacts
1.	yes/no	_____
2.	yes/no	_____
3.	yes/no	_____

Accepted: yes / no

2.2.2. Screen-film

Inter cassette sensitivity and attenuation variation and optical density range

AEC setting: __

(Manual mAs: ____)

Cassette id	exposure [mGy]	deliv.mAs [mAs]	density [OD]	density (manual) [OD]
1	____	____	____	____
2	____	____	____	____
3	____	____	____	____
4	____	____	____	____
5	____	____	____	____
6	____	____	____	____
7	____	____	____	____
8	____	____	____	____
9	____	____	____	____
10	____	____	____	____
11	____	____	____	____
12	____	____	____	____

Average values: ____ mAs ____ OD ____ OD

Variation: ____ % ____ OD ___ OD

Reference cassette : __

Accepted: yes / no

Screen-film contact

Cassette id: Description of artefacts:

__ _____

__ _____

__ _____

Accepted: yes / no

2.3 Film processing

2.3.1. Base line performance of the processor

Temperature

Point of measurement in bath:_____

	Developer	Fixer
reference/nominal:	____	____
thermometer.		
reference	____	____
local:	____	____
console:	____	____

Process time

Time from processor signal to film available: ____ s

2.3.2. Film and processor

Sensitometry

Daily performance

Artifacts

2.3.3. Darkroom

Light leakage

Fog (after 4 min.) of a pre-exposed film on the workbench:

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

Average deviation: ____ OD

Accepted: yes / no

Positions of light sources and leaks in the darkroom:

- _____
- _____

Safelights

Type of lighting: _____, direct/indirect

Height : ca. ___ metre above workbench

Setting: __

Filter condition : insufficient/good/not checked

Fog (after 4 min.) of a pre-exposed film on the workbench:

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

Average deviation: ____ OD

Accepted: yes / no

Film hopper

Fogging due to lightleakage in film hopper is absent: yes/no

Accepted: yes / no

Cassettes

The following cassettes show lightleakage:

Cassette id:	leaking position
__	_____
__	_____
__	_____

Accepted: yes / no

2.4 Viewing conditions

2.4.1. Viewing box

Viewing box luminance

Reading from the luminance metre (detector at the centre of the image plane) : ____ Cd/m²

Homogeneity

Cover the view box pane with mammography films, measure the luminance (remove films first) at all centre positions of these films.

Position	1	2	3	4	5
Top	____	____	____	____	____
Bottom	____	____	____	____	____

Homogeneity: ____ % (= 100% .(L_{max} - L_{min}) / L_{centre})

Accepted: yes / no

2.4.2. Ambient light level

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

Accepted: yes / no

2.5 System properties

2.5.1 Dosimetry

Entrance surface air kerma

exposure [mGy]	deliv.mAs [mAs]	density [OD]
____	____	____
____	____	____

Exposure for D = 1.00 OD+b+s : ____ mGy

Accepted: yes / no

2.5.2 Image Quality

Spatial resolution

Position of the centre of the pattern:
Hight above the bucky surface: ____ mm
Distance from thorax side of the bucky: ____ mm
Distance from AC axis: ____ mm

Resolution	$R_{\perp}$ AC-axis	$R_{\parallel}$ AC-axis
image 1	____	____
image 2	____	____
image 3	____	____
image 4	____	____

Accepted: yes / no

Image contrast

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

Graph(s) attached

Threshold contrast visibility

Observer	# objects identified
1	____
2	____
3	____

Accepted: yes / no

Exposure time

AEC setting for a routine image: ____
mAs number obtained: ____ mAs
exposure time: ____ s

Accepted: yes / no