QUALITY CONTROL IN DIGITAL BREAST TOMOSYNTHESIS (DBT)

EFOMP PROTOCOL

Draft version 0.11

Working Group

Chair

Ruben van Engen (NL)

Members

Paola Baldelli (IE)

Margarita Chevalier (ES)

Paola Golinelli (IT)

Patrice Heid (FR)

Alistair Mackenzie (UK)

Nick Marshall (BE)

Kristin Pedersen (NO)

Stephan Schopphoven (DE)

Consultants

Hilde Bosmans (BE)

David Dance (UK)

Hugo de Las Heras (DE)

Oliver Diaz (ES)

Niall Phelan (IE)

Valentina Ravaglia (IT)

Paolo Russo (IT)

Julie Sage (FR)

Ioannis Sechopoulos (NL)

Ken Young (UK)

Observers

Simona Avramova-Cholakova (UK)

Mauro Campoleoni (IT)

Tormod Egeland (NO)

Richard Elek (HU)

Lesley Grattan (UK)

Melissa Hill (FR)

Christopher Hoog (FR)

Elizabeth Keavey (IE)

Alessandro Loria (IT)

Nicoletta Paruccini (IT)

Massimiliano Porzio (IT)

Veronica Rossetti (IT)

Antonio Sarno (IT)

Concetta Stancampiano (IT)

Alessandro Savini (IT)

Alberto Torresin (IT)

Constantinos Zervides (CY)

Foreword

….

Table of contents

List of Abbreviations

AEC	Automatic exposure control
AGD	Average Glandular Dose
DBT	Digital breast tomosynthesis
DEL	Detector element
DM	Digital mammography
EFOMP	European Federation of Organisations for Medical Physics
FOV	Field-of-view
HVL	Half value layer
mAs	milliAmpere seconds
MPE	Medical physics expert
MPV	Mean pixel value
PE	Polyethylene
PMMA	Polymethyl methacrylate, also known as acrylic, acrylic glass, or plexiglass
PV	Pixel value
QA	Quality assurance
QC	Quality control
ROI	Region-of-Interest
SD	Standard deviation
SNR	Signal-to-Noise Ratio
SDNR	Signal Difference-to-Noise Ratio
WG	Working group

1 Introduction

This EFOMP Digital Breast Tomosynthesis Quality Control protocol has been developed to address the need for guidance on Quality Control (QC) procedures for digital breast tomosynthesis (DBT) systems. The EUREF DBT QC protocol, version 1.3 served as the starting point.

Scope of the protocol:

This protocol applies to tomosynthesis systems which measure x-ray transmission through the breast over a limited range of angles, followed by reconstruction of a series of images of the breast for different heights above the detector. These images represent breast tissue at the height of the corresponding focal planes as well as a remaining portion of overlying tissue. In this protocol such systems will be referred to as DBT (Digital Breast Tomosynthesis) systems. This imaging modality is distinct from computed tomography (CT), in which a three-dimensional image is reconstructed using x-ray transmission data from a rotation of at least 180º around the imaged volume (Dobbins 2009, Sechopoulos 2013).

This protocol does not apply to CT or other mammographic modalities such as conventional 2D imaging, stereotactic imaging using pairs of images, or any other form of reconstructive tomography.

This protocol does not give any advice or guarantee on the suitability of DBT equipment for any particular clinical task.

1.1 DBT systems

DBT systems incorporate a flat panel detector, as used in conventional 2D full field digital mammography (DM) and an x-ray tube that moves above this detector. When imaging in DBT mode, a series of low dose projection images in which the whole breast is irradiated in each exposure, is made over a range of angles. These projection images are mathematically combined (reconstructed) to form a set of planes. Structures at a given height within the imaged object are brought into focus in the plane at the corresponding height within the reconstructed planes. There are several designs of systems for acquiring DBT images. These design features will affect the image quality, dose and methods required for QC. The specifications of some current DBT systems can be found in appendix 1.

As part of the image acquisition process, individual DBT projection images from the detector are corrected for bad pixels and non-uniformities of the radiation field, for non-uniformities in the x-ray sensitive layer in the detector, offset and gain of detector elements and geometrical distortion. The corrected projection images may then be pre-processed before they are used for the reconstruction. After reconstruction,

mammography specific post-processing may be applied. Alternatively, some of the mammography specific processing may be incorporated into the image reconstruction process.

1.2 System requirements

A DBT system should fulfil the requirements in the Integrating the Healthcare Enterprise (IHE) Digital Breast Tomosynthesis Profile. The reconstructed DBT image should be in breast tomosynthesis object (BTO) format.

DBT systems should be equipped with a zero-degree angle stationary mode in which it is possible to select the x-ray spectra used in ordinary DBT mode and use the same automatic exposure control settings as used clinically.

The **unprocessed** projection images must be made accessible for QC purposes and be provided in an easily accessible format e.g., a 'DICOM for processing' file for each projection image or one breast projection object (BPO) file for the entire sequence of projection omages. The order of the images in the series of projections should be easily identifiable. All DICOM tags regarding the exposure and tags used for the identification of the image should be included.

The series of unprocessed projection images in zero-degree angle stationary mode must also be supplied with all appropriate detector corrections and flat-fielding and be available in an easily accessible DICOM format.

The bad pixel map applied to the detector when used in tomosynthesis mode should be accessible to the user without intervention of a representative of the supplier/manufacturer and in easily accessible format.

1.3 QC tests: definitions and purpose

This protocol describes QC tests which are recommended at different points in the life-cycle of DBT systems.

Acceptance test

Test carried out after installation of a system, or after major modifications have been made to existing equipment

- to ensure compliance with specifications
- to ensure that the functional performance of the equipment meets established criteria
- to characterize the system
- to set reference values for QC parameters which will be followed over time.

Routine QC tests

Series of tests carried out at regular intervals (e.g., yearly, or half-yearly) during the lifetime of a system

- to ensure that the functional performance of the equipment continues to meet established criteria
- to detect changes in component performance or in overall system performance

Constancy tests

Series of tests performed at regular intervals (e.g., daily, or weekly) during the lifetime of a system

- to check long term stability.

Finally, relevant QC tests must be performed **after replacement of parts** of the DBT system, such as the detector, x-ray tube, filters, or software which might influence dose level and/or the quality of the images.

Table 1 Recommendation on which QC tests should be perform in acceptance, routine and constancy tests and after update or replacement of parts of the x-ray unit. X: recommended, O: optional.

QC tests	Acceptance	Routine	Constancy	Other
2 X-RAY SOURCE				
2.1 Focal spot motion	X	O		Relevant software change
2.2 HVL and tube voltage	X	X		X-ray tube or filter replacement
2.3 X-ray beam alignment and collimation	X	X		X-ray tube replacement
2.4 Tube output	X	X		X-ray tube or filter replacement
3 COMPRESSION				
3.1 Compression force	X	X		
3.2 Displayed breast thickness value	X	X		
4 AUTOMATIC EXPOSURE CONTROL				
4.1 Short term repeatability	X	X		X-ray tube replacement, detector replacement, relevant software change
4.2 Long term stability	X	X	X	Detector replacement, relevant software change
4.3 AEC performance	X	X		Detector replacement, relevant software change
4.4 Local dense area	X	O		Relevant software change
4.5 Exposure duration	X	O		Relevant software change
4.6 Guard timer/security cut-	X	O		Relevant software change

off				
5 DETECTOR CHARACTERISTICS				
5.1 Response function	X	O*		Detector replacement, relevant software change
5.2 Noise components analysis	X	O		Detector replacement, relevant software change
5.3 Detector element failure	X	X		Detector replacement, relevant software change
5.4 Uncorrected defective detector elements	X	X		Detector replacement, relevant software change
5.5 System projection MTF	X	X		Relevant software change
6 TECHNICAL IMAGE QUALITY 3D				
6.2 Technical image quality of the reconstructed 3D image	X	X		Detector replacement, relevant software change
6.3 MTF in the reconstructed image	O	O		Detector replacement, relevant software change
6.4 Artefact spread function	X	X		After relevant software changes
6.5 Geometric distortion	X	O		Relevant software changes
6.6 Missed tissue at chest wall side/at top and bottom of the reconstructed image	X	X		Detector replacement, relevant software change
6.7 Image homogeneity and artefact evaluation	X	X	X	X-ray tube, filter or detector replacement , relevant software change
7 DOSIMETRY				
7.1 Dosimetry	X	X		X-ray tube, filter or detector replacement, relevant software change

* If the system has a non-linear response, this procedure should be performed at each routine test.

1.4 Definition of action levels, limiting values and reference values

Action levels are specified for all test procedures in this protocol. Further, action levels are specified as either limiting values or reference values. Definitions for these terms are given below.

Action level

Value(s) of a QC parameter, for which corrective action is required if exceeded.

Reference value

The value of a QC parameter obtained with baseline images (typically at acceptance), which is used as reference for subsequent QC tests

Typical values

The typical value of a QC parameter based on measured data, mostly by the members and consultants of the WG. For some currently available DBT system, the amount of data to set limiting and typical values was limited, and in the future, other vendors and types of equipment will emerge on the market. Therefore, these values will be evaluated and adapted over time.

Limiting value

The maximum or minimum value of a QC parameter considered acceptable. Limiting values are either based on corresponding values for digital mammography or on measurements by the members and consultants of the WG.

Limiting values on average glandular dose

In this DBT protocol, a new breast dosimetry model is introduced. As a consequence, values calculated for average glandular dose (AGD) will not be comparable to AGD values calculated with current (or old) breast dosimetry models. The new dosimetry model is explained in more detail in paragraph 1.7.

[The following section on the limiting values for the new breast dosimetry is work-in-progress]

The limiting values for AGD using the new breast dosimetry are derived from the limiting values in the EUREF DM and DBT protocols and the EFOMP DM protocol (REFS). Using the x-ray spectra found in clinical practice for specific breast thicknesses for all major mammography unit manufacturers, the current (or "old") limiting values for average glandular dose have been converted to incident air Kerma using the current (or old) dosimetry models. These incident air Kerma values have been used as input to the new dosimetry model to obtain average glandular dose values using the same x-ray spectra as those at which the incident air Kerma was calculated. This relationship between the average glandular dose values of the current (old) and new breast dosimetry models have been used to set limiting values for the new dosimetry model. The resulting limiting values were controlled by using a large number of dosimetry measurements from QC tests on all major brands of DBT equipment.

As action levels and limiting values must be based on data and experience and the available data and experience at the point of publication of this protocol is still limited, an effort will be made to collect data and experience in a systematic manner in order to establish whether the action levels and limiting values given in this protocol are reasonable. This data will be used for future updates of the protocol.

1.5 QC and design of DBT systems

Different system design and implementations occur, for example, in the movement of the x-ray tube and/or the detector, the use or not of an anti-scatter grid, beam qualities used, and the detector readout sequence (Appendix 1: Specifications and geometry of common breast tomosynthesis systems). The test methods described in this protocol are intended to be applicable to all currently available DBT systems.

In practice, the implementation of DBT QC tests may differ from system to system. If DBT systems can perform both DBT and DM imaging, some measurements may be performed in DM mode. In those cases, it must be verified that all relevant (exposure) conditions are similar (e.g., target material and filter thickness) and that in the case of detector tests, the working of the detector is identical (e.g., binning of detector elements, response curve, and detector corrections). The measurement of x-ray beam parameters is a practical challenge when a system is operating in DBT mode with moving x-ray tube and pulsed exposures. Therefore, measurements of x-ray beam parameters, like half value layer (HVL), should be performed in the zero-degree angle stationary mode.

The pixel values in reconstructed DBT focal planes are related to tissue density, but a well-defined relationship with attenuation, like the Hounsfield units in CT imaging, does not exist. The pixel values in (unprocessed) projection images are assumed to have a linear relationship to the exposure at the image receptor (or can be linearized) and the images can be assumed to be largely shift invariant. Therefore, QC measurements such as detector response should be performed in the unprocessed ('For Processing') projection images.

Some DBT systems require a minimum compression force to perform an exposure in the clinical automatic exposure control (AEC) mode or to ensure the correct operation of the clinical AEC mode, see appendix 3.

For systems using variable exposure per projection image, it is important to check the exposure for each projection as this might influence both dose calculations and technical image quality parameters.

Following exposure and detector read-out, often not all of the charge traps in the convertor layer of the detector have been cleared. Lag and ghosting are the two main processes arising from any uncleared signal and may affect subsequently acquired images. Lag is the uncleared signal appearing in the next image and would potentially appear as a shadow of the previous image. Ghosting tends to be a longer term process due to energy traps that are not easily cleared, these traps generally occur during either a very large exposure to the detector, particularly if there is a highly attenuating object

in the beam then this will be 'burnt' into the detector or by repeated exposures of a similar type of object e.g. small paddle on a larger detector.

Ghosting will mostly clear over weeks or months, but can be temporarily hidden using flat fielding correction. In DM, there are methods for clearing the lag image in the detector between exposures. However, for DBT there is little time to clear the detector between successive read-outs. Lag can be quantified using a method given by Marshall et al (REF) was used to estimate the signal in the image due to lag and some example results are shown in Mackenzie et al (REF). A full quantification of the effect of lag and ghosting is difficult as the results are dependent on the history of the detector both long term and recent history. TMIST avoid quantification by undertaking a qualitative examination of artefacts in the reconstructed planes (REF). Any lag and ghosting artefacts present in the projection images will be in a fixed location, and thus would mainly be seen in the lower reconstructed planes and be blurred. It may be useful to characterise the lag of new systems, but there are no tests that are suitable for routine QC. The protocol does include a test to examine for artefacts in the reconstructed planes (6.6 homogeneity and artefact evaluation), partly due to the artefacts from lag and ghosting effects.

The test protocols must still account for potential adverse effects on the QC due to lag and ghosting. In several tests in this protocol, the 'first projection image of the DBT series' is used. This projection image will not be influenced by lag from previous exposures of the DBT series. If the first projection image serves as a pre-exposure with fixed tube current-exposure time, is used for calibration purposes, or differs in other ways from the other images in the series of projections, the second projection image should be used instead. Information on which projection image should be used for QC measurements for a selection of DBT systems can be found in appendix 2. It is important to protect the detector during some of the tests to prevent of an image of test objects or measuring equipment being burnt into the detector.

1.6 Assessment of the clinical acceptability and the technical image quality of DBT systems

One of the most important aspects of a breast imaging system is the ability to visualize all relevant structures in a breast. For a mammography system this means that both small objects (e.g., small calcifications) and low contrasts (e.g., small tumours in an early stage) should be visualized such that a radiologist can make an accurate diagnosis.

Currently, the test for clinical acceptability of each manufacturer's system for acquiring DBT images is undertaken using clinical trials but unfortunately, these trials are very expensive and time consuming. These studies were vital for demonstrating the clinical acceptability but will not necessary be practical for new versions of tomosynthesis systems and so methods are required to test the acceptability of new systems and

system upgrades/revisions. It may be that this can be done using virtual clinical trials, which are quicker and cheaper but still require considerable expertise and knowledge of the systems and might require more access to the systems (e.g., to insert projection images for the evaluation of a new reconstruction algorithm). Ideally, there needs to be practical testing that can be undertaken in a clinical environment.

As a surrogate for the assessment of a system's ability to visualize actual breast structures, measurements of technical image quality representing relevant clinical tasks can be performed. Such measurements could be performed using task-based methods, in which the efficacy with which a reader can perform a specified task is quantified. This task-based image quality assessment includes the following:

- phantom images acquired on the system of interest
- objects in the phantom for the task to be performed
- a (human or mathematical) observer to perform the task
- a figure-of-merit quantifying the ability to perform the task

It is worth discussing the equivalent testing regime for digital mammography. It has been shown that the threshold gold thickness of small details relates to cancer detection in digital mammography (add references, Mackenzie A, Warren LM, Wallis MG, Given-Wilson RM, Cooke J, Dance DR, Chakraborty DP, Halling-Brown MD, Looney PT, Young KC, The relationship between cancer detection in mammography and image quality measurements, Phys Med. 2016 Apr;32(4):568-74; Warren L M, Mackenzie A, Cooke J, Given-Wilson R M, Wallis M G, Chakraborty D P, Dance D R, Bosmans H and Young K C, Effect of image quality on calcification detection in digital mammography, Med Phys. 2012 Jun; 39(6): 3202–3213). Therefore, it is possible to create limiting values on the threshold gold thickness results for the acceptance of systems and monitor the quality of digital mammography systems throughout its lifetime. It should be noted that this method tests the system up to the point of image post-processing. Consequently, the testing of the effect of image processing on clinical image quality is not included.

The scientific knowledge of testing digital mammography systems was built over many years. Ideally, a similar testing regime for the image quality of DBT should be created. The testing regime should be able to judge if a new system is clinically acceptable and be sensitive to changes in the DBT system and predict any detrimental effect on cancer detection.

A number of phantoms have been developed or can be adapted for testing the technical image quality of DBT systems. Each of these phantoms will have their own advantages and disadvantages.

Most phantoms currently used to quantify image quality in 2D mammography have homogeneous backgrounds and therefore do not incorporate the removal of overlying

structures in the determination of technical image quality and cannot be used to (fully) quantify the image quality of the reconstructed image. However, these phantoms could have a role in constancy testing and to quantify some aspects of technical 3D image quality, especially the ability to visualize small details by a DBT system.

Using human observers to perform the task (scoring the phantom images) is labour-intensive and the results suffer from inter and intra observer variation. These issues make it difficult to use human readers for routine QC purposes. One means of mitigating this problem is through the use of model observers (MOs), where a series of numerical operations are applied to patches of image data (i.e. regions of interest (ROIs) extracted from the image). The MO algorithm is applied to sets of signal-present and signal-absent images, resulting in distributions of decision variables for the signal present and signal absent data. The detectability of the signal can be calculated from these distributions (see Appendix XX for more details) and used as a figure-of-merit for technical image quality. The use of model observers is still under development and/or under validation.

Due to the circumstances described above, this protocol recommends undertaking baseline tests of technical image quality, such as detection of small detail signal difference to noise ratio and z-resolution measurements, to set reference values that can be used to track changes in image quality that may affect clinical outcomes. For the acceptance of DBT systems into clinical practice, it will be necessary to compare against results from type testing, published results or those from other systems already installed either at that institution or wider scientific community. Also, as in DM there should be periodic clinical audit on the quality of breast images from DBT.

Using simple QC test objects is a practical solution to ensuring the quality of DBT images until better testing regimes are created and validated. Some analogy can be made with signal-difference-to-noise ratio (SDNR) measurements in DM where the absolute results are not directly related to cancer detection but SDNR data are useful for tracking changes in parameters that influence large area signal and a simple measure of image noise. It should be noted that SDNR data can only be compared with other systems of the same model (Ref: IAEA DM protocol). These simple QC tests are not undertaken in isolation; a range of tests on the characteristics of the detector and quality of x-rays must also be performed. Note that the standards set for the visibility of details in DM images cannot be applied to DBT.

A more detailed presentation concerning test phantoms and task-based imaging studies is given below.

1.7 Phantoms to quantify technical image quality of the reconstructed DBT image

Phantoms used to quantify the technical image quality of the reconstructed 3D image should ideally include a number of design features:

a) They should resemble a breast in shape, attenuation, and other characteristics to a large extent, preferably taking the form of an anthropomorphic phantom. The extent to which the phantom must represent breast structure and lesion simulating targets is under investigation but it is expected that target detection results generated by phantom should correspond to detection performance of similar targets in a group of real, typical breasts. Reconstruction algorithms can be affected by the object being imaged, phantoms insufficiently resembling breasts may be reconstructed differently compared with clinical images. Furthermore if the AEC is to be used when imaging the phantoms, photon attenuation and scatter should be similar to that of breasts. Phantoms should be designed such that the AEC responds to the phantom in a manner similar to breasts.
b) The phantoms should be able to assess the degree to which a DBT system suppresses background structures surrounding a lesion and that influence lesion detection. The phantoms should therefore have a 3D structure rather than be homogenous. The structure should mimic breast structure or have an equivalent effect on the detectability of lesion simulating targets in the phantom.
c) The phantoms should not contain high-attenuating materials (e.g. lead or stainless steel), apart from those simulating calcifications, as such materials can produce artefacts.
d) Image processing can enhance the appearance of lesions of interest. Therefore, embedded objects to be detected should have the appearance of these types of lesions.

Currently, phantoms with all these characteristics remain under development and are not yet available for QC testing. The use of existing phantoms to quantify some aspects of 3D technical image quality is possible, however, the following limitations should be taken into consideration:

a) The phantoms have homogeneous backgrounds and therefore do not assess the ability of a system to suppress overlying breast structures.
b) The targets are generally not designed to appear like clinically realistic lesions.
c) Different DBT systems use different acquisition methods and reconstruction algorithms, resulting in images where clinical image and test object acquisitions have different appearances. There can be large differences in the appearance or texture of image noise and artefact suppression algorithms can affect the z-resolution. As a result, results from QC tests can differ greatly between two clinically acceptable units.

d) The image reconstruction might take breast image characteristics into account, leading to potential differences in reconstruction of phantom images compared to clinical images.
e) The tests will include image processing, which is not considered in the current DM protocols. Changes in the reconstruction or processing software may cause changes in the QC results.

Several physical anthropomorphic breast phantoms have been developed based on digital models or breast-image data (Glick and Ikejimba, 2018; Bliznakova, 2020). Breast-image-based phantoms are typically quite realistic but might have limited spatial resolution (Badal, Clark and Ghammraoui, 2018; Schopphoven *et al.*, 2019). Model-based physical phantoms can have higher spatial resolution, but structures might be less realistic. There may also be some limitations in the 3D printing manufacturing process with regard to resolution and the differences in attenuation of the materials which can be printed (Rossman *et al.*, 2019).

There are also phantoms available that are not anthropomorphic but contain 3D background structures such as randomly placed spherical structures embedded in water or glandular and adipose tissue equivalent materials mixed in a 3D structure (Cockmartin *et al.*, 2017; Glick and Ikejimba, 2018). These may be practicable alternatives to anthropomorphic phantoms.

For task-based image quality studies, phantoms used should have inserted signals that can simulate the detection of microcalcifications, masses or linear structures. Ideally, an extensive technical image quality evaluation test should incorporate all three tasks as the ability of any system to visualize these features might differ.

1.8 New breast dosimetry model and phantom

The current (or old) breast dosimetry model commonly used in Europe was developed in 1990 by Dance (Dance, 1990)in which the method and conversion factors were given to estimate average glandular dose from incident air Kerma. In the following years several updates were published to accommodate additional target filter combinations, more realistic composition of breast tissue as a function of breast thickness and the use of other technologies such as DBT and contrast mammography(Dance, Skinner, *et al.*, 2000; Dance, Young and van Engen, 2009; Dance, Young and Van Engen, 2011; Dance and Young, 2014). The Dance model makes assumptions on skin composition and thickness (adipose tissue, 5 mm thick) and the distribution of breast tissue (homogeneous mixture of adipose and glandular tissue).

With the emergence of 3D imaging technologies in breast imaging, it became possible to determine the location of fibroglandular tissue in breasts. This has facilitated the

estimation of average glandular dose for a population using real breast tissue distributions which, in turn, led to the understanding that the existing breast dosimetry model resulted in an overestimation of AGD. The conclusion was that the breast dosimetry model required adaptation and consequently the dose values associated with the radiation risk estimated for mammography (2D and DBT) will differ from before. Note that this does not mean that the risk for the women undergoing mammography ahs changed, it is our estimation of the risk that changed.

In this protocol, measurements and calculations follow the new dosimetry model. AGD values calculated using the new breast dosimetry model will differ from AGD values calculated with the same exposure factors using the 'old' dosimetry model and cannot be directly compared.

Note: for the new breast dosimetry model, the measurement point is located at 5 cm from chest wall side, laterally centred on the breast support table, as opposed to 6 cm from chest wall side, laterally centred in the old model. To ensure consistency in this protocol, this new position has been adopted for all relevant measurements and in an updated definition of the reference ROI.

In recent years, AEC systems of DM and DBT systems have become increasingly advanced. For some devices, this means that breast image characteristics are considered when determining the required exposure to a breast. In practice this means:

(1) the exposure factors selected by the AEC in a test setting might differ from the exposure factors chosen when imaging real breasts because the AEC responds differently to homogeneous slabs used in AEC QC tests compared to breasts.

(2) when imaging QC phantoms, the use of AEC modes designed specifically for exposure of test phantoms might be necessary. For such AEC modes, part of the functionality which is active when imaging actual breasts is disabled and therefore not tested.

To counter these limitations, the new breast dosimetry model includes the development of a phantom designed to trigger the AEC as would a typical breast. As this phantom is currently neither widely available nor yet in common use, therefore all relevant QC test procedures alternatively come with the option of using existing phantoms. (Polymethyl methacrylate (PMMA) slabs and spacers or slabs of PMMA and Polyethylene (PE))

Remark: When this report is published, the new breast dosimetry model might not be implemented by all manufacturers, meaning that the AGD value in the DICOM header might still be calculated according to the 'old' methods. If national or local QC protocols require a comparison between the AGD calculated by the system and by the medical physicist, then knowledge of the dosimetry model used by the manufacturer will be required.

1.9 Optimization of performance

One of the tasks of the medical physicist is to participate actively in the optimization of imaging equipment. This includes the selection of the clinical acquisition mode, the selection of image processing settings, and the optimization of manual exposure tables for implant imaging. The QC tests in this protocol could be used as a tool for optimization, although the medical physicist should always check whether a specific QC test is suitable for his/her purpose or that adaptation is required.

Physicists cannot meaningfully contribute to the optimization process without spending sufficient time in the clinic, allowing the physicist to understand the needs of the clinicians and how the equipment is used in practice. The physicist should review clinical images together with clinicians to get a basic understanding of the concept of good quality clinical images and its relationship with exposure factors and/or image processing settings. This will facilitate useful optimization of equipment and an understanding of the clinical and medical consequences of specific malfunctions and/or artefacts on the clinical images.

It is strongly encouraged that medical physicists should be allocated sufficient time and resources in the clinic as this will ultimately support the provision of high quality health care.

1.10 Software

The working group will not release software for the QC tests in this protocol, but will give links on the website (www. …) to software provided by third parties.

QC tests

2 X-ray source

2.1 Focal spot motion

Introduction

For DBT systems in which the focal spot is in motion while the target is emitting x-rays, the effective focal spot size is extended in the direction of tube motion, leading to increased geometric blurring in the direction of the tube movement. This source of blurring must be assessed for such x-ray systems. The degree of blurring depends on the exposure time per projection and on the transit time of the tube around the centre of rotation (CoR). Some systems keep the x-ray exposure time constant as the tube current-time product (mAs) is changed, others vary the exposure time and change the tube current-time product and/or tube voltage. For this latter system type, geometric blurring increases with increasing tube current-time product and is therefore larger for thicker breasts.

All systems try to keep the exposure time low, given the tube loading constraints which apply. The exposure time per projection can be measured directly with a dosemeter or can be taken from the image DICOM header, provided this has been verified as accurate. See section 4.5 for more details on this.

Definitions

The focal spot motion length is the path length in the direction of tube motion over which x-rays are emitted while the x-ray tube is moving, for a single projection image.

Purpose

The visibility of small structures like small calcifications and spicules is a vital aspect of mammography imaging. This type of detail can be lost due to system blurring and therefore quantification of blurring due to the movement of the x-ray tube during exposure is important.

Test equipment

- A suitable exposure time meter, alternatively the exposure time value in the DICOM header can be used provided this has been confirmed to be accurate.
- Standard test block

Test frequency

- At acceptance
- Optional at subsequent routine QC tests
- After relevant software change

Test procedure

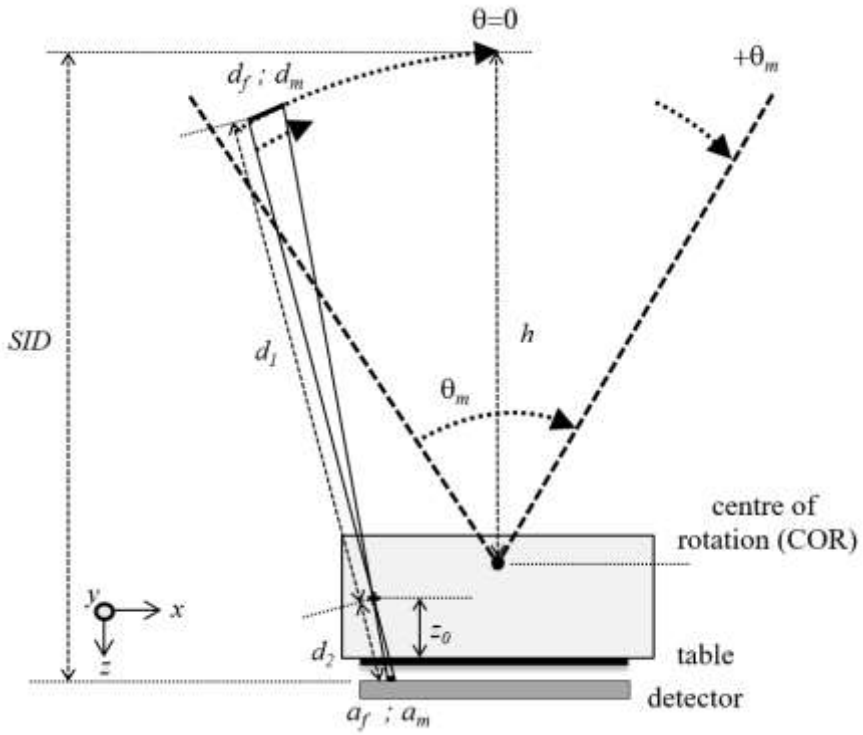


Figure 1 Definition of distances for calculation of focal spot motion. The term d_f is the dimension of the focal spot, the term d_m is the extended focal spot size due to motion of the anode during exposure (for systems with tube motion during exposure). The term d_1 is the distance from the focus to the object of interest, the term d_2 is the distance from this object to the detector entrance plane. Θ_m is the angular range of the imaging system in question. As an example, geometric blurring is shown for an object at some height z_o above the breast support table.

- For an image of the standard test block in clinically used AEC mode, measure the exposure time of a projection image (t_{proj}) or take the exposure time value in the DICOM header
- Calculate the focal spot motion length (d_m) using:

$$d_m = h\,\theta_m \frac{t_{proj}}{t_{scan}} \qquad (1)$$

The term θ_m is the angular range for the system, expressed in radians, t_{scan} is the total scan time.

- Compare focal spot motion length (d_m) against focal spot size (typically 0.45 mm at the reference position) to have an idea of the influence of geometric blurring due to focal spot motion.
- Compare focal spot motion length (d_m) with the reference value from acceptance.

Remark: A system with continuous tube motion may be updated to use shorter exposure times, resulting in a reduction in the focus motion length. These new, lower values should be adopted as new reference values.

Remark: The blurring, expressed as the projected focal spot travel length (a_m) of an object at some point z_0 above the breast support table from the extended focal spot size due to focal spot motion (d_m) can be calculated using lengths d_1 and d_2 as:

$$a_m = d_m \frac{d_2}{d_1} \quad (2)$$

Remark: For the current continuous motion DBT systems, a + 20% change in focal spot motion length (d_m) will lead to approximate changes of -7% and -12% in the spatial frequency for the 50% value of the system projection MTF, at heights of 40 mm and 60 mm above the table, respectively.

Action levels

The focal spot motion length (d_m) should not change by more than +20% compared to the reference value; investigate AEC programming and system projection MTF if this occurs.

2.2 HVL and tube voltage

Introduction

The radiation quality of the x-ray beam is one of the primary factors influencing image quality and dose. X-ray generators used in digital mammography are very stable but are subject to calibration at installation and as part of routine service. Also, the x-ray filters or deployment mechanism can be damaged, requiring replacement. Therefore, it is important to ensure that the correct filter material and thickness is in place.

Definitions

Radiation quality is determined by x-ray tube voltage, target material and added filtration in the x-ray beam.

Purpose

To determine the HVL values to be used in breast dosimetry. To check whether HVL for the entire range of clinically used beam qualities (target/filter/kV combinations) is within the typical range. To check the accuracy of the tube voltage.

Test equipment

- Calibrated x-ray multi-meter and/or ion-chamber dosimeter with aluminium filters

Test frequency

- At acceptance and subsequent routine QC tests
- After x-ray tube replacement
- After filter replacement

Test procedure

Method 1: using a calibrated x-ray multimeter to measure HVL and tube voltage

Figure 2 Setup of the HVL test using a calibrated x-ray multimeter

- In practice, these measurements are performed simultaneously with tube output measurements for dosimetry, therefore the compression paddle should be positioned as high as possible and the x-ray beam should be collimated to the area of the radiation sensor.
- Protect the detector using a radiopaque sheet.
- Position the radiation sensor at the reference point, see figure 2.
- Measure peak tube voltage (kV_p) and HVL for a range of clinically used x-ray spectral points [kV;Target;Filter] in zero-degree angle stationary mode.

Method 2: using an ion chamber and aluminium filters to measure HVL

Figure 3 Setup of the HVL test using ion chamber and aluminium filters

- Protect the detector using a radio-opaque sheet.
- Position the radiation sensor at the reference point, see figure 3.
- To establish HVL, the air kerma should be measured in scatter-free conditions, with and without Aluminium foil in the beam in order to establish the thickness of Aluminium needed to reduce the air kerma by greater than 50%.
- Position the compression paddle as high as possible and use the compression paddle to support the Aluminium foil.
- Collimate the x-ray beam to an area slightly larger than the area of the radiation sensor.

- Make a manual exposure in zero-degree mode with the compression paddle in place without added Aluminium foil and record air kerma.
- Systematically add increasing thickness of Aluminium foil to the beam and keep repeating the manual exposure until the air kerma is ≤ 50% of the air kerma without Al foil.
- Determine HVL using the equation:

$$HVL = \frac{X_1 \cdot \ln\left(\frac{2 \cdot Y_2}{Y_0}\right) - X_2 \cdot \ln\left(\frac{2 \cdot Y_1}{Y_0}\right)}{\ln\left(\frac{Y_2}{Y_1}\right)} \quad (3)$$

where Y_0 is the air kerma without additional attenuation and Y_1 and Y_2 are the air kerma readings with added aluminium filter thicknesses of X_1 and X_2 respectively.

- Repeat the measurement for a range of clinically used x-ray spectral points [kV;Target;Filter].

Note: Filters used in DBT should be tested at least once in DBT mode and the results compared to those with the same filters in 2D mode.

Action levels

Tube voltage (kV) error should be ≤ 1kV

HVL should be within typical range for system type, see table 2.

Table 2 Typical HVL values

	HVL (mm Al) for target filter combination							
kV	Mo Mo	Mo Rh	Rh Rh	Rh Ag	W Rh	W Ag	W Al (0.5mm)	W Al (0.7mm)
25	0.32 ± .02	0.38 ± .02	0.37 ± .02		0.50 ± .03	0.51 ± .03	0.34 ± .03	0.42 ± .03
28	0.35 ± .02	0.42 ± .02	0.42 ± .02	0.46± .02	0.53 ± .03	0.58 ± .03	0.39 ± .03	0.49 ± .03
31	0.38 ± .02	0.45 ± .02	0.45 ± .02	0.51 ± .02	0.56 ± .03	0.61 ± .03	0.44 ± .03	0.55 ± .03
34	0.40 ± .02	0.47 ± .02	0.47 ± .02	0.55 ± .02	0.59 ± .03	0.64 ± .03	0.49 ± .03	0.61 ± .03
37				0.58 ± .02	0.62 ± .03	0.67 ± .03	0.53 ± .03	0.66 ± .03

2.3 X-ray beam alignment and collimation

Introduction

In x-ray imaging, the x-ray beam and detector should be aligned. This reduces unnecessary dose to the women undergoing mammography and loss of clinical information due to parts of the detector being unexposed. This is most important at the chest wall side. For systems which do not adjust the collimation of the x-ray field for each projection image, the x-ray field will extend over the lateral edges of the detector to prevent loss of information. It is difficult to quantify how much the x-ray field extends over the edge of the detector as the projection images are low dose images. Some systems use dynamic collimation so that the x-ray field of individual projections coincide with the detector area.

Definitions

The distance between the edge of the x-ray field and the edge of the image is taken as a measure of x-ray beam alignment.

Purpose

Reducing unnecessary dose to the women and avoiding loss of information due to unexposed parts of the detector.

Test equipment

- Lead rulers and self-developing film
- Alternatively: a suitable digital x-ray ruler

Test frequency

- At acceptance and subsequent routine QC tests
- After x-ray tube replacement

Test procedure

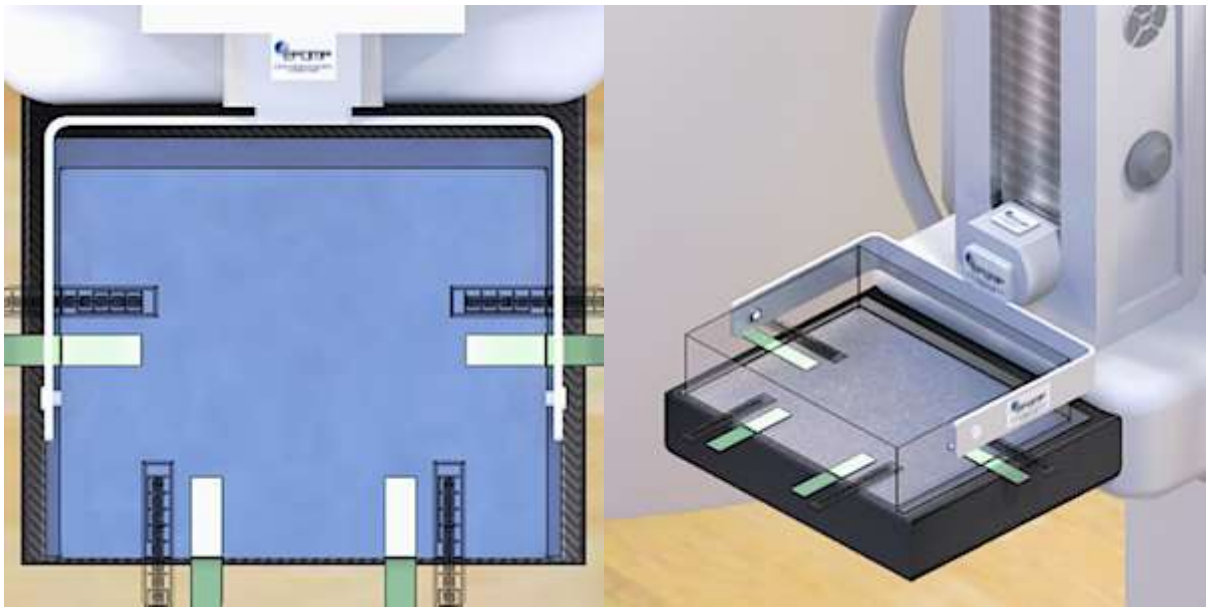


Figure 4 Setup for the x-ray beam alignment and collimation test

- Position lead rulers on the breast support table to mark the chest wall edge of the breast support table as indicated by the light field as shown in figure 4.
- Mark the middle of two pieces of self-developing film and position them on the breast support table with the mark aligned with the lead ruler.
- Make an exposure in DBT mode to give sufficient blackening of the film, without saturating the detector. This may be achieved by making multiple exposures, or by placing attenuating material (for example a 2 mm thick aluminium plate) between the self-developing film and the detector and using a large exposure.

Analysis

- Evaluate the coincidence of the x-ray field and the tomosynthesis image by finding the position of the x-ray field relative to the light beam from the self-developing film, and the position of the light beam relative to the image from the image of the lead rulers in the reconstructed focal plane in which the rulers are in focus. It may be helpful to examine the projection images.

For systems with dynamic collimation, the procedure described above, but with the rulers at lateral sides, can be used to check the accuracy of the dynamic collimation.

Action levels

The x-ray field must not extend more than 5 mm beyond the edge of the image receptor and the reconstructed tomosynthesis image. At the lateral sides the x-ray field should not extend beyond the breast support table.

2.4 Tube output

Introduction

Measurement of tube output is necessary to establish the air kerma incident to the breast used in breast dosimetry.

Tube output should be stable and consistent for all exposures.

Definitions

Tube specific output (μGy/mAs) is the incident air kerma per tube current-time product at the breast support table surface, including the attenuation of the compression paddle, typically corrected by the inverse square law to 1m distance from the focal spot (μGy/mAs@1m).

Purpose

To facilitate the calculation of incident air kerma (mGy) at the breast surface for all relevant compressed breast thickness from the tube current-time product (mAs), see section 7.1 on dosimetry.

Test equipment

- Calibrated x-ray dosimeter or ion-chamber dosimeter

Test frequency

- At acceptance and subsequent routine QC tests
- After x-ray tube replacement
- After filter replacement

Test procedure

Figure 5 Setup of the tube output test

- The compression paddle must be positioned as high as possible.
- Protect the detector using a radio-opaque sheet, see figure 5.
- Perform measurements in zero-degree angle stationary mode with the radiation sensor positioned at the reference point.
- Measure tube output (mGy) for the range of radiation qualities used in the dosimetry section [kV;Target;Filter].

  Interpolation may be performed between tube voltage measurements.

- Perform 5 measurements of the tube output using the x-ray spectrum selected by the AEC for the standard test block to determine short term repeatability.

Note: if an ion-chamber dosimeter without backscatter correction is used, this should be taken into account when measuring incident air kerma. Consult the manual of the dosimeter for the correct setup.

Action levels

Tube output is measured for breast dosimetry purposes but should be within typical range for the system type.

The variation of tube output for subsequent exposures of the standard test block should be ≤ 5%.

3 Compression

3.1 Compression force

Introduction

Compression of the breast during image acquisition is important for reasons of image quality and dose. However, breast compression is uncomfortable and can be painful. It is therefore important that compression should be sufficient and that maximum compression is limited to avoid excessive pain. Furthermore, any cracks and sharp edges on the compression device may cause unnecessary pain or injury to the women undergoing mammography.

Definitions

The compression force is the force applied to the breast in order to reduce the thickness and reduce breast movement. It is well established that firm breast compression is required to ensure acceptable image quality

Purpose

To verify the applied maximum compression force and any decline in compression force during one minute of compression.

Test equipment

- Compression force meter

Test frequency

- At acceptance and subsequent routine QC tests

Test procedure

- Inspect all compression paddles for cracks, sharp edges, and damage.
- Position the compression force meter on the bucky, such that compression force is measured at the reference point.
- A PMMA slab or a steel plate may be used to protect the bucky table and compressible material may be used to protect the compression paddle.
- Measure the maximum motorised compression force.
- Record any loss of compression force over 1 minute under compression.

Action levels

Maximum motorized compression force should exceed 150N.

Maximum motorized compression force must not be greater than 200N.

The decrease in compression force within 1 minute must not exceed 10N.

No damage, sharp edges and/or cracks should be present on any compression paddle.

3.2 Displayed breast thickness value

Introduction

The accuracy of the displayed thickness of the breast is important:

(1) Mammography systems use the displayed thickness of the breast to determine the x-ray spectrum and the target image quality in fully automatic mode.
(2) For the assessment of clinical breast dose, breast thickness is used to determine glandular dose.

Definitions

The thickness displayed on the system and given in the DICOM header of the images is defined as the displayed thickness value. It is acknowledged that the displayed thickness is dependent on the method of calibration by a manufacturer and that deviations between measured and displayed values might (partly) be attributed to the difference in methods of measurement between calibration and the measurement given below.

Purpose

To verify the displayed thickness value.

Test equipment

- Compressible foam blocks of dimensions 180 mm × 240 mm in which a strip has been cut out to allow measurement of compressed thickness, see figure 6.
- Calliper, ruler or other appropriate device

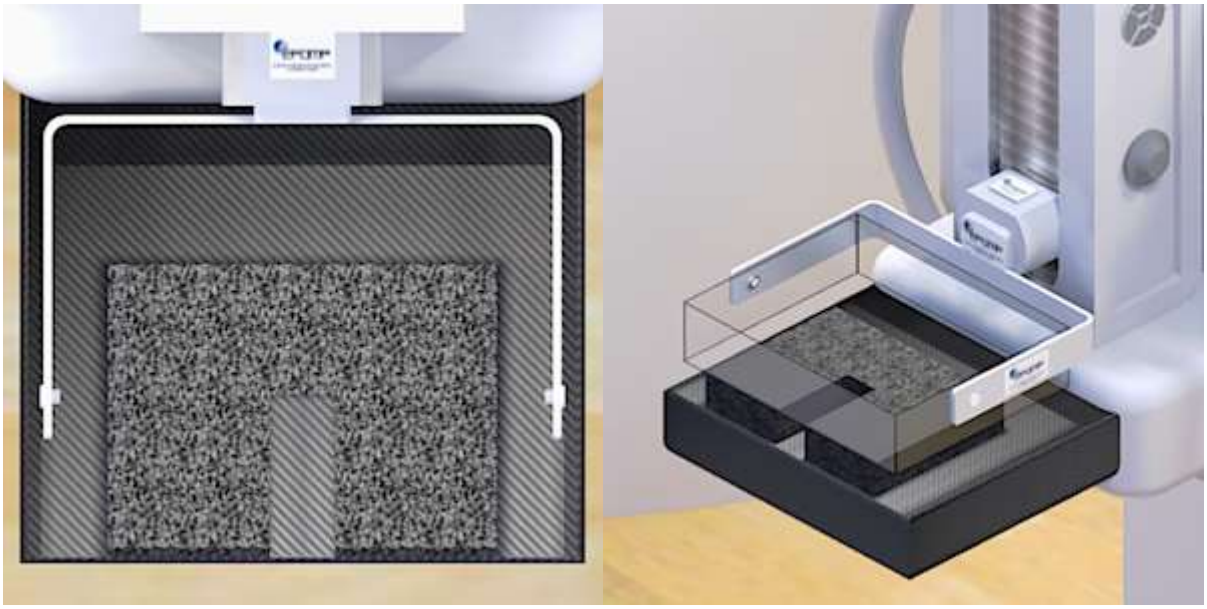
Test frequency

- At acceptance and subsequent routine QC tests

Test procedure

- Apply a compression force of 100 N to the block of compressible foam, see figure 6.

Figure 6 Setup for the displayed breast thickness value test



- Record the thickness indication and measure thickness at the reference point with an appropriate device (for example a calliper and ruler).
- Perform this measurement with several blocks of foam such that thicknesses can be verified from 20 to 90 mm.

Action levels

If the displayed and measured thickness deviate > 2 mm, correction factors need to be applied when determining clinical breast dose. (Faulkner and Cranley, 2005).

4 Automatic exposure control

4.1 Short term repeatability

Introduction

In mammography (screening), it is important that clinical images are comparable in a set of images from one patient/client. For the mammography system this means that the system should always give similar exposures if the same object is imaged, and that the perception and quality of the images is similar.

The AEC in DBT systems measures the signal on the detector after a low dose pre-exposure and use a small detector area with lowest detector signal or lowest SNR to determine the exposure factors (kV, mAs) for the actual exposure.

Definitions

The variation in exposure between a series of images of the same test object is taken as a measure of short-term repeatability.

Purpose

To check the short-term repeatability of the AEC system. The same images can be used for the evaluation of image homogeneity and presence of artefacts (see 6.7)

Test equipment

- Standard test block covering the whole detector

Test frequency

- At acceptance and subsequent routine QC tests
- After x-ray tube replacement
- After detector replacement
- After relevant software change

Test procedure

Figure 7 Setup for the short term repeatability test

- Position the standard test block on the bucky. For some systems an area with full irradiation at lateral and nipple sides is required, see appendix 3.
- Position the compression paddle in contact with the block.
- Apply a compression force of 100 N.
- Select the AEC mode clinically used and make an exposure in DBT mode. For systems in which the clinically used AEC mode functions similarly in DBT and zero-degree angle stationary mode, exposures can also be made in the zero-degree angle stationary mode.
- Record the exposure settings (anode/filter combination, tube voltage, current–time product). Repeat this procedure 4 times.

Analysis

- If the system has a non-linear response, the images need to be linearized.
- Measure the MPV and standard deviation (SD) in the reference ROI on the first projection image of the 5 scans, see appendix 3.
- Calculate the SNR (MPV/SD) in the first projection image of the 5 scans.
- Calculate the average value of the current–time product (mAs) and SNR.
- Calculate the *variation* of both parameters as the maximum value of the differences between the average value and each individual value divided by the average value (expressed in %).

Note: If it is noticed that the system switches between x-ray 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.

Action levels

Variation in total current–time product (mAs) ≤ 5%

Variation in SNR ≤ 10%.

4.2 Long term stability

Introduction

In mammography (screening), it is important that clinical images are comparable in a set of images and between sets of images. This means that the system should always give similar exposures if the same object is imaged and that the perception and quality of the images is similar.

Due to aging or malfunctioning of a mammography system, a decrease in quality might occur. In practice, this could mean that some quality control parameters change over time. This might negatively impact the visibility of structures in clinical images and change the perception of images.

The AEC in DBT systems measures the signal on the detector after a low dose pre-exposure and use a small detector area with lowest detector signal or lowest SNR to determine the exposure factors (kV, mAs) for the actual exposure.

Definitions

Long term stability is defined as the deviation of the incident air kerma (or tube current-exposure time product) and the mean pixel value and SNR in the reference ROI over time.

Purpose

To check long term stability of mammography equipment.

Test equipment

- Standard test block covering the whole image receptor

Test frequency

- At acceptance and subsequent routine QC tests
- After detector replacement
- After relevant software change

- Beside evaluating long term stability during QC tests, it is advised to perform this test regularly in clinical practice (daily or weekly).

Note: for daily or weekly QC this test can be combined with test 6.6 Image homogeneity and artefact evaluation.

Test procedure

Figure 8 Setup for the long-term stability test

- Position the standard test block on the bucky. For some systems an area with full irradiation at lateral and nipple sides is required for the clinically used AEC to function properly, see appendix 3.
- Position the compression paddle in contact with the block.
- Apply a compression force of 100 N.
- Select the AEC mode clinically used and make an exposure in DBT mode. For some systems for which the clinically AEC mode functions similar in DBT and zero-degree angle stationary mode, it is also possible to make exposures in the zero-degree angle stationary mode.

- Record the exposure settings (anode/filter combination, tube voltage, current–time product).
- Repeat this procedure at least 4 times during a QC test.

Analysis

- If the system has a non-linear response, the images need to be linearized.
- Measure the MPV and standard deviation (SD) in the reference ROI on the first projection image, see appendix 3.
- Calculate the SNR (MPV/SD) in the first projection image.
- Calculate the average value of the current–time product (mAs) and SNR.
- Calculate the *variation* of both parameters as the maximum value of the differences between the average value and each individual value divided by the average value (expressed in %).

Action levels

Variation in the reference ROI: pixel value ≤ ± 10%, SNR ≤ ± 10%,

Variation between the incident air kerma (or tube current-exposure time product) between daily/weekly images ≤ ± 10%.

4.3 AEC performance

Introduction

In mammography (screening), it is important that clinical images obtained with sufficient pre-defined image quality and within appropriate dose levels. This is ensured by the automatic exposure control (AEC), which adjusts the exposure based on the attenuation characteristics (thickness and composition) of individual breasts.

In QC procedures, it is not possible to simulate all clinically encountered breast thicknesses and compositions to evaluate the AEC performance. Therefore, a subset of simulated breasts is used in the method described below.

Clinical image quality and dose levels should preferably be reviewed together periodically with clinicians.

The AECs in DBT systems measure the signal to the detector after a low dose pre-exposure and use a small region of the detector that has the lowest detector signal or lowest SNR to determine the exposure factors (kV, mAs) for the main exposure.

Definitions

The automatic exposure control device is intended to provide sufficient image quality at appropriate dose levels. In this QC test, SDNR is used as a measure of image quality for a series of images of simulated breasts over a clinical range of composition and thickness.

Purpose

To check the performance of the AEC using a set of phantoms simulating breasts of different thickness and composition. Three alternative methods are proposed. Method 1 is based on the universal dosimetry phantom (ref). Method 2 follows the procedure proposed for digital mammography systems in (ref) and requires readily available QC equipment. Method 3 is based on the use of a combination of PMMA and polyethylene (PE) slabs (Bouwman, 2013). Dosimetry procedures to calculate average glandular doses for the three methods are described in the Dosimetry section.

Test equipment

Method 1: Dosimetry phantom

- Aluminium sheet of 10mm x 10mm side and 0.2 mm thick
- 1 baseplate 20 mm thick to simulate the glandular tissue of the 50 percentile breast
- Seven additional plates of 10 mm thickness simulating fatty tissue

Method 2: PMMA slabs and spacers

- Aluminium sheet of 10mm x 10mm side and 0.2 mm thick
- Seven PMMA plates of 10 mm thickness and one 5 mm thick PMMA plate.
- A set of spacers with thicknesses of 2 mm (2x), 5 mm (2x), 8 mm (2x) and 10 mm (4x)

Method 3: PMMA and PE slabs

- Aluminium sheet of 10mm x 10mm side and 0.2 mm thick
- Five PMMA plates with thicknesses (in mm): 20.0, 27.5, 30.0, 32.5 and 35.0.
- Seven PE plates (density = 0.94 g cm^{-3}) with thicknesses (in mm): 2.5, 10.0, 17.5, 27.5, 37.5, 47.5 and 55.0.

Test frequency

- At acceptance and subsequent routine QC tests
- After detector replacement
- After relevant software change

Test procedure

Figure 9 Setup for the AEC performance test, method 1

Method 1: Dosimetry phantom

- Position the base slab of the dosimetry phantom on the bucky.
- Position the aluminium sheet of dimensions 10x10 mm and 0.2 mm thick at the reference position, as shown in Figure 9.
- Place the compression paddle in contact with the base slab and apply a compression force of 100 N.
- Make a DBT exposure of the phantom in the clinically relevant AEC mode.
- Repeat the procedure for phantom thicknesses up to 90 mm thickness.

Remark: When the Al sheet interferes with the AEC sensor, the exposure can be made in manual mode with settings as close as possible to the clinical AEC settings.

Method 2: PMMA slabs and spacers

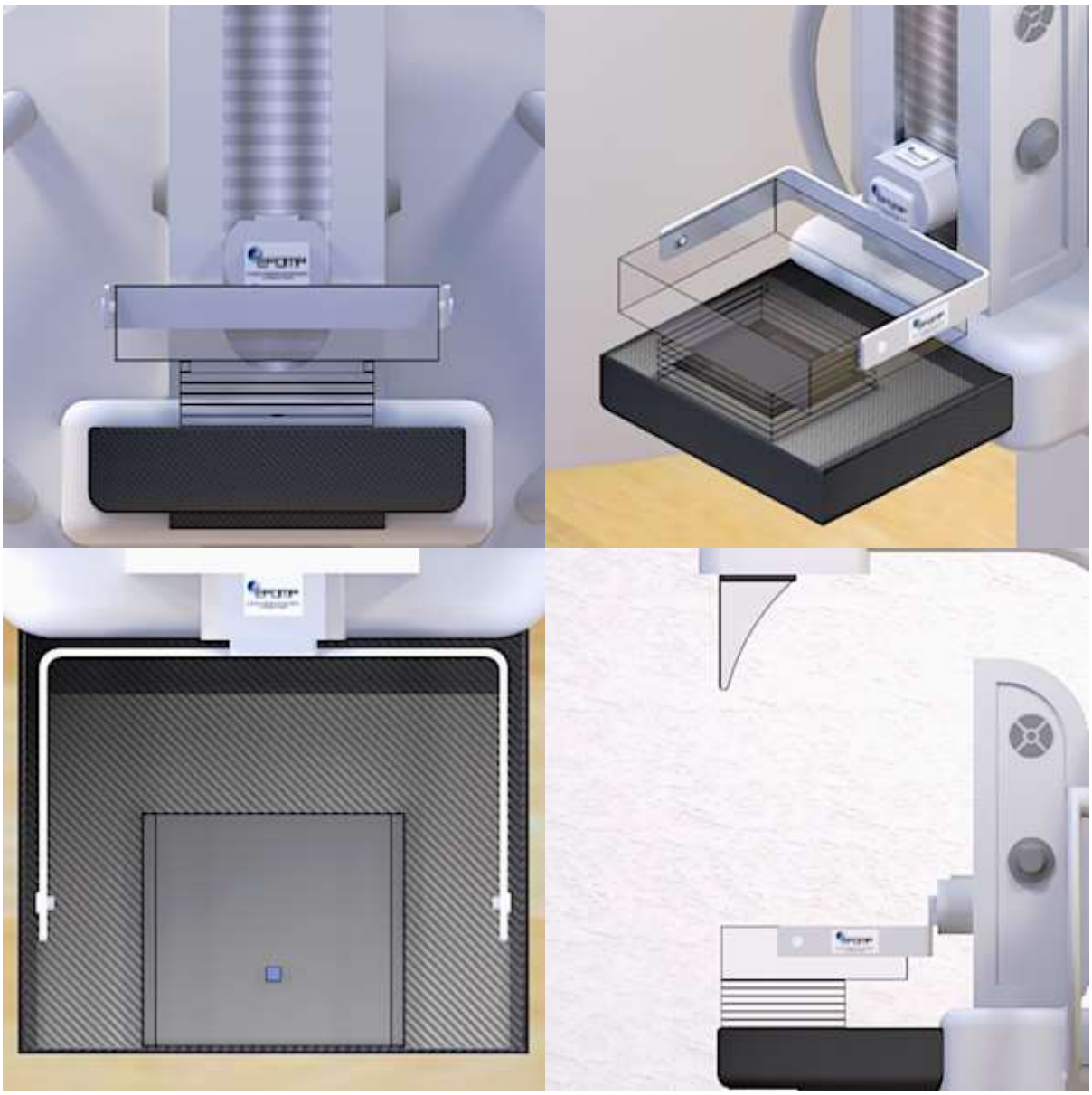


Figure 10 Setup for the AEC performance test, method 2

- Position one 10 mm thick PMMA plate on the bucky. For some systems the phantom should not completely cover the FOV area. For these systems an area with full irradiation at lateral and nipple sides is required for the clinical AEC to function properly, see appendix 3.
- Position the aluminium sheet of dimensions 10x10 mm and 0.2 mm thick at the reference position, as shown in Figure 10.

- Position a second 10 mm thick PMMA plate on top of the first plate taking care not to displace the Al sheet (Figure 10).
- Place the compression paddle at the height given in Table 3 for 20 mm of PMMA to obtain the thickness of the equivalent breast with similar attenuation and apply a compression force of 100N.
- Make a DBT exposure of the PMMA stack in the clinically relevant AEC mode.
- Repeat the exposure for the PMMA thicknesses according to Table 3 by adding additional slabs of PMMA on top of the stack.
- The compression paddle should be positioned at the height given in Table 3. This is achieved by leaving an air gap between the PMMA plates and the compression paddle. If compression is necessary to make an exposure, then spacers should be used, see appendix 3. They must be positioned such that they do not reduce transmission of x-rays to the central and chest wall regions of the image at any tube angle. This may be achieved by placing spacers at far lateral sides or along the back edge of the PMMA (Figure 10).

Remark: When the Al sheet interferes with the AEC sensor, the exposure can be made in manual mode with settings as close as possible to the clinical AEC settings for the equivalent breast thickness.

Table 3 Height of the compression paddle when using different PMMA thicknesses

PMMA thickness (mm)	Height of the compression paddle (mm)	Spacer thickness (mm)
20	21	-
30	32	2
40	45	5
45	53	8
50	60	10
60	75	15
70	90	20

Method 3: PMMA and PE slabs

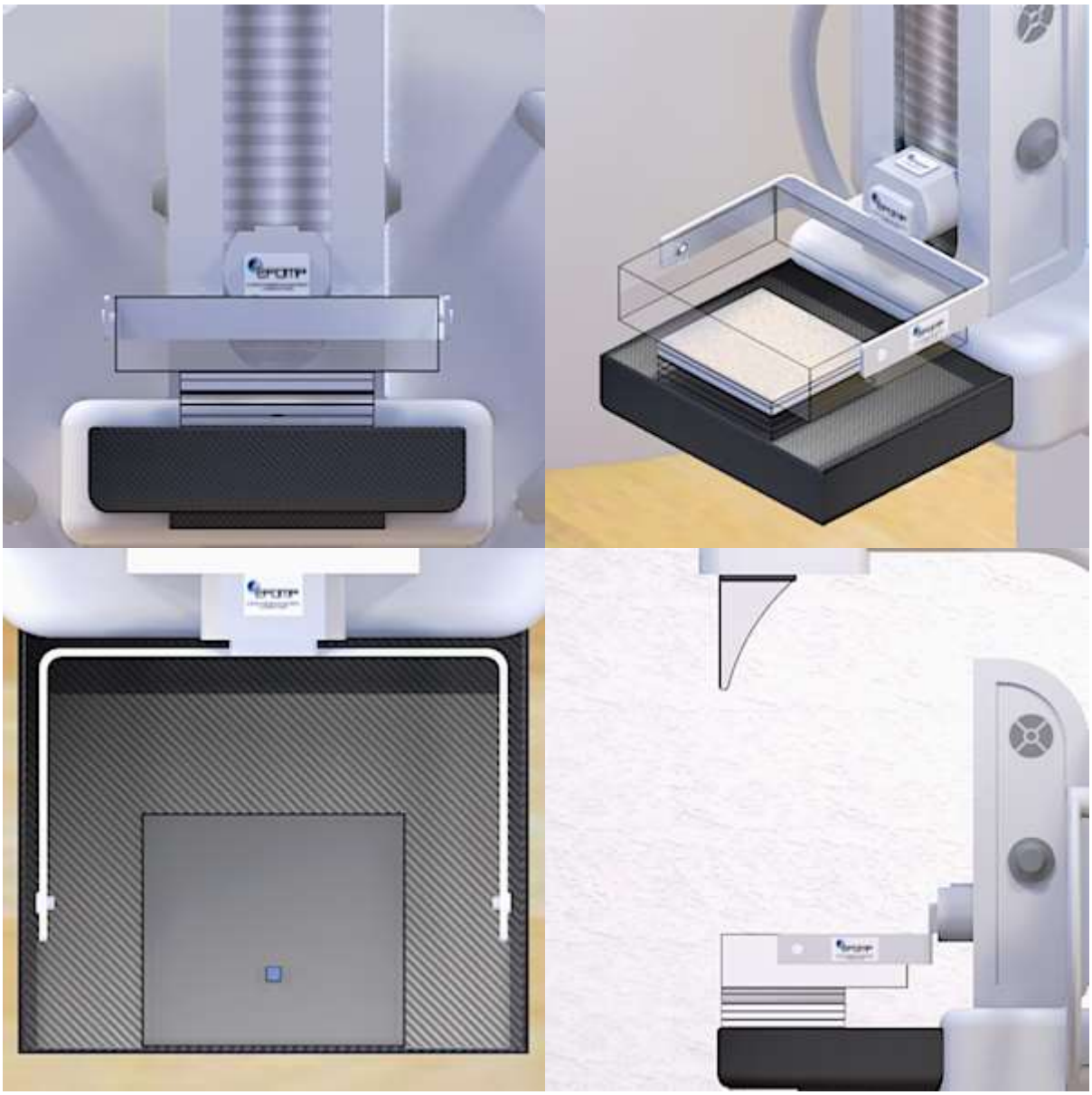


Figure 11 Setup for the AEC performance test, method 3

- Position one 10 mm thick PMMA plate on the bucky. For some systems the phantom should not completely cover the FOV area. For these systems an area with full irradiation at lateral and nipple sides is required for the clinical AEC to function properly, see appendix 3.
- Position the aluminium sheet of dimensions 10x10 mm and 0.2 mm thick at the reference position, as shown in Figure 11.
- Position a second 10 mm thick PMMA plate on top of the first plate taking care not to displace the Al sheet.
- Place the compression paddle in contact with the PMMA stack and apply a compression force of 100 N.

- Make a DBT exposure of the PMMA stack in the clinically relevant AEC mode.
- Repeat the exposure for the PMMA and PE thicknesses according to Table 4. PMMA slabs should be always at the bottom of the stack and all PE slabs should be on top of the PMMA stack (see Figure 11)

Remark: When the Al sheet interferes with the AEC sensor, the exposure can be made in manual mode with settings as close as possible to the clinical AEC settings for the equivalent breast thickness.

Table 4 Thickness of PMMA and PE to match the attenuation of the standard breast with similar thickness

Standard breast thickness (mm)	PMMA thickness (mm)	PE thickness (mm)
20.0	20.0	0.0
30.0	27.5	2.5
40.0	30.0	10.0
50.0	32.5	17.5
60.0	32.5	27.5
70.0	32.5	37.5
80.0	32.5	47.5
90.0	35.0	55.0

The procedure for the image analysis is independent of the method of image acquisition.

Analysis

- For each DBT acquisition, select the first projection image. See remark and appendix 3.
- Position a 5 mm x 5 mm ROI (reference ROI) in the centre of the image of the aluminium sheet (Figure 12).

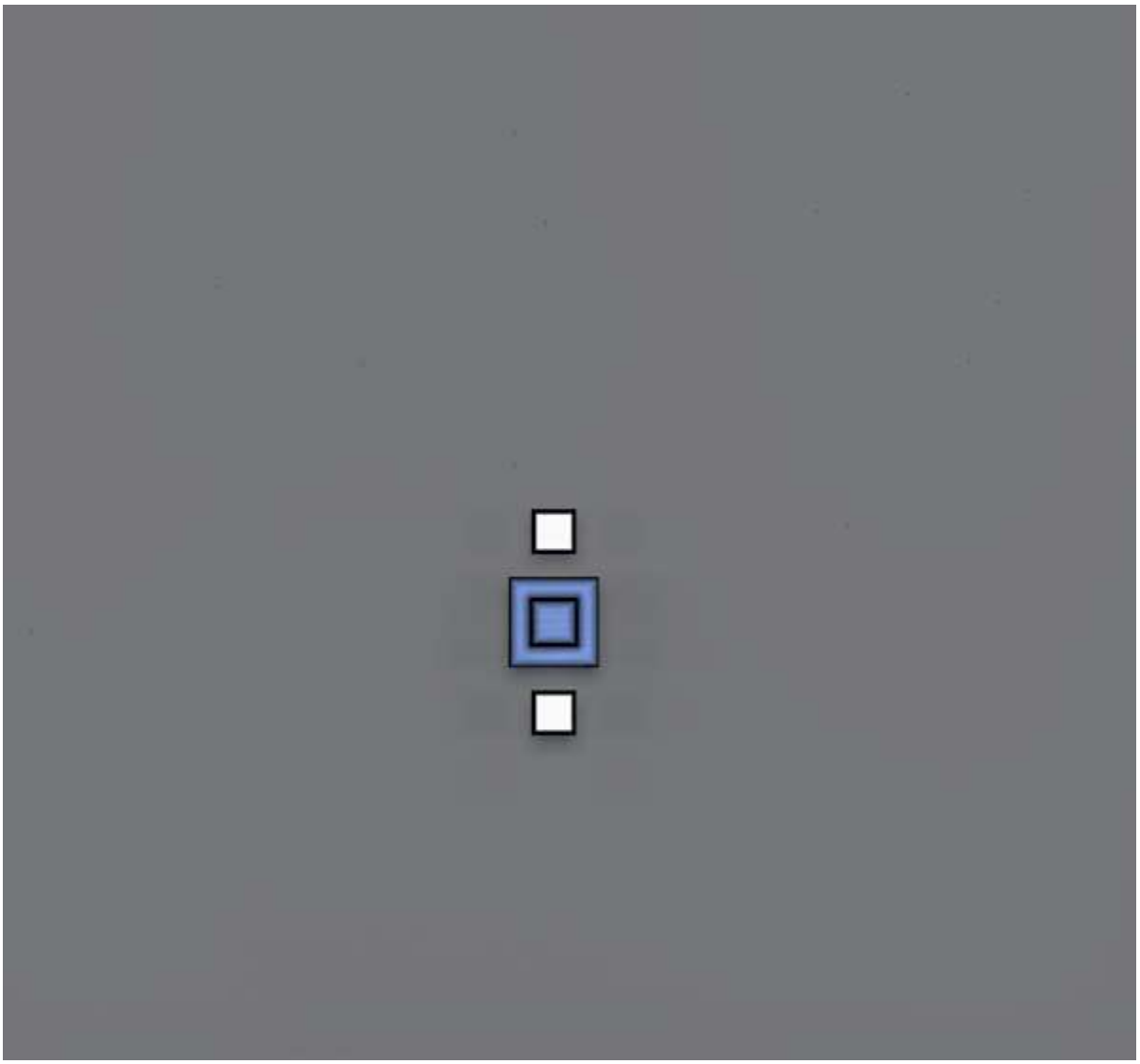


Figure 12 Position of the ROIs on the projection images

- Position two 5mm x 5mm ROIs in the background areas on the chest wall and nipple sides of the aluminium sheet (fig. 5c). The centre of both background areas should be at 10 mm from the centre of the ROI in the aluminium sheet. If the projection image has a significant degree of non-uniformity it may be necessary to compensate for this by using ROIs subdivided into 1mm x 1mm elements and using the averages of the mean pixel values and standard deviations from the elements.
- Measure the mean pixel values (PV) and standard deviations at the three ROIs.
- If the system has a non-linear response, the images need to be linearized.
- Calculate the PV(background) and SD(background) according to:

$$\mathrm{SD(background)} = \frac{\sum_1^2 \mathrm{SD(ROI}_n\mathrm{)}}{2} \qquad (4)$$

$$\text{PV(background)} = \frac{\sum_1^2 \text{PV(ROI}_n)}{2} \quad (5)$$

- Calculate the SDNR of the aluminium object:

$$\text{SDNR} = \frac{PV(signal) - PV(background)}{\text{SD(background)}} \quad (6)$$

Where PV(signal) is the mean pixel value measured in the ROI positioned at the Al sheet image.

Remarks:

For some systems the DBT sequence of projections appears not ordered sequentially when saved. To identify the images, the projection angle can be found in the DICOM header in the following tags depending on the vendor, examples are: 0018x,1470x (Hologic); 0018x,1530x (Siemens); 0018x,1531x and 0045x,1006x (GE).

Action levels

SDNR values should be within 15% of the reference values set at acceptance and should be within 15% of the values of systems of the same vendor, type and software version.

4.4 Local dense area

Introduction

Structures in breasts, e.g. the glandular structures, are not distributed homogeneously over the area of the breast, and areas of lower and higher attenuation can be found in each breast. As the detector dose and image quality will be lowest in the areas of high attenuation, the AEC should aim to obtain sufficient image quality in these areas. This is even more important as (glandular) structures might mask abnormalities and as the risk of tumours is highest in the glandular tissue in the breast.

The AEC in DBT systems measures the signal on the detector after a low dose pre-exposure and use a small detector area with lowest detector signal or lowest SNR to determine the exposure factors (kV, mAs) for the actual exposure.

Definitions

A local dense area is an area of higher glandularity within the breast. The variation of SDNR on the first projection image of scans of a simulated 50 mm thick fatty breast with a variable glandular region is taken as a measure of the response of the AEC to a local dense area.

Purpose

The purpose of the local dense area test is to verify whether the AEC system correctly adjusts exposure factors to achieve the desired target image quality level (SDNR) within the densest area of the breast.

Test equipment

- A phantom that mimics the attenuation of a 50 mm thick fatty breast (0% glandularity) and objects which simulate areas of higher glandularity.

  Method 1: Using PMMA plates + spacers
  - PMMA plates (dimensions 180 mm × 240 mm, 40 mm thick)
  - two spacers (10 mm thick) made of soft material in order not to influence the AEC choice

  Method 2: Using PMMA and PE plates

  - PMMA plates (20 mm thick)
  - PE plates (Polyethylene density 0.94 g/cm^3, dimensions 180 mm × 240 mm, 30 mm thick)

- Objects that mimic areas of higher glandularity are simulated by 3 small PMMA plates (dimensions 20 mm × 40 mm, 4 mm thickness) plus Aluminium object (10x10 mm, 0.2 mm thickness)

Method 3: Dosimetry phantom

- The series of base slabs of the new dosimetry phantom simulating different percentiles density (5, 25, 50, 75 and 95 percentiles).
- Three 10mm thick slabs simulating fatty tissue.

Table 5 Summary of the materials for the three methods to perform the local dense area QC test

Phantom		Material	Dimensions	Thickness
Method 1 and 2: simulate a fatty breast	Method 1	PMMA plates	180mm × 240mm	40 mm
		Spacers (made of radio-transparent low density material or positioned outside the AEC area)		10 mm
	Method 2	PMMA plates	180mm × 240mm	20 mm
		PE plates (density 0.94 g/cm3) (Bouwman, 2013)	180mm × 240mm	30 mm
Method 1 and 2: simulate higher glandularity areas		3 Small PMMA plates	20mm × 40mm	4 mm
Method 3: Dosimetry phantom		Base slabs with 5, 25, 50, 75 and 95 percentile glandularity and three 10 mm thick slabs simulating fatty tissue		50 mm
Method 1, 2 and 3: to calculate SDNR		1 Aluminium sheet	10mm × 10mm	0.2 mm

Test frequency

- At acceptance
- Optional at subsequent QC tests
- After detector replacement
- After relevant software changes

Test procedure

Methods 1 and 2: Simulating a fatty breast with PMMA or PMMA+PE

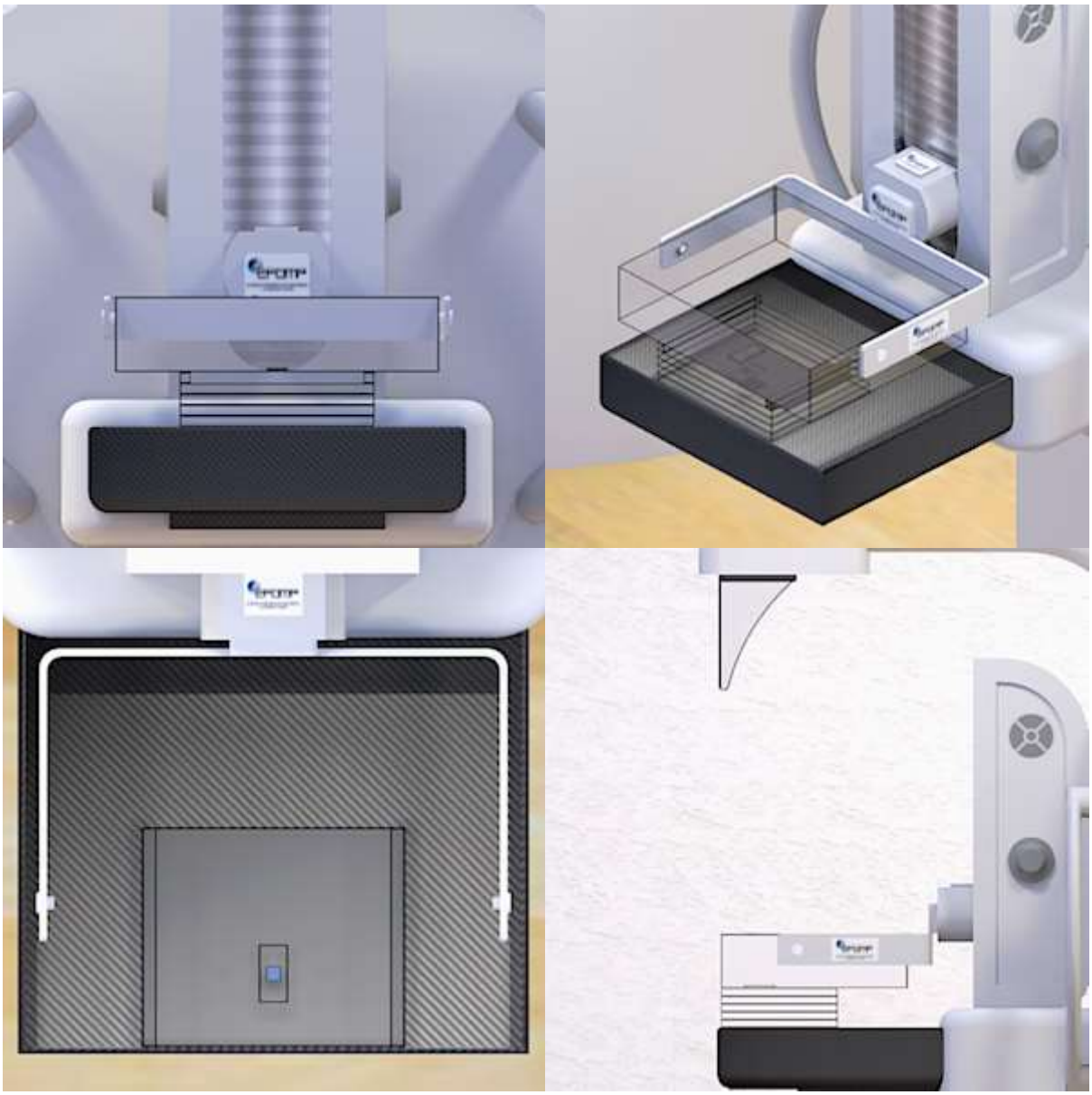


Figure 13 Setup of the local dense area test when using PMMA plates

Figure 14 Setup of the local dense area test when using PMMA and PE plates

- Place the 50 mm thick fatty breast phantom on the breast holder and the standard compression paddle at a height of 50 mm above it; make sure that the phantom does not completely cover the Field Of View (FOV) area, see Figure 13 and 14.
- If the mammographic equipment requires compression for automatic exposure functioning, place the spacers at the side of the nipple at least at 19 cm away from the chest wall edge or at far lateral sides to avoid affecting the AEC system.
- Apply a compression force of 100 N, see appendix 3.
- Put the aluminium sheet on the compression paddle within the AEC sensor area, in the central part of the detector, 50 mm far from the chest wall.

Tip: Disable the automatic paddle decompression mode (remember to enable this function at the end of the test).

- Make an exposure in the clinically relevant AEC mode with moving tube and record the exposure factors (mAs, kV, Anode/Filter).
- Position the first 4 mm thick small PMMA plate over the aluminium sheet. (see Figure 13 and 14)
- Make an exposure with the same AEC clinical mode and record the exposure factors (mAs, kV, Anode/Filter).
- Add the second small 4 mm thick PMMA plate on top of the previous one and repeat the procedure until a total thickness of 12 mm small PMMA plates is reached.
- The last set up is approximately equivalent to a 50 mm thick standard breast with 100% glandularity in the central region.

Method 3: Dosimetry phantom

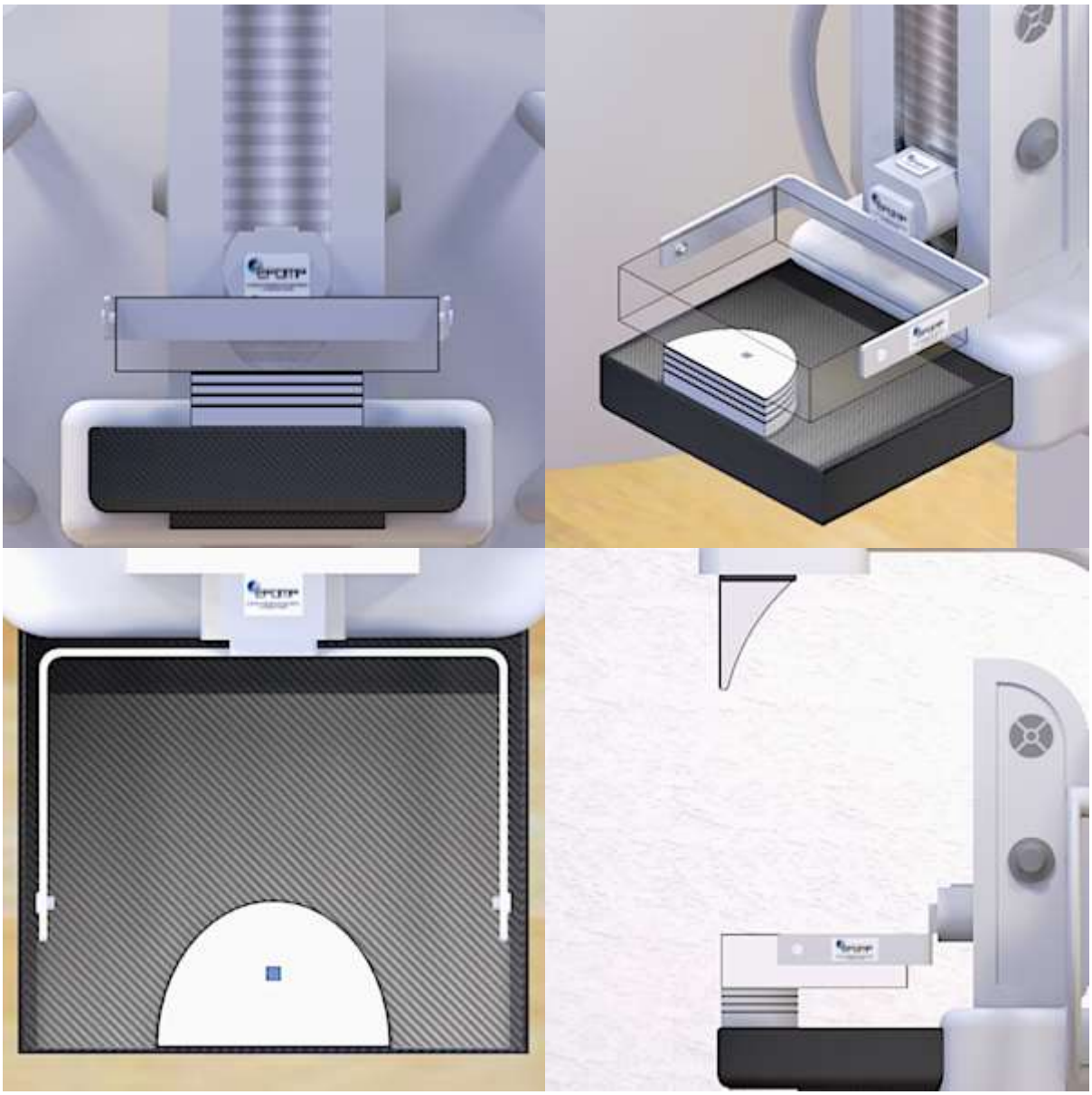


Figure 15 Setup of the local dense area test when using the dosimetry phantom

- Place the dosimetry phantom with the 5th percentile density on the breast holder and add three 10 mm thick plates simulating fatty tissue, see Figure 15.
- Apply a compression force of 100 N. See appendix 3 for systems which require compression for the correct workings of the clinically used AEC.
- Put the aluminium sheet on the compression paddle within AEC sensor area, in the central part of the detector, 50 mm far from the chest wall.

  Tip: Disable the automatic paddle decompression mode (remember to enable this function at the end of the test).

- Make an exposure in the clinically relevant AEC mode with moving tube and record the exposure factors (mAs, kV, Anode/Filter).
- Replace the base slab with the 25th , 50th, 75th and 95th percentile density slabs and repeat the procedure for each base slab.

Analysis

- On the first "for processing" projection image, see appendix 2, measure PV (signal) and SD in the area of extra attenuation (corresponding to the small PMMA plates) within a ROI of 5 mm x 5 mm inside the Aluminium sheet.
- Position two 5mm x 5mm ROIs in the background area, inside the simulated glandular area, perpendicularly to tube motion direction (see Figure …) and measure PV and SD.
- Calculate the PV(background) and SD(background) according to:

$$\text{SD(background)} = \frac{\sum_1^2 \text{SD(ROI}_n)}{2} \quad (7)$$

$$\text{PV(background)} = \frac{\sum_1^2 \text{PV(ROI}_n)}{2} \quad (8)$$

- Calculate the SDNR of the aluminium object:

$$\text{SDNR} = \frac{PV(signal) - PV(background)}{\text{SD(background)}} \quad (9)$$

- Calculate $SDNR_i$ in the projection image of each tomosynthesis acquisition performed and calculate the average $SDNR_{avg}$ for the 5 acquisitions. Evaluate the Deviation of the SDNRi of each acquisition with respect to the $SDNR_{avg}$:

$$SDNR\_deviation_i(\%) = 100 \cdot \frac{\left(SDNR_i - SDNR_{avg}\right)}{SDNR_{avg}} \quad (10)$$

and compute the Max Deviation SDNR(%) = max (ABS(SDNR_deviation(%)))

Action levels

Dose should increase when breast glandularity increases.

At acceptance or after relevant software changes, establish the reference value of Max Deviation SDNR(%) and compare it with the typical values in Appendix for the specific system.(to be added)

The Max deviation SDNR ≤ 15% (provisional limiting value).

4.5 Exposure duration

Introduction

Exposure duration is assessed in terms of exposure time per projection and total scan time. For systems in which the x-ray tube moves during acquisition of the projections, exposure time per projection influences the degree of blurring in the projection images due to focal spot motion. Total scan time is measured as this relates to the risk of patient motion between the first and last projections of a given scan.

Definitions

Exposure time per projection is the time per exposure for the individual projection images. Total scan time is the time between the start of the exposure of the first projection image and the end of the exposure of the last projection image.

Purpose

To quantify blurring in the projections due to focus motion during image acquisition and blurring due to patient motion during the scan.

Test equipment

- Suitable exposure time meter.
- PMMA blocks covering the thickness range 2 cm to 7 cm.

Test frequency

- At acceptance
- Optional at subsequent QC tests
- After relevant software change

Test procedure

Figure 16 Setup for the exposure duration test

- Cover the x-ray detector with a radiopaque sheet and position the meter at the reference point, see Figure 16.
- Set the zero-degree angle stationary mode and the acquisition factors of the clinically used AEC mode (tube voltage, Anode/Filter and current-time product) for 45 mm PMMA.
- Put the meter in the appropriate measuring mode and perform the scan. Measure the duration of each projection image and the time between the start of the first exposure in the scan and the end of the last exposure.
- Repeat for the other thicknesses, up to and including 7 cm.

Analysis

- Calculate the percentage difference between the exposure time recorded in the DICOM header tag [0018x,1150x Exposure Time] in the AEC performance test (paragraph 4.3) and the measured exposure time for a given PMMA thickness.

Remark: Once the accuracy of the exposure time per projection has been verified then this time can be extracted routinely from the AEC image DICOM headers, to assess the stability of the system exposure programming.

Action levels

The exposure time for a projection in the DICOM header should be within 15% of the measured value.

No limiting values are set for exposure time per projection, clinical evaluations are required to evaluate the impact of long pulse width and potential motion artefacts from long scan times.

Similar settings are expected on the same type of system/software version.

If the measured exposure time per projection is regarded as long or if total scan time is long, this may be reason for an evaluation of small and low contrast structures in clinical images.

Values taken from the AEC image DICOM header can be used to ensure stability.

4.6 Guard timer/security cut-off

Introduction

Security cut-off and guard timer mechanisms shall be present as part of the AEC device either to terminate the exposure or to restrict the maximum deliverable mAs to prevent x-ray tube damage and patient overexposures.

Definitions

The security cut-off protects the patient if the image quality which the AEC aims for, cannot be achieved with the selected radiation quality (target/filter/kV). The exposure will then be terminated after the pre-exposure or in the first milliseconds of the exposure. The guard timer protects the x-ray tube from damage caused by reaching or exceeding its heat-loading capacity.

Purpose

To check the correct functioning of the security cut-off and guard timer

Test equipment

- Suitable high attenuating object e.g. metal plate

Test frequency

- At acceptance
- After relevant software change

Test procedure

Figure 17 Setup of the guard timer/security cut-off test

- Position the highly attenuating object on the breast support table covering the detector or the AEC sensor area of the detector, see Figure 17.
- Position the compression paddle at a height of 50 mm. If the system requires a minimum compression to make images in the clinically used AEC mode, position the standard test block on the high attenuating object and apply a compression of 100 N.
- Make an exposure in the clinically used AEC mode and record whether the exposure is terminated.

Analysis

- Verify that the current-time product value agrees with the pre-exposure value.

Warning: To avoid excessive current–time product (mAs), consult the user manual for maximum permitted exposure time.

Action levels

The exposure should be terminated after the pre-exposure.

5 Detector characteristics

5.1 Response function

Introduction

The response function describes the relationship between the x-ray signal at the x-ray detector input plane and the PV signal generated in the image. The response function is measured for a typical x-ray energy and should describe the signal transfer over the range of detector input exposure levels found in breast imaging. The response function is characterized by a model function that is fitted to the data. This is typically linear, although other functions such a logarithmic or power functions are used by some manufacturers. There may be some energy dependence of the response function, with the gradient tending to increase with increasing x-ray energy. The main requirement is that model function should be monotonic, and the fitted function should describe the measured data well. Small changes in response function can be expected after a detector calibration.

Definitions

The response function is the mean pixel value (MPV) measured in the 'For Processing' images, plotted as a function of air kerma at detector input plane (K).

Purpose

To establish the relationship between the output mean pixel value and detector exposure and to verify that this is described by a simple, monotonic function.

Test equipment

- Calibrated dosemeter
- 2 mm thick Al sheet of purity ≥99%,
- Radiopaque sheet to shield the x-ray detector.
- Spreadsheet to calculate the response function and perform the noise component analysis.

Remark: for some DBT systems a 2 mm thick aluminium attenuator is insufficient to achieve detector dose levels similar to those in clinical practice. For these systems, the use of a 3 mm thick aluminium attenuator is suggested.

Test frequency

- At acceptance
- Optional at subsequent routine QC tests
  Note: For systems with a non-linear response, it is required to measure the response function at each QC test to facilitate the linearization of images.
- After detector replacement
- After relevant software change

Test procedure

Figure 18 Setup of the response function QC test

- Remove all detachable parts from the x-ray beam, including the compression paddle. If a compression paddle is required, then ensure that this is positioned at a height of 60 mm.
- Attach the 2 mm thick aluminium plate at the exit port of the x-ray tube.
- Cover the x-ray detector with the radiopaque sheet and select zero-degree angle stationary DBT exposure mode, see Figure 18.
- Set the target/filter combination and tube voltage selected in the clinically used AEC mode for the standard test block.
- In manual mode, measure/calculate the air kerma/projection at the input plane of the x-ray detector (K) for a range of mAs values. Estimate the mAs values required to produce K values ranging from ~5 μGy/projection up to ~100 μGy/projection. The mAs (and K) between each step should change by a factor of approximately 1.4.
- Remove the radiopaque sheet and acquire the DBT scans at the calculated mAs values, or the closest that mAs can be set. The antiscatter grid will be removed for almost all systems; for systems where the antiscatter grid must be in position for DBT scans to be made, see the note below.
- Obtain the 'For Processing' projection images for analysis.
- Repeat the measurement for all clinically used target/filter combinations, with clinically relevant tube voltage for each combination.

Analysis

- Measure the MPV and variance using the reference ROI in the first projection image. The use of the first projection image limits the influence of lag and ghosting on the measurements. Plot mean pixel value against detector incident air kerma.
- Fit the appropriate model function and record the fit coefficients and the correlation coefficient; use these to track the detector response function over time.
- Check whether the response function matches the specification of the manufacturer.

Remark: If the exposure parameters of the first projection image in a DBT sequence of images have not been determined by the AEC, the second projection image should be used instead, see Appendix 3.

Remark: For systems in which the grid cannot be removed for DBT image acquisition, a transmission factor should be estimated in 2D DM mode using the same x-ray spectrum and Al filter used to acquire the response function scans.

Action levels

Where $R^2 \leq 0.98$ detector response should be investigated.

The response function should match the specification of the manufacturer.

5.2 Noise components analysis

Introduction

Using a simplified model, the variance measured in the image can be assigned to one of three sources: electronic noise, x-ray quantum noise and structure noise. These components can be isolated using a weighted polynomial curve fit to the variance plotted as a function of detector air kerma/projection (K). The resulting components can be plotted as a fraction of the total variance vs K.

Definitions

The total variance (σ^2) is described as a function of K using a polynomial model, with the fit coefficients representing electronic noise, quantum noise and structure noise:

$$\sigma^2 = e + qK + sK^2 \qquad (11)$$

where e is the electronic noise fit coefficient, q quantum noise coefficient and s is the structure noise coefficient. K is the air kerma/projection at the input plane of the x-ray detector. This equation applies to systems with a linear response. If response is non-linear, the images need to be linearized before noise components analysis can be performed.

Purpose

The aim is to establish the relative fraction of the three noise sources as a function of K, the quantum limited range and to confirm that quantum noise forms the highest component of image noise at typical clinical air kerma/projection levels.

Test equipment

- Calibrated dosemeter
- 2 mm thick Al sheet of purity ≥99%,
- Radiopaque sheet to shield the x-ray detector.
- Spreadsheet to calculate the response function and perform the noise component analysis.

Remark: for some DBT systems a 2 mm thick aluminium attenuator is insufficient to achieve detector dose levels similar to those in clinical practice. For these systems, the use of a 3 mm thick aluminium attenuator is suggested.

Test frequency

- At acceptance
- Optional at subsequent routine QC tests
- After detector replacement
- After relevant software change

Test procedure

- Use the images made in 5.1 Response function.

Analysis

- If the response of the system is non-linear, linearize the images using the response function.
- Use the variance measured from the response function images (Section 5.1).
- Plot variance against the detector incident air kerma/projection.
- Fit the polynomial curve in equation (11); weight the variance at a given air kerma by that air kerma.
- Record the fitted noise coefficients and use to track x-ray detector noise components over time.
- Use the coefficients to calculate the level of electronic, quantum and structure variance at a given air kerma level.
- Express the three variance terms as a percentage of the total variance and plot against detector air kerma/projection. In order to establish the typical clinical detector air kerma/projection, use the measured pixel value from AEC reproducibility test. Linearize this pixel value via the response function to give the clinical detector air kerma/projection.
- Estimate and record the percentage of quantum noise to total noise at this air kerma level.
- Calculate and record the approximate air kerma at which electronic noise dominates the image variance as e/q. Do likewise for structure noise: q/s.

Action levels

Quantum noise must be the largest noise component over the clinical detector air kerma range.

Track the fitted values of the noise coefficients over time.

For a given model of x-ray detector, similar values are expected for the percentage of electronic, quantum and structure noise. Use the coefficients to compare performance between the same model of x-ray detector.

5.3 Detector element failure

Introduction

All detectors contain an array of physical elements (detector elements or 'dels') that are sensitive to radiation. There can be individual or clusters/groups of these dels which are not functioning correctly for a variety of reasons. Via specific algorithms, manufacturers calculate values for the pixels of the non-functioning dels using the values of adjacent pixels in the image. It is important that the pixel values that have been interpolated for the non-functioning dels do not influence the clinical performance of the system. Furthermore, the interpolation of pixels should not lead to disturbing artefacts. The dels for which values have been interpolated are listed in a 'bad pixel map'.

Note that the term 'del' refers to a physical element within the detector array; the smallest element in the resulting image (e.g. a projection image or reconstructed plane) is termed a 'pixel'.

Definitions

A pixel whose value is interpolated is regarded as malfunctioning. This includes the pixels associated with dels given in the bad pixel map plus non-corrected non-functioning dels that lead to incorrect pixel values in the image (see the test-item 'uncorrected defective detector elements').

Purpose

To check that the interpolation of pixels for non-functioning dels is not introducing disturbing artefacts with the potential to influence diagnostics.

Test equipment

- None/manufacturer's "bad pixel map" on the DBT system

Test frequency

- At acceptance and subsequent routine QC tests
- After detector replacement
- After relevant software change

Test procedure

- Obtain the most recent "bad pixel map" for tomosynthesis mode from the system or contact the manufacturer/ supplier to obtain the "bad pixel map" (see appendix 4).

Analysis

- Superimpose on the map the uncorrected bad pixels and evaluate the number and position of bad dels in the image.

Remark: The bad pixel for tomosynthesis mode map might differ from the bad pixel map in DM mode due to the differences in readout of the detector or pixel binning after readout.

Remark: Currently, at some sites/in some countries the software to get access to the bad pixel map is not always activated or it is not possible to obtain the bad pixel map.

Action levels

Manufacturer's limiting values, see appendix 4.

5.4 Uncorrected defective detector elements

Introduction

It is possible that the bad pixel map does not include all malfunctioning dels. These additional malfunctioning dels will be visible on the images as pixels with deviating values. These pixels should be identified when evaluating the number of 'bad pixels' and added to the 'bad pixels' given in the bad pixel map.

Note that the term del refers to a physical element within the detector array; the smallest element in the resulting image (e.g. a projection image or reconstructed plane) is termed a 'pixel'.

Definitions

An uncorrected defective detector element is a malfunctioning del that has not been mapped in the 'bad pixel map' and the value of which is not interpolated.

Purpose

To quantitatively assess the image in order to determine the presence/position of pixels associated with malfunctioning dels, that have not been included in the 'bad pixel map'.

Test equipment

- Standard test block that covers the entire detector

Test frequency

- At acceptance and subsequent routine QC tests
- After detector replacement
- After relevant software change

Test procedure

Figure 19 Setup for the uncorrected defective elements test

- The uncorrected defective detector elements test is performed on projection images acquired in tomosynthesis mode or projection images acquired in zero-degree angle stationary mode images.
- Take an image of the standard test block in manual mode without the compression paddle, see Figure 19. If exposures cannot be made without compression paddle, position the paddle at 50 mm height.

Analysis

- On the first projection images determine whether any pixel deviates more than 20% compared to the average value in an ROI of 2 mm x 2 mm.

Remark: Pixels associated with defective detector elements that are not included in the 'bad pixel map' will deviate in all projection images.

Action levels

No pixels associated with uncorrected defective detector elements should be visible.

No pixel value in an ROI of 2mm x 2mm should deviate > 20% from the average value in this ROI.

5.5 System projection MTF

Introduction

The MTF in the tube travel direction may be strongly influenced by the effective size of the focal spot due to tube motion, which in turn depends on the exposure pulse length per projection image. Blurring (for some object) in the projection images due to focal spot size and focal spot motion depends on the height above the bucky.

Hence, a system MTF in the projection images should be measured at a number of positions above the bucky, corresponding to a range of breast thicknesses. The x-ray factors (tube voltage, mAs) set for a given height should be relevant to that height, such that the x-ray pulse length corresponds to the clinical situation which is simulated.

Definitions

The system MTF measured in the projection images in the clinically used AEC mode includes the following sources of blurring: focal spot size, focal spot motion and detector MTF. The detector MTF includes the effect of blurring due to the x-ray converter, pixel size and detector binning. The system MTF measured in the projection images in the zero-degree angle stationary mode includes the same blurring sources with the exception of focal spot motion.

Purpose

In mammography the visibility of small structures like small calcifications and spiculae and low contrast structures like small lesions are important. Therefore, quantifying the blurring in projection images is important as these are input to the image reconstruction and thus are a major component of blurring in the 3D tomosynthesis image.

Test equipment

- A thin radiopaque edge with straight, sharp edges of minimum dimension 50 x 50 mm^2 suitable for the measurement of the MTF.
- 2 mm thick aluminium plate
- Appropriate MTF calculation software
- Low contrast supports

Remark: for some DBT systems a 2 mm thick aluminium attenuator is insufficient to achieve an exposure time similar to those in clinical practice. This might influence the MTF in the direction of tube movement. For these systems a thicker attenuator might be more appropriate.

Test frequency

- At acceptance and subsequent routine QC tests
- After relevant software change

Test procedure

Figure 20 Setup for the system projection MTF test

- Perform this test after the test of AEC performance vs thickness, so that the x-ray factors are known as a function of breast simulating material.
- Remove the compression paddle.
- Position a 2 mm thick aluminium plate as close as possible to the x-ray tube to attenuate the whole x-ray beam.
- The MTF edge device should be oriented in the left-right direction (i.e., tube travel direction). Place the MTF edge on the bucky oriented at a small angle (~ 3°) to the pixel matrix, with the centre of the edge to be used on the midline at a distance of approximately 50 mm from the chest wall edge, see Figure 20.

Perform a DBT (not in zero-degree mode) scan, manually setting the x-ray factors selected by the AEC for 20 mm breast simulating material.

- Rotate the MTF edge through 90° and repeat to acquire the MTF edge image in the orthogonal direction i.e., chest wall-nipple direction. Alternatively, the MTF can be measured in both directions in a single image using a suitable MTF test tool with two orthogonal edges.
- Repeat the pairs of orthogonal images with the edge positioned at 20 mm, 40 mm and 70 mm above the table surface. The MTF edge should be supported on low contrast supports (e.g., expanded polystyrene blocks or small plastic blocks), positioned underneath the edge such that they do not influence the area used for MTF analysis.
  Note: Measuring MTF at 20 mm, 40 mm and 70 mm above the breast support table is optional for routine QC tests.

Analysis

- Calculate the MTF from the projection image closest to the 0° position (i.e. DICOM tag '0018,1530 Detector Primary Angle' ~0°). Re-bin the MTF data at 0.10 mm^{-1} spatial frequency intervals. Find the spatial frequency for MTF values of 50% (MTF_{50}).

Remark: Ideally one would increase the current–time product (mAs) to some factor greater than the AEC value for a given thickness to reduce the influence of noise on the measurement. However, this is likely to increase the exposure duration for each pulse and this must be avoided, unless the system can increase the tube current and keep the exposure times constant.

Remark: Some systems use pixel binning of the projection images. The binning used by the system should be noted as it is an important source of blurring. If the pixel spacing (detector element size etc) is not present in the DICOM header or if you are unsure of the pixel spacing in the projection images, then the pixel spacing should be checked using an object of known length positioned on the breast table (correcting for magnification). Note that some systems may save the projections binned or un-binned; it is possible that systems save un-binned projection images and bin these images before reconstruction. (As such, this binning step can be considered as part of the reconstruction as it cannot be discriminated from a reconstruction filter).

Remark: If the temporal response of the x-ray detector (e.g. in terms of x-ray fluorescence or charge trapping and release in a photoconductor) is not sufficiently fast with respect to the projection image acquisition rate then signal carry over (lag) between projections will be seen. The cumulative effect of the lag is changing brightness near the region of the edge. This results in a ramp function superimposed on the high value part of the edge spread function and ultimately leads to a reduction in MTF at low spatial frequencies. Record the spatial frequencies at 50% on the MTF curve.

Remark: Edge images acquired for systems with a non-linear detector response curve must be linearized before MTF calculation while linearization is not essential for systems with a linear

detector response curve. The generic (standard) response curve, as measured using 2 mm Al in section 4.1. can be used for all the edge images, regardless of beam quality setting.

Action levels

The frequency (mm^{-1}) result at the MTF_{50} point should be within 10% of the value specified by the manufacturer.

Investigate when there is more than 20% difference in the MTF_{50} point from the reference value.

6 Technical image quality 3D

6.1 Technical image quality of the reconstructed 3D image

Introduction

Using simple QC test objects is a practical solution to ensuring the quality of DBT images until better testing regimes are created and validated. This protocol recommends undertaking baseline tests to set reference values that may indicate a change in image quality that may affect clinical outcomes.

Definitions

Image quality in DBT is the quantity which is used to express the visibility (or sometimes the interpretability) of benign and malignant structures in clinical mammography images allowing a radiologist to make a diagnosis. In quality control tests, this parameter is simplified to technical image quality defined as the ability to visualize objects in phantom images.

Purpose

At acceptance: To set reference values for technical image quality.

At subsequent routine QC tests: To compare test result with the established reference value. To detect and investigate any changes in performance over time and decide if and when corrective actions are necessary.

Test equipment

- Option 1: CDMAM phantom and accompanying PMMA slabs
- Option 2: TORMAM phantom and accompanying PMMA slabs
- Option 3: DM phantom facilitating the assessment of the visibility of small objects
- Option 4: Task-based phantoms with structured background

Note: the phantom should be sufficiently sensitive to changes in technical image quality. It is therefore recommended to use a DM or task-based phantom for which the ability to detect changes in image quality has been validated.

Test frequency

- At acceptance and subsequent routine QC tests
- After detector replacement
- After relevant software change

Test procedure

Option 1: CDMAM phantom

- Image the CDMAM phantom in the middle of a 40 mm stack of PMMA using exposure factors as would be selected automatically for a 60 mm equivalent breast.
- Repeat until a total of six exposures has been made, moving the phantom slightly between exposures.
- Score the reconstructed tomosynthesis images with the CDMAM phantom using human observers and calculate the CD-curve according to the supplement to the fourth edition of the European Guidelines.
- Compare the score to the reference value.

  For some DBT systems it is possible to score the focal plane where the image of the CDMAM phantom is in focus using the software analysis tool CDCOM (Karssemeijer and Thiijssen, 1996; Veldkamp, Thijssen and Karssemeijer, 2003), in which case 8 to 16 CDMAM images should be used. It is advisable to ensure that the entire CDMAM phantom is brought into focus in a single focal plane by careful positioning of the phantom to compensate for any tilt of the reconstructed focal planes relative to the breast support table.

  As CDCOM is designed to read images in the DM format, it is necessary to extract the focal plane where the CDMAM is in focus from the reconstructed tomosynthesis image. Where there is significant low frequency non-uniformity in the reconstructed focal planes, flatfielding should be applied before automated reading using CDCOM. A suitable flatfielding algorithm involves cropping to the useful area of the CDMAM and padding out to achieve an image size equal to the nearest power of two. An appropriate filter such as a Butterworth filter should be applied in the frequency domain to remove the higher frequencies including the grid and contrast details of the CDMAM, using a fourth order filter with a cut-off of 5mm. The original image is then divided by the original image and the pixel values rescaled.

Note that the use of CDCOM for reading tomosynthesis images has not been validated by comparison with human reading as was done for DM (Young, 2006)and converting the results of this automated analysis to predicted human values using the method described in the Supplement to the European Guidelines may not be correct. However, automated reading and analysis of tomosynthesis CDMAM images using software designed for 2D images may be a useful interim tool for monitoring the stability of DBT image quality.

Note that for some systems the breast support table is not parallel to the image receptor but tilted slightly. To get all the objects of phantoms in focus in one focal plane it is necessary to tilt the phantom with the same angle in the opposite direction.

Option 2: TORMAM phantom

- Image the TORMAM phantom on top of a 30 mm stack of PMMA using automatically selected exposure factors.
- Carry out a visual assessment of the image of the TORMAM. For this assessment it is necessary to use a primary display monitor under appropriate conditions, with window level and width and zoom functions adjusted to maximise visibility of the details.
- A scoring system may be used, where points are accumulated for discs, filaments and specks according to how clearly they are visualised.
- Compare the score to the reference value.

Note that for some systems the breast support table is not parallel to the image receptor but tilted slightly. To get all the objects of phantoms in focus in one focal plane it is necessary to tilt the phantom with the same angle in the opposite direction.

Option 3: DM phantom facilitating the assessment of the visibility of small objects

Beside the phantoms mentioned above any DM phantom with objects simulating small calcifications and/or thin linear structures could be used for the (cautious) evaluation of the ability to image small details.

- Image the phantom using automatically selected exposure factors or set the exposure factors manually which would have been chosen for the equivalent breast thickness and composition.
- Compare the score to the reference value.

Note that for some systems the breast support table is not parallel to the image receptor but tilted slightly. To get all the objects of phantoms in focus in one focal plane it is necessary to tilt the phantom with the same angle in the opposite direction.

Option 4: Task-based phantom with structured background

Task-based phantoms are becoming commercially available or will be in the near future. Some of the phantoms might not include all the features mentioned in paragraph 1.6. These task-based phantoms might be used to quantify (aspects of) the image quality of the reconstructed DBT image. It should be noted that task-based methods are still under development and validation, but these kinds of phantom might provide additional information on 3D image quality, which the DM phantoms cannot provide.

- Image the task-based phantom using automatically selected exposure factors or set the exposure factors manually which would have been chosen for the equivalent breast thickness and composition.
- Compare the score to the reference value.

Action levels

Option 1: CDMAM phantom

The measured contrast threshold values at acceptance can be used as reference for subsequent QC tests and can be compared to other systems of the same brand, type and software version. Note: The limiting values for DM image quality measurements cannot be applied to DBT.

Option 2: TORMAM phantom

The visibility of details at acceptance can be used as a reference for subsequent QC tests and can be compared to other systems of the same brand, type and software version. Note: Standards for the visibility of details in a DM TORMAM image cannot be applied to DBT.

Option 3: DM phantom facilitating the assessment of the visibility of small objects

The visibility of details at acceptance can be used as a reference for subsequent QC tests and can be compared to other systems of the same brand, type and software version. Note: Standards for the visibility of details in DM images cannot be applied to DBT.

Option 4: Task-based phantom with structured background

The measured detectability score at acceptance is used as a reference for subsequent QC tests and can be compared to other systems of the same brand, type and software version.

6.2 MTF in the reconstructed image

Introduction

The sharpness of features within the breast is especially important for the detection and characterization of microcalcifications. The MTF is a metric used in many imaging modalities to quantify the sharpness of the images produced by the system. The MTF measured in the reconstructed planes includes all the sources of blurring that contribute to the total system MTF. DBT is a pseudo-3D technique and should ideally be measured using a method that gives the 3D MTF. The method given below does not give the 3D MTF but instead the in-plane MTF (x-y) in two directions across the image i.e., in tube travel and chest wall-nipple directions.

Definition

Depending on the DBT system configuration, the sources of blurring can include geometrical blurring due to focus size and focus motion, the detector pre-sampling MTF which may have binning, plus the filtering and interpolation applied by the reconstruction algorithm. Two methods are described to measure the MTF: a thin Tungsten (W) wire or a thin semi-transparent edge composed of Aluminium. In both methods, the test object is angled by ~3° so a super-sampled line spread function (LSF) or edge spread function (ESF) can be constructed, for the wire and edge methods, respectively. The MTF is calculated by taking the modulus of the fast Fourier transform (FFT) of the LSF and normalizing to 1.0 by dividing by the maximum of the MTF curve. If using the edge test object, the ESF calculated from edge image is differentiated to give the LSF before applying the FFT.

Purpose

In mammography, the visibility of small structures like calcifications and the boundaries or interfaces of mass lesions plays a crucial role in the successful application of mammography imaging. The sharpness of these structures is determined by the blurring processes within the DBT system and therefore a quantitative measure sharpness in the planes is a useful performance metric.

Test equipment

- A test object to measure the in-plane MTF: a 25 µm W wire at least 50 mm in length or a 0.2 mm thick Al sheet at least 50 x 50 mm in size. If using the wire, this should be held straight by applying tension. The edges of the Al sheet from which the MTF is calculated must be straight and machined sharp. The wire or edge should be supported between two PMMA sheets each of thickness 10 mm and minimum size of 150 x 150 mm (total thickness 20 mm).
- Software for the calculation of MTF.

Test frequency

- Optional test at acceptance and subsequent routine QC tests
- Optional after detector replacement
- Optional after relevant software change

Test procedure

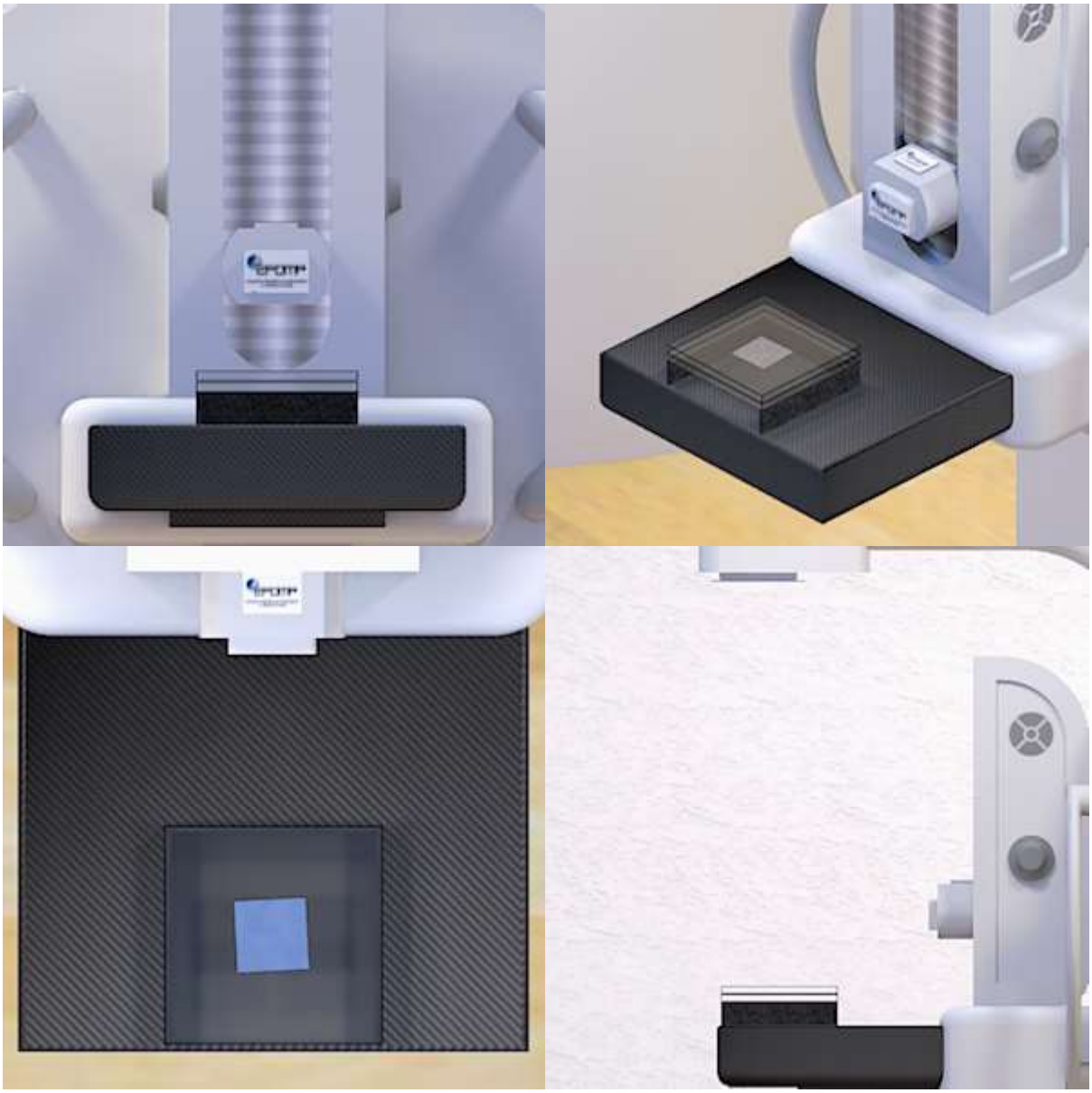


Figure 21 Setup of the MTF in the reconstructed image test

- Position the MTF phantom such the wire or edge is held 40 mm above the breast table. This can be done using small plastic blocks placed at the phantom edge. To measure the MTF in the chest wall-nipple direction, position the wire or edge to run left-right across the detector at 50 mm from the chest wall edge (but still at

~3° to reconstruction matrix), see Figure 21. To measure the MTF in the tube-travel direction, rotate the MTF phantom 90°, so the wire is centred left-right and is orthogonal to the tube-travel direction (but aligned ~3° to reconstruction matrix). It is vital that the wire or edge is held parallel to the detector and therefore remains entirely within a given reconstructed plane. The phantom must not be vibrating or moving as this will degrade the measured MTF.

- The factors used by the system for the standard test block under AEC control should be set manually for the acquisition and a DBT scan acquired using the clinical reconstruction algorithm.

Analysis

- Find the in-focus plane containing the wire or edge and calculate MTF for the tube-travel and front back directions.
- Normalize the MTF curves to the maximum value of the MTF, re-bin to 0.10 mm^{-1} spatial frequency resolution and record the spatial frequency where the MTF is 0.5 ($MTF_{0.5}$).

Remark: The use of linear system theory metrics on reconstructed images can be questioned. For iterative reconstruction techniques, it is not known whether linear system theory metrics are reproducible or meaningful. The measurement of MTF in the x-y plane is proposed to monitor stability of the tomosynthesis system and to allow comparison of results obtained from systems of the same model.

Remark: It is common for there to be a reduction in MTF at low spatial frequencies as a result of the reconstruction filters used. It is possible that there will be two values where the MTF has a value of 0.5; where this happens, record the higher spatial frequency value.

Remark: system linearity and stationarity of statistics is assumed. The use of a small signal (thin wire or edge) helps to fulfil this assumption; recent work (REF) has shown that these metrics calculated from this type of test object are consistent with threshold contrast-detail results.

Remark: The wire or edge should not be close to the edge of the PMMA sheets or the supporting blocks as these parts of the phantom can generate high contrast artefacts that influence the measurement.

Action levels

A 20% change in $MTF_{0.5}$ value from the reference set at acceptance should be investigated. The $MTF_{0.5}$ value can be used as a reference level to compare DBT units of the same model.

6.3 Artefact spread function (ASF)

Introduction

Due to the limited angle and limited number of projections, the reconstructed tomosynthesis volume is undersampled. As a result, insufficient information is acquired to localize structures with respect to their height above the breast table. Signal generated by an object at some location in a given plane therefore appears in adjacent planes, potentially obscuring structures in these planes. Quantification of the magnitude of this signal spread between planes provides some information on the resolution in the z-direction (i.e., between planes) and may prove useful as a measure of geometric stability of the system over time. Systems with a wider angular range have more extensive sampling in the z-direction and are expected to have reduced spread of artefacts between planes and an improved resolution in the z-direction.

Definitions

The signal spread can be quantified using the artefact spread function (ASF), which has also been termed the slice sensitivity profile (SSP). The ASF can be measured by imaging a small object, typically a sphere, against a uniform background. The intensity of the artefact generated by this object in adjacent planes relative to the intensity of the object generating the artefact can be expressed as follows:

$$ASF(z) = \frac{\overline{PV}_{artefact}(z) - \overline{PV}_{bkg}(z)}{\overline{PV}_{object}(z_O) - \overline{PV}_{bkg}(z_O)} \qquad (12)$$

Here, z_0 is the plane containing the real feature, z is the location of a plane containing the artefact of the feature, $\overline{PV}_{object}(z_0)$ and $\overline{PV}_{bkg}(z_O)$ are the mean pixel values measured respectively in the object and background in plane z_0, and $\overline{PV}_{artefact}(z)$ and $\overline{PV}_{bkg}(z)$ are the mean pixel values in the artefact of the object and in the background, measured in the adjacent planes z. The Full Width Half Maximum (FWHM) is established from the resulting curve is used to quantify the ASF.

Purpose

Although tomosynthesis reduces the overlying structures issue associated with digital mammography, there is still some inter-plane spread of structures that might obscure objects of interest. The ASF is used to quantify this signal spread between planes.

Test equipment

- A PMMA slab (e.g. 5 mm thick) containing a number of small diameter spheres (e.g. 1 mm diameter) or thin objects (e.g. discs), spaced 2 cm or further apart in an array or an equivalent slab with objects.

Note: the thickness and composition of the objects will determine the contrasting signal generated by object and the resulting signal spread between adjacent planes. Therefore the same type of phantom needs to be used during subsequent QC tests of a system.

- PMMA slabs of 10 mm thickness
- Software to calculate FWHM

Test frequency

- At acceptance
- After relevant software change

Test procedure

Remark: Images acquired using the geometric test phantom (section 6.5) may be used for this purpose, enabling the two tests to be combined.

Figure 22 Example of the setup of the artefact spread function test (other phantoms may be used)

- Position five 10 mm thick slabs of PMMA on the bucky, followed by the phantom containing the stimuli and then another sheet of 10 mm thick PMMA.
- Make an exposure using the clinically used AEC mode, see Figure 22. Repeat the acquisition with the slab containing the stimuli between the third and fourth PMMA sheet and again between the first and second sheet.

Analysis

- Visually inspect the reconstructed stack for artefacts and examine how they change and shift between focal planes.
- Calculate the ASF(z) function using equation (x). Normalize the curve to a maximum of 1.0 as follows: subtract the background value from the curve using

the average value of $\overline{PV}_{bkg}(z)$, then divide by the maximum value of the background-subtracted to give the normalized $ASF_{norm}(z)$. Calculate the FWHM by estimating the points at which the curve has fallen to 0.5 on the normalized curve. Use interpolation to estimate the two z values at the 0.5 points above and below the in-focus plane, from which the FWHM is calculated.

If different plane spacing or slabbing options are available on the system, then the ASF for the these spacing values should also be assessed at acceptance and after relevant software upgrades.

Remark: for some systems, the peak artefact signal for objects situated off the central axis will not follow a straight line through the reconstructed stack. This occurs for systems that use a Cartesian coordinate system for the reconstructed volume, which results in an artefact in the volume that is angled towards the x-ray focus (see (Maki, Mainprize and Yaffe, 2016)for more details). This does not occur for systems that use cone beam coordinate system for the reconstructed volume. For systems where the off-axis ASF is angled (i.e., Cartesian cords used), two options are available to compensate for this angulation. In the first option, the maximum pixel value within the artefact for each plane should be found. Automated software or DICOM viewer tools can be used to produce composite images of the maxima, which are reduced to single lines of maxima from which the FWHM is calculated either by linear interpolation or fitting a polynomial spline to the data. This is the method used in the software provided on the EFOMP website. In the second option, the reconstructed volume can be transformed from a Cartesian coordinates (x,y,z) to cone beam coordinates (x',y',z) as follows:

$$(x', y', z) = (xM, yM, z) \qquad (y)$$

where M is the magnification at height z above the detector: $M = SSD/(SDD - z)$ where SSD is the source to detector distance (Maki, Mainprize and Yaffe, 2016). The value of M should be calculated for each plane in the stack containing the objects used to evaluate the ASF; note the value of z in equation (y) is the height above the detector, while z in equation (x) is plane height within the stack. Once the reconstructed volume is resampled to cone beam coordinates, the ASF can be calculated using the method in equation (x).

Remark: If neither of these options are available then the ASF should be calculated from an object positioned close to the central axis, as ASF for systems using Cartesian systems will suffer less distortion from angulation and are expected to be more reproducible.

Action levels

The FWHM value ≤ 10% difference with reference value.

The FWHM values of different systems of the same brand, type and software version should be similar.

6.4 Geometric distortion

Introduction

Due to the reconstruction techniques in DBT imaging there is a potential for geometrical distortion in the reconstructed planes. The distortion may adversely affect the apparent location of structures in 3D images which may be used as guidance for additional imaging and/or to combine the findings in DBT imaging with findings using other imaging techniques. This would be particularly important for tomosynthesis biopsy.

Note: It is worth undertaking this test before any image quality measurements (especially CDMAM test object), as the test object may also need to be tilted to be parallel to the imaging plane to ensure that whole phantom is brought into focus within a single focal plane.

Definitions

The geometric distortion is defined as the percentage difference in distance between spheres from the true distance.

Purpose

To quantify geometric distortion in the reconstructed DBT image.

Test equipment

- Geometric distortion phantom with rectangular array of 1 mm diameter aluminium spheres embedded in a 5 mm thick PMMA sheet (similar to the artefact spread function phantom) (see Figure 23). The tolerance of the positioning of the spheres should be within ±0.1mm. The distance between the centres of the spheres is 55 mm in the *x* and *y* directions. Equivalent phantoms may also be used.
- Six 10 mm thick PMMA slabs

Figure 23 Example of the geometric distortion phantom

Test frequency

- At acceptance
- Optional at subsequent QC tests
- After relevant software change

Test procedure

Figure 24 Setup of the geometric distortion test

- The geometric distortion phantom is imaged within the total of 60 mm stack of PMMA, see Figure 24. The test object will be imaged at three heights:
    - on top of 10 mm and below 50 mm thick PMMA
    - on top of 30 mm and below 30 mm thick PMMA

  - on top of 50 mm and below 10 mm thick PMMA
- The test object needs to be placed parallel to the reconstruction plane, this may not be parallel to the breast support, and in these cases it may be necessary to use spacers below the PMMA blocks to adjust the level of the phantom.

Analysis

- A ROI is selected to cover a large number of the spheres. Some of the spheres at the edge of the image may not be sufficiently sharp to allow accurate measurement and so should not be included in the ROI.
- Analysis software can be used to find the in-focus position of each sphere in the *x*, *y* and *z* directions. The distance between the spheres can be calculated and compared to the expected value in the *x*, *y* and *z*-directions.

Links to software will be made available via the (to be added) website.

This information can be used to assess whether the focal planes are flat (i.e. no distortion in the *z* direction), whether they are tilted relative to the plane of the breast support surface, and to assess whether there is any distortion or inaccuracy of scaling within the focal planes.

Remark: This test may be combined with the artefact spread function test.

Action levels

Any distortion or scaling error should be within the manufacturer's specification. If the image has to be used for localisation purposes then the magnitude of any distortion or scaling error becomes more important.

6.5 Missed tissue at chest wall side/at top and bottom of the reconstructed image

Introduction

Due to the design of the breast support, compression device and position of the detector in the bucky, some tissue at the chest wall side might not be imaged. It is important to minimize this amount of missed tissue. The reconstructed DBT image should be constructed such that all breast tissue between the breast support and the compression paddle is visualised.

Definitions

The missed tissue at chest wall side is the breast tissue which is on (or above) the breast support table but not in the reconstructed DBT image. The missed tissue at chest wall side is quantified as the distance between the edge of the breast support and the edge of the reconstructed DBT image at the chest wall side.

A reconstructed DBT image should reach from the breast support table to the top of the breast (compression paddle). This can be checked by the sharp depiction of a high contrast object on the breast support table and underneath the compression paddle.

Purpose

To check whether the DBT image reaches from the breast support table to the compression paddle and to check the amount of potential missed tissue at chest wall side (in mm).

Test equipment

- Lead rulers and small high contrast objects (e.g., staples, paperclips), or a phantom with markers at known distances from chest wall side and markers at the top and bottom.
- 2 mm thick aluminium plate, or the standard test block
- Tape measure

Test frequency

- At acceptance and subsequent routine tests
- After detector replacement
- After relevant software change

Test procedure

Missed tissue at chest wall side

Figure 25 Setup of the missed tissue at chest wall side test

- Position two lead rulers on the breast support table perpendicular to the chest wall edge with a marker point at the breast support edge, see Figure 25; acquire an DBT image.

Analysis

- Evaluate the amount of missed tissue, i.e., the amount of tissue between the chest wall edge of the bucky and the chest wall edge of the reconstructed focal plane. At

acceptance this measurement should be also performed at 30 mm and 60 mm height above the compression paddle.

Missed tissue at the top and bottom of the reconstructed DBT image

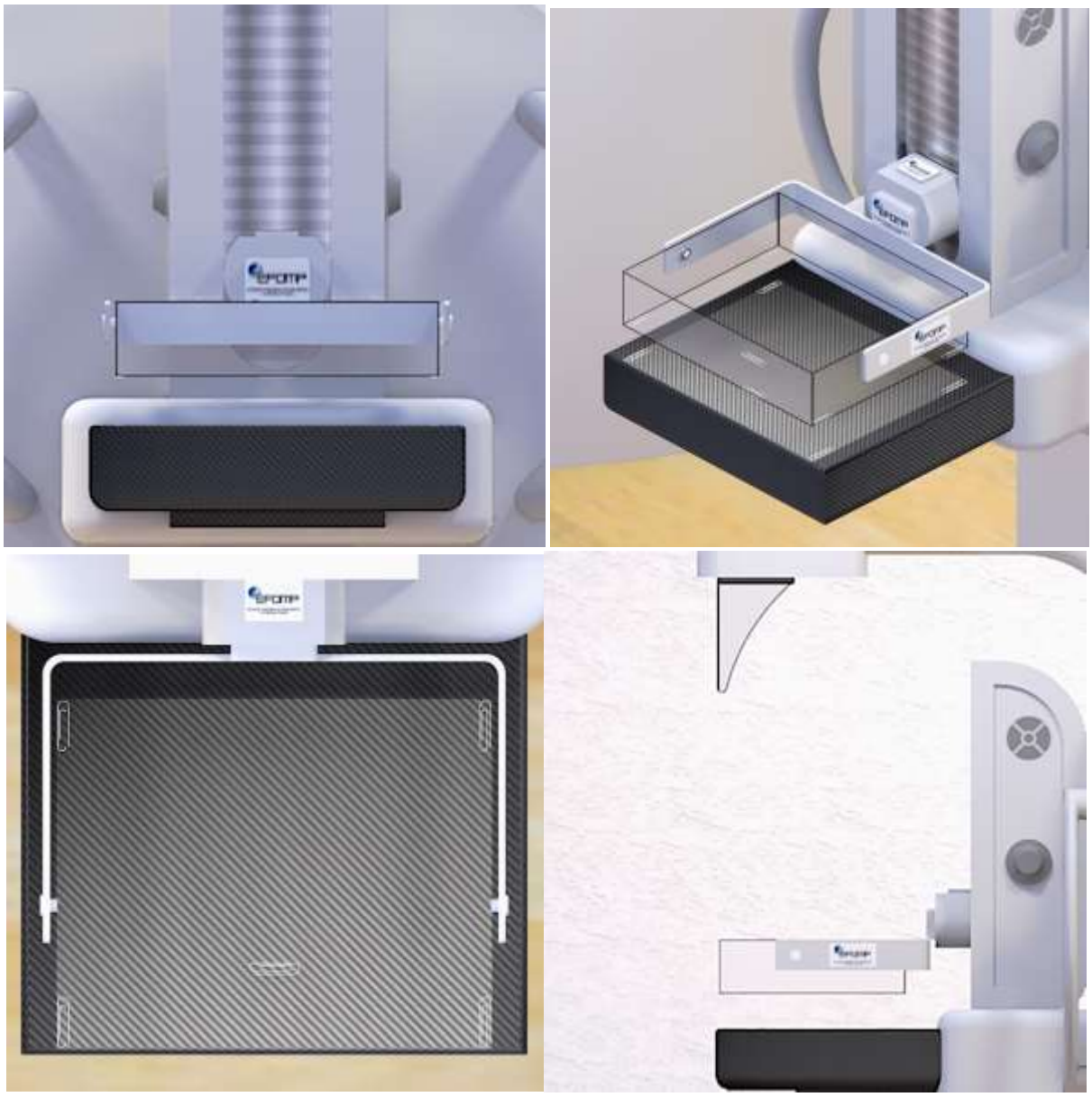


Figure 26 Setup of the missed tissue at the top and bottom of the reconstructed DBT image

- Position some small high contrast objects at the centre, near the chest wall edge and in each corner, on the breast support surface.
- Position the compression paddle at a height of 45 mm. Place some attenuating material between the breast support and compression paddle and acquire a tomosynthesis image under AEC control, see Figure 26.
- Repeat the procedure with the high contrast objects taped to the underside of the compression paddle.

Analysis

- Check that all objects are brought into focus in focal planes near to the bottom and top of the reconstructed DBT image, respectively.

Remark: take care not to scratch the bucky or compression paddle with the small high contrast objects.

Action levels

Width of missed tissue at chest wall side ≤ 5 mm.

All high contrast objects at the breast support table and underneath the compression paddle should be brought into focus in the reconstructed tomosynthesis image.

6.6 Image homogeneity and artefact evaluation

Introduction

Inhomogeneities and/or artefacts might negatively impact the visibility of structures in the clinical images or might resemble clinical structures, both potentially leading to misdiagnosis.

Definitions

An image is homogeneous when the pixel value and SD in the image are approximately equal over the image. There are two types of inhomogeneities: artefacts which might resemble or obscure structures on clinical images and trends in pixel value or noise patterns over (part of) the image. The Heel effect is an example of the latter, which in general will not influence diagnostics.

Artefact: Presence of (an area with) higher or lower pixel value or noise level in the images due to system imperfections, malfunctioning of the system or reconstruction algorithm.

Purpose

To check the presence of inhomogeneities and artefacts.

Test equipment

- Standard test block covering the whole field of view.

Test frequency

- At acceptance and subsequent routine QC tests
- After x-ray tube replacement
- After filter replacement
- After detector replacement
- After relevant software change

- Beside performing image homogeneity and artefact evaluation in QC tests, it is advised to perform this test regularly in clinical practice (daily or weekly).

Note: for daily or weekly QC this test can be combined with test 4.2 Long term stability.

Test procedure

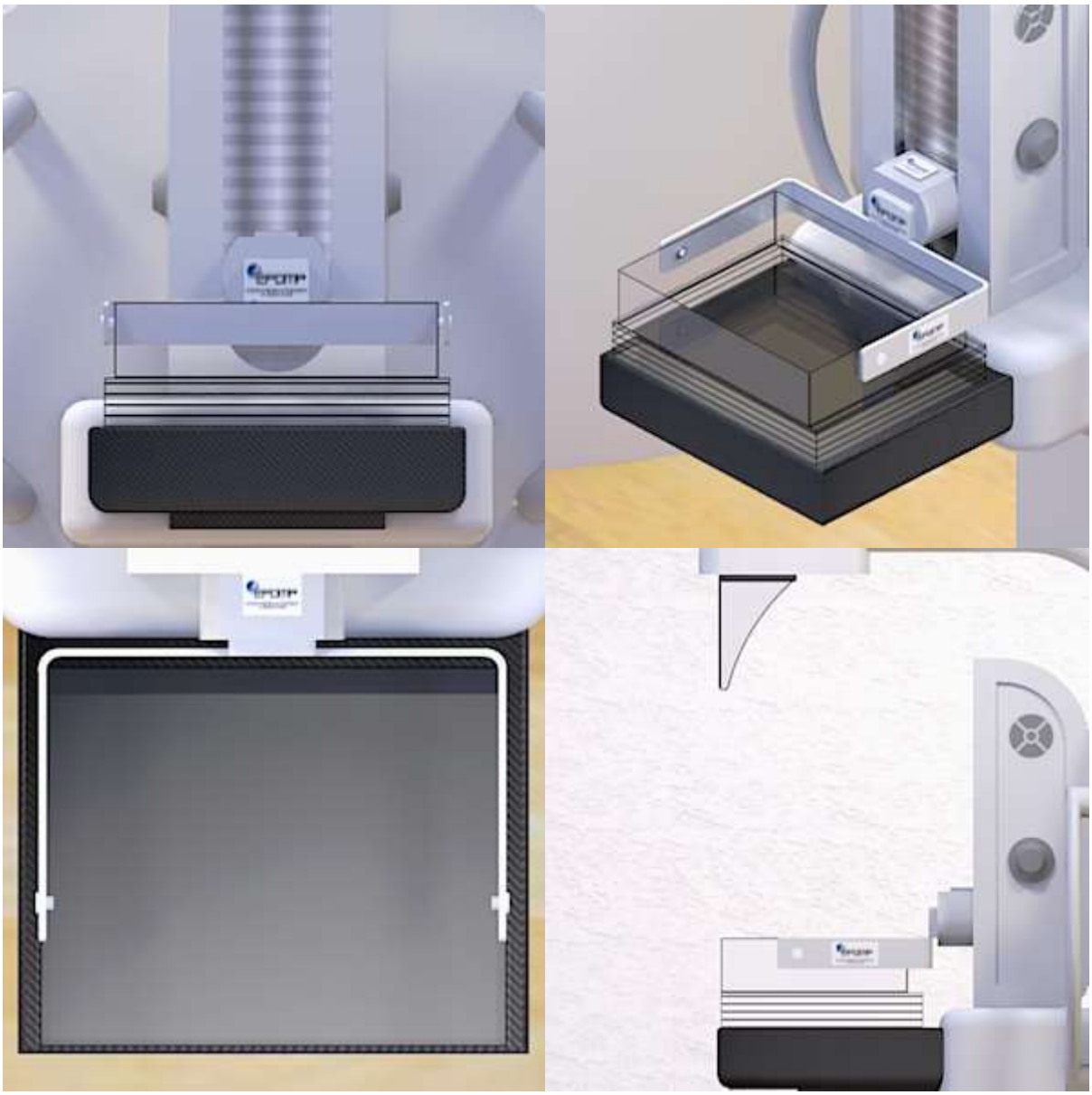


Figure 27 Setup of the image homogeneity and artefact evaluation test

- Position the standard test block on the bucky such that the whole detector is covered and make a DBT exposure in the clinically used AEC mode, see Figure 27. If the clinically used DBT mode requires an area of full irradiation at lateral and nipple side, see appendix 3, the image should be made in manual mode mimicking the exposure factors in clinically used AEC mode.

Analysis

Method 1:

- Visually inspect all focal planes of the reconstructed tomosynthesis image for artefacts and inhomogeneities.

  Note: Detector artefacts might be easier to evaluate on zero-degree angle stationary mode images or projection images.

Method 2:

- The focal planes of the reconstructed tomosynthesis image are divided in half overlapping ROIs of 10 mm by 10 mm.
- In each ROI the average pixel value and standard deviation is measured and calculated.
- SNR is calculated for each ROI by dividing the average pixel value by the standard deviation.
- In addition to this, the focal planes of the reconstructed tomosynthesis image are divided in ROIs of 2 mm by 2 mm and variance is calculated. If the system has a non-linear response the images need to be linearized.

  Note: Detector artefacts might be easier to evaluate on zero-degree angle stationary mode or projection images. The method for evaluation of projection images is similar to that used for DM.

Action levels

Method 1: no disturbing artefacts and or clinically relevant inhomogeneities should be present.

Method 2: The mean pixel value and SNR of each ROI should be between 97% and 103% of respectively the mean pixel value and SNR of neighbouring ROIs. The maximum deviation in mean pixel value of each ROI should be ≤ ± 10% of the mean pixel value in all ROI's (provisional value). The maximum deviation in SNR of each ROI should be ≤ ± 50% of the mean SNR in all ROI's (provisional value).

The variance of each ROI should be compared with the variance of neighbouring ROIs. If the variance in an ROI is > 30% higher than the variance in neighbouring ROIs, the image should be investigated visually for an artefact at this position.

No disturbing artefacts should be present.

7 Dosimetry

Several papers have been published regarding the new breast dosimetry, but the final report with accompanying software has not been published yet. The two chairs of the EFOMP/AAPM dosimetry WG are consultants to the DBT working group, which allowed the implementation in this draft version of the DBT QC protocol. As the new breast dosimetry is part of this protocol, the approval of this protocol can only take place after approval of the breast dosimetry report.

7.1 Dosimetry

Introduction

The average glandular dose (AGD) cannot be measured, instead conversion factors are used to relate a measured quantity, the air kerma at a reference point, to the AGD.

The conversion factors and procedures for estimating the AGD provided here for tomosynthesis systems are based on the models, phantoms, and methods developed by the joint EFOMP/AAPM Workgroup/Task Groups 282 and 323 and are described more fully in their corresponding reports [REFs]. Contrary to previous European breast dosimetry protocols, computer software is provided to calculate the AGD based on a measurement of air kerma, exposure factors recorded for the examination, and information on the geometry of the system. The conversion factor employed is calculated by the software for the specific x-ray spectrum and breast characteristics entered by the user.

In this document we only consider the situation using a DBT system with a full-field detector and an x-ray tube that rotates above it so that the whole breast is irradiated in each exposure over a range of angles (full-field geometry). The conversion factors for determining the AGD from measured air kerma values were estimated for models of the breasts compressed for both the CC and MLO view. As specified in the reference reports, the compressed breasts vary in horizontal area with compressed breast thickness, with two example models shown in Figure 28. These breast models are based on quantitative analysis of both 2D images (mammograms) and 3D images (dedicated breast CT images) of patient's breasts, from which both the exterior shapes and the interior composition of the breasts were characterized. The resulting breast models comprise an inner region consisting of a mixture of adipose and glandular tissue that varies in proportion with location, surrounded on all sides, except on the chest wall, by a 1.5 mm layer of skin.

For the purposes of the breast dosimetry estimates described in this Chapter, breast density refers to the volumetric breast density over the entire breast. That is, the breast density is defined as the ratio of the volume occupied by the glandular tissue divided by the volume occupied by the entire breast, including the skin, and, in the case of the MLO view, the pectoral muscle.

To increase the clinical relevance of the conditions evaluated, the breast density values to be evaluated are described in terms of percentiles, not percentage, density. That is, it is strongly recommended that the dosimetric characteristics of systems are evaluated for specific breast density percentiles for each view and breast thickness. Both the WG/TG 323 breast dosimetry phantoms, and the WG/TG 282 breast dosimetry software relate the specified percentiles to the appropriate percent volumetric breast density considering the view and breast thickness in question. This guarantees that the imaging conditions being evaluated fall within those that can realistically be expected to be encountered during clinical practice. Further detail on how the percentile/percentage breast density relationships were established can be found in the WG/TG 282 report.

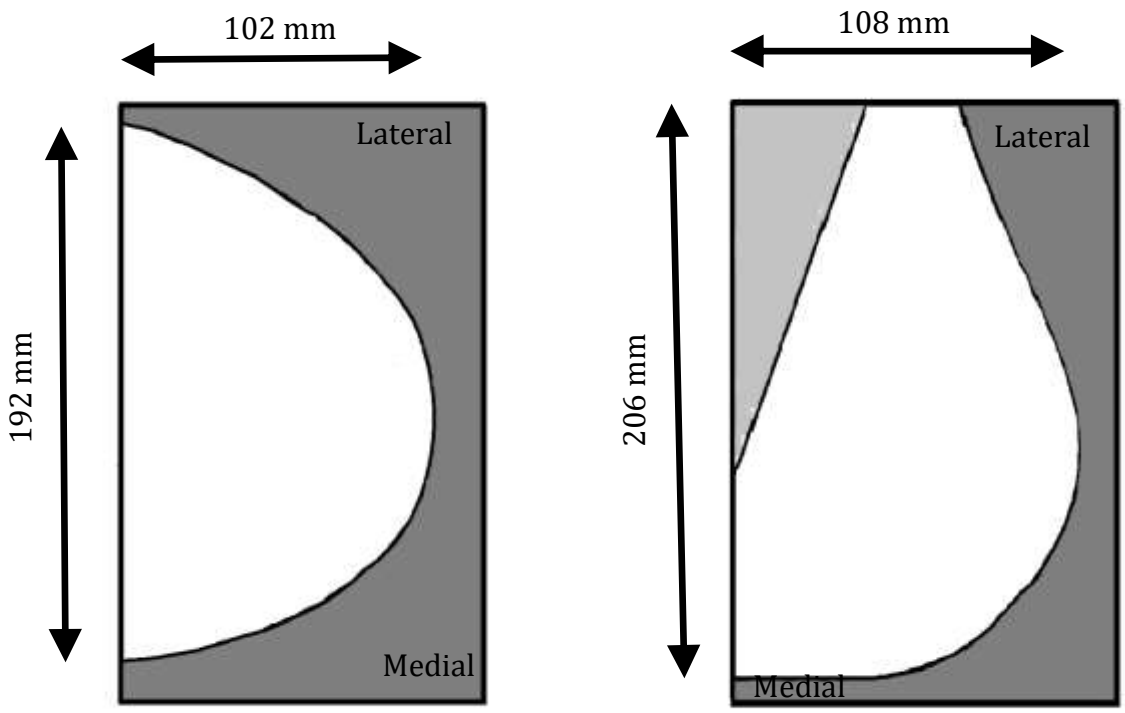


Figure 28 Examples of the models of the compressed breasts for the (left) CC and (right) MLO views used for the dosimetry estimates. These breast models are the ones that represent compressed breast thicknesses of 58 mm.

As well as the use of the WG/TG 323 breast phantoms for dosimetry mentioned above, this protocol also describes the use of simple slab-based PMMA (Dance, Skinner, *et al.*, 2000; Dance, Young and Van Engen, 2011) and PMMA/PE phantoms (Bouwman, 2013). These widely-used phantoms may not provide as good a simulation of a real breast as the WG/TG 323 breast phantom.

Definitions

In breast tomosynthesis, the average glandular dose is the sum of the doses received from individual projections. To estimate the average glandular dose D_g, the following equation is used:

$$D_g = K_{ref}\Gamma \tag{17}$$

In this expression K_{ref} is the reference air kerma free-in-air at 500 mm from the source and 40 mm anterior from the chest wall edge of the x-ray beam, in units of mGy, and Γ is the air kerma to dose conversion coefficient, in units of mGy/mGy. The reference air kerma should be determined for the zero-degree (straight through) position and should reflect the exposure of the full tomosynthesis acquisition, i.e., using the total current-time product (mAs) for the entire projection set. The single conversion factor Γ is calculated via the software provided for the specific x-ray spectrum (target, filter(s), tube voltage, and 1st half-value layer) and breast characteristics (view, density, and thickness) entered by the user.

The conversion factor Γ is calculated in real-time using the equation:

$$\Gamma = \frac{\sum_{a=A_{min}}^{A_{max}} \sum_{e=E_{min}}^{E_{max}} \psi(e) \left(\frac{\mu_{tr}}{\rho}\right)_{air} (e) \gamma(t,g,e,a)}{N_a \sum_{e=E_{min}}^{E_{max}} \psi(e) \left(\frac{\mu_{tr}}{\rho}\right)_{air} (e)} \tag{13}$$

where:

$\sum_{a=A_{min}}^{A_{max}}$	is the sum over all projection angles included in the acquisition.
$\sum_{e=E_{min}}^{E_{max}}$	is the sum over all x-ray energies modelled to be included in the x-ray beam.
$\psi(e)$	is the modelled mono-energetic energy fluence of x-rays of energy e of the incident x-ray beam, at the reference point, when the x-ray source is positioned at the 0° projection angle.
$\left(\frac{\mu_{tr}}{\rho}\right)_{air}(e)$	is the mass energy transfer coefficient for air for x-rays of energy e.
$\gamma(t,g,e,a)$	is the mono-energetic conversion coefficient for the compressed breast of thickness t and volumetric glandularity g, for x-rays of energy e at the a projection angle per unit air kerma at the reference point.

The x-ray spectrum model, $\psi(e)$, is based on the target, filter(s), tube voltage and 1st half-value layer of the spectrum used for the tomosynthesis acquisition being investigated. For this dosimetry estimate, the x-ray spectrum models developed by Hernandez et al are used(Hernandez *et al.*, 2017). The monochromatic conversion factors, $\gamma(t, g, e, a)$, are based on almost 250,000 Monte Carlo simulations of mammographic and tomosynthesis acquisitions. Therefore, it is not feasible to tabulate these γ or Γ conversion factors, and the use of the breast dosimetry software provided with the WG/TG 282 report is required. What follows is a brief overview of the methodology to measure K_m and the use of the dose estimation software to obtain Γ and D_g. The reports of WG/TG 282 and WG/TG 323 may be consulted for more detailed information.

Purpose

To estimate the average glandular dose to model breasts using phantoms representing breasts of several thicknesses.

Test equipment

- Suitable dose meter

Method 1:

- WG/TG 323 breast dosimetry phantom

Method 2:

- PMMA slabs and blocks of foam or spacers

Method 3:

- PMMA and PE slabs

Test frequency

- At acceptance and subsequent routine QC tests
- After x-ray tube replacement
- After filter replacement
- After detector replacement
- After relevant software change

Test procedure

The doses to a range of typical breasts should be assessed using blocks of the WG/TG 323, PMMA+spacers or PMMA+PE breast dosimetry phantoms as breast substitutes and allowing the AEC to determine the exposure factors including any automatic selection of kV, target/filter combination, and current-time product (mAs).

Method 1: Estimation of AEC-selected exposure factors based on the WG/TG 323 phantom

The AEC systems of current tomosynthesis systems evaluate the content of the imaged breast assuming that a real patient breast is being imaged. Therefore, in some systems, the use of an unstructured phantom, such as PMMA or PMMA/PE slabs, can result in unexpected behaviour. In addition, these PMMA and PMMA/PE slabs can only represent the attenuation of specific breast thickness/density combinations. To ameliorate this issue, the joint EFOMP/AAPM WG/TG 323 has designed a phantom with the specific aim of stimulating the AEC as closely as possible to how real patient breasts of the same characteristics would, and to allow for the phantom to represent breasts of different combinations of thicknesses and densities. This phantom consists of 7 adipose tissue-equivalent slabs, allowing for the representation of breasts of different compressed breast thickness, in addition to a set of 5 base slabs that each contain a glandular tissue-equivalent insert. Each of these insert-containing slabs replicate breasts of different densities, specifically 5^{th}, 25^{th}, 50^{th}, 75^{th}, and 95^{th} percentile densities, independent of breast thickness. For the AEC evaluation, only the 50^{th} percentile insert-containing slab is used, together with as many adipose slabs to be able to represent the desired compressed breast thickness.

Figure 29 Setup for estimating glandular dose using the WG/TG 323 phantom

- Position the base slab with 50th percentile density on the bucky.
- Place the compression paddle in contact with the base slab and apply a compression force of around 100 N, see Figure 29.
- Make a DBT exposure in the clinically relevant AEC mode.
- Add a 10 mm thick adipose tissue slab and repeat the procedure, continue adding adipose tissue slabs until images have been made at breast thicknesses of 20, 30, 40, 50, 60, 70, 80 and 90 mm. If desired, replace the base slab with one for a different breast density and repeat the procedure for all thicknesses.
- Record the exposure factors for each simulated breast thickness and density.
- Measure the air kerma in the zero-degree angle stationary mode at the reference point using the method given below and the recorded exposure factors.

Table 6 Dosimetry phantom thickness, height of the compression paddle, and hence thickness of the modelled compressed breast using the 50 percentile density base slab.

Dosimetry phantom thickness (mm)	Height of the compression paddle (mm)
20	20
30	30
40	40
45	45
50	50
60	60
70	70
80	80
90	90

Method 2: Estimation of AEC-selected exposure factors based on PMMA slabs

This method relies on simulating typical breasts with PMMA (Dance, Skinner, *et al.*, 2000) as listed in table 7. It should be noted that the height of the paddle must match the thickness of the model breast that is simulated as the automatic selection of kV, target, or filter may be dependent on the breast thickness. In addition for systems that require compression to determine the exposure factors in fully automatic mode spacers should be added (e.g., expanded polystyrene blocks) to the PMMA to make up a total thickness to that of the equivalent breast. Small pieces of more attenuating materials can also be used as spacers, provided they are outside the sensitive area of the AEC. On systems that do not require compression to determine the exposure factors in fully automatic mode, spacers are not necessary.

Figure 30 Setup for estimating glandular dose using PMMA slabs

- Position a 20 mm thick PMMA plate on the bucky.
- Place the compression paddle at the height given in Table 7 for 20 mm of PMMA to obtain the thickness of the equivalent breast with similar attenuation.
- Make a DBT exposure of the PMMA stack in the clinically relevant AEC mode. For some systems a specific phantom acquisition mode may need to be selected.
- Repeat the exposure for the PMMA thicknesses according to Table 7 by adding additional slabs of PMMA on top of the stack.
- The compression paddle should be positioned at the height given in Table 7. This is achieved by leaving an air gap between the PMMA plates and the compression paddle. If compression is necessary to make an exposure, then spacers must be used, but they must be positioned such that they do not reduce the transmission

of x rays through the central and chest wall regions of the image at any tube angle. This may be achieved by placing spacers along the back edge of the PMMA (Figure 30) or at the far lateral sides of the image receptor.

- Record the exposure factors for each simulated breast thickness.
- Measure the air kerma in the zero-degree mode in the reference point using the method given below and record the exposure factors.

Table 7 PMMA thickness, height of the compression paddle, and hence thickness of the modelled compressed breast, and equivalent volumetric breast density represented by the different PMMA thicknesses.

PMMA thickness (mm)	Height of the compression paddle (mm)	Equivalent volumetric breast density (%)*
20	21	45
30	32	39
40	45	26
45	53	19
50	60	13
60	75	6
70	90	3

* Note that in this table the volumetric breast density is used, which is a property of the whole breast. In the original publication (Dance, Skinner, *et al.*, 2000), the density used was by mass and for just the central region of the breast and therefore the values are different.

Method 3: Estimation of AEC-selected exposure factors based on PMMA and PE slabs

The method relies on the equivalence in attenuation between different thicknesses of PMMA and PE and typical breasts (Bouwman, 2013).

Figure 31 Setup for estimating glandular dose using PMMA and PE slabs

- Position a 20 mm thick PMMA plate on the bucky
- Place the compression paddle in contact with the PMMA block and apply a compression force of around 100 N, see Figure 31.
- Make a DBT exposure of the PMMA stack in the clinically relevant AEC mode. For some systems a specific phantom acquisition mode may need to be selected.
- Repeat the exposure for the PMMA and PE thicknesses according to Table 8. PMMA slabs should be always at the bottom of the stack and all PE slabs on top of the PMMA stacks (see Figure 31)
- Record the exposure factors for each simulated breast thickness.
- Measure the air kerma in the zero-degree mode in the reference point using the method given below and the recorded exposure factors.

- Repeat the procedure for Standard breast thicknesses from 30 to 90 mm, see table 8.

Table 8 Thickness of PMMA and PE to match the attenuation of the standard breast with the same total thickness.

PMMA thickness (mm)	PE thickness (mm)	Height of the compression paddle (mm)	Volumetric breast densities (%)*
20.0	0.0	20	44
27.5	2.5	30	41
30.0	10.0	40	31
32.5	17.5	50	21
32.5	27.5	60	14
32.5	37.5	70	8
32.5	47.5	80	5
35.0	55.0	90	3

* Note that in this table the volumetric breast density is used, which is a property of a whole breast. In the original publication (Bouwman, 2013). the density used was by mass and for just the central region of the breast and therefore the values are different.

Measurement of air kerma for the AEC-selected exposure factors

Although Γ is weighted by K_{ref} to estimate D_g, the dosimetry software takes as input the air kerma measured, K_m, using the procedures described here. To measure K_m, the dosimeter should be placed on the breast support table, with the centre of the active area of the dosimeter located at the centreline of the imaging detector along the chest wall, and 50 mm anterior to the chest wall edge of the breast support table (Figure 32). The compression paddle should be left in the beam but positioned as close to the x-ray tube as possible. Finally, the collimation of the system to produce the largest x-ray field should be selected, and the tube should be fixed at the 'zero-degree' position.

It is recommended that when performing these measurements some type of attenuating material (e.g., steel plate, lead apron, etc.) be placed on the breast support table, underneath the dosimeter to avoid ghosting issues. In addition to K_m, note the vertical distance between the effective measurement location of the dosimeter (usually marked with a red line on the dosimeter), l_m, and the vertical distance between the source and the top of the breast support table, l_t.

Figure 32 Schematic showing the setup for the measurement of K_m.

Measure the air kerma using this setup in zero-degree mode for a given reasonable current-time product, e.g., 50 mAs, for each of the set of other exposure parameters determined in the previous step using the phantoms. Then scale the measured air kerma to the actual current-time product set by the AEC for each corresponding exposure to obtain K_m.

If the dosimeter is not shielded for backscatter or if this is not known, then the measurement of air kerma should be performed free in air, with the dosimeter higher above the breast support table and still with the paddle as far away as possible, and the appropriate inverse square law correction should be made.

If not already available, measure the 1st half-value layer for each of the spectra selected by the AEC for the different breast phantoms evaluated. The 1st half value layer must be measured with the compression paddle present, See section 2.2.

Estimation of average glandular dose for the AEC-selected exposures

Use the WG/TG 282 software to estimate the average glandular dose to the evaluated breast models as would result from acquisition with the AEC-selected exposures. Table 9 summarizes the inputs necessary for this protocol and the value ranges for each. For the three sets of standard phantoms used here, entering phantom thicknesses and the volumetric breast densities in the dosimetry software is not necessary. For other uses of this software, consult the TG report for more information.

For each breast exposure input, the software will output the Γ and D_g estimated.

Table 9 Summary of inputs to the dosimetry software program, with specification of their expected format, units used, and options

Input	Unit	Format	Options
Breast model			
#Breast model set	-	Text	WG/TG 323, PMMA, PMMA/PE
Acquisition			
Modality	-	Text	DBT
Source to dosimeter distance, l_m	mm	Integer	> 0
Source to breast support table distance, l_t	mm	Integer	> 0
DBT projection angle range	deg	Decimal	≥ 0.0 to ≤ 60.0
§DBT number of projection angles	-	Integer	≥ 1
†§DBT specific projection angles	deg	Decimal	-30.0 – +30.0
†§DBT relative variation in tube current-exposure time product across projections	-	Decimal	≥ 0.0
Spectrum model			
Anode material	-	Text	Mo, Rh, or W
Tube voltage	kV	Integer	20 – 49
‡Filter elements	-	Text	Any chemical element symbol
‡Filter thicknesses	mm	Decimal	> 0.0
1st Half value layer	mm Al	Decimal	> 0.0
Measured air kerma, K_m	mGy	Decimal	> 0.0

#If either the WG/TG 323,, PMMA, or PMMA/PE breast model set is used as input to the software, then no other input for the breast model is needed.
†Inputs available in input-file mode only.
‡The same number of inputs for filter element and thickness is required.
§If provided, the number of inputs for the exposure variation with projection angle must match the number of projection angles.

Assessing clinical breast doses

It is also encouraged to estimate the average glandular dose to the model breasts for a series of breast examinations performed on each mammography system. The procedure can be found in appendix 5. The actions level given below do not apply.

Action levels

Using the x-ray spectra found in clinical practice for specific breast thicknesses for all major mammography unit manufacturers, the existing limiting values for glandular dose have been converted to incident air Kerma using the current (or old) dosimetry model for the clinically used range of x-ray spectra for each breast thickness. These incident air Kerma values have been used as input to the new dosimetry model to obtain glandular dose values using the same x-ray spectra at which the incident air Kerma was calculated. These glandular dose values have been used to set limiting values for the new dosimetry model. The resulting limiting values still need to be checked by a large number of dosimetry measurements from QC tests on all major brands of DBT equipment.

Table 10a Average glandular dose limiting values for PMMA + spacers phantoms

Breast thickness	Average glandular dose
	Limiting value (provisional)
(mm)	(mGy)
21	1.2
32	1.45
45	1.8
53	2.2
60	2.6
75	3.6
90	4.7

Table 11b Average glandular dose limiting values for PMMA + PE phantoms

Breast thickness	Average glandular dose
	Limiting value (provisional)
(mm)	(mGy)
20	1.2
30	1.35
40	1.6
50	2.0
60	2.6
70	3.1
80	3.8
90	4.7

Remark: Limiting values for intermediate breast thicknesses may be obtained by interpolation of the values in these tables using a second order polynomial function.

8 Glossary

AEC Automatic Exposure Control

Acceptance test QC tests performed after installation of the system, which determines the acceptability of an individual system and sets reference values for future QC tests.

Action level Value(s) of a QC parameter, for which corrective action is required if exceeded.

AGD Average Glandular Dose, absorbed dose in the glandular tissue in a (model) breast, using a specified calculation method.

Angle (projection -) The projection angle is the angle between a line extended from the detector through the object and the normal to the detector.

Angle (tube rotation-)

The tube rotation angle is angle between the line connecting 'the center of rotation and the source' and the zero-degree line).

Angular range The difference in angle between the first and last projection of a tomosynthesis acquisition.

Bad pixel A picture element in an image for which the del reading is not sufficiently based on the imaged object.

Bad pixel map A map (either an image or a table) which defines the position of all pixels for which the pixel value is not based on its own del reading (in 2D mammography or projection images in DBT). The maps from 2D and DBT might be different.

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

Centre of rotation Centre point of the rotational movement of the x-ray tube

DBT Digital breast tomosynthesis

Detector binning Individual dels that are combined to create one pixel in the image. Information for a particular system can be found in the DICOM header in tag 0018x,701Ax

1\1 is no binning; 1\2 is grouping of 2 dels into a single pixel for 1 direction; 2\2 is 4 dels grouped into 1 pixel

Detector corrections

Corrections in DR systems in which the values of defective detector elements/columns/rows are recovered using the detector bad pixel map; additional corrections are also made for variations in individual detector element sensitivity, electronic gain and large area variations in signal (e.g. heel effect, beam divergence).

Del Single discrete detector element in a DR detector.

Del pitch (Also referred to as pixel pitch)Physical distance between the centres of adjacent dels. This is DICOM tag (0018;1164) and is called imager pixel spacing. This is generally equal to detector element spacing.

DM Full Field Digital Mammography, 2D mammography

Exposure time (projection image) or pulse lenght

The duration of the x-ray exposure for a projection image

Filtered Backprojection mode (FBP)

Mode on a DBT system in which the 3D reconstruction is performed using a backprojection technique with additional filtering.

First projection image

The first projection image made in a DBT sequence of images with exposure parameters which have been determined by the AEC. Note: This does not have to be the first image in the DBT sequence if the image with largest angle is the pre-exposure. The projection image which needs to be used for QC tests for the different brands is given in appendix 3.

Focal spot line Line from the focal spot to the centre of the image receptor

Focal plane A plane within a reconstructed image in which objects at the height it represents are brought into focus.

Full-field geometry Geometry of DBT systems incorporating a detector as used in conventional 2D full field digital mammography (DM), and an x-ray tube that moves above this detector. A series of individual projection images, in which the whole breast is irradiated in each exposure, are acquired over a range of angles.

Ghosting signal Long term residual signal in the detector that can cause change to sensitivity of the detector and cause artefact, it can also be known as burning a detector.

Iterative reconstruction algorithm

Mode on a DBT system in which the 3D reconstruction is performed using iterative algorithms in addition or alternatively to FBP

Lag Residual signal carried over from previous projection images into successive projection images.

Linearised pixel value

In DM or tomosynthesis projection images there may not be a directly proportional relationship between pixel value and air kerma at the detector surface. Linearized pixel values are obtained by inverting the system response in which pixel values are plotted against detector air kerma. Following this step, a pixel value measured in an image in which

	pixel values have been linearized is equal to the detector air kerma. This assumes similar beam qualities for the response curve and the image in question. A linearized image has zero off-set.
Noise	All fluctuations in pixel values except those directly related to the imaged anatomy or structures within a test object. The standard deviation or the variance in a ROI in the image is taken as measure of noise.
Pixel	Picture element, the smallest unit in an electronic image.
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 system.
Pixel value offset	Fixed value that has been added to the values of all pixels during the generation of the projection image. Not all systems have a pixel value offset in the projection images.
Projection image	An image within a series of images, acquired at a specific tube rotation angle.
Processed image	The image after image processing, ready for presentation on the monitor or print-out. In the DICOM file the value of the element Presentation Intent Type (0008,0068) is 'FOR PRESENTATION'.
Processed projection image	A projection image in which the DICOM tag (0008, 0068) is set to 'FOR PRESENTATION'. A manufacture might process the projection images before image reconstruction.
Raw image	See unprocessed image
Reconstructed DBT image	Output image of a DBT system consisting of a stack of reconstructed focal planes
Reconstructed focal plane	An image representing a particular height within a reconstructed volume, with only objects at that height brought into sharp focus.
Reconstructed volume	The volume represented by a reconstructed DBT image**.**
Reference point	A point on the breast support table at 50 mm perpendicular to the chest wall edge of the table and centred laterally, following the new breast dosimetry. Note that in previous protocols the reference point was at 60 mm from chest wall side.

Reference region-of-interest (in the projection image)

A region-of-interest (size:5 x 5 mm) in the projection image. The centre of the region-of-interest is positioned 50 mm perpendicular to the chest wall edge of the table and centred laterally.

Reference value The value of a QC parameter obtained with baseline images (typically at acceptance), which is used as reference for subsequent QC tests or the typical value of a QC parameter**.**

Routine QC test QC test performed periodically after acceptance of a system.

Scan Complete cycle of a tomosynthesis acquisition

Scan Time The time between the start of the first exposure (this could be a test shot in the zero-degree postion) and the end of the last exposure of a tomosynthesis sequence.

Scanning geometry Geometry of DBT systems utilising a narrow collimated x-ray beam which scans across the breast as the x-ray tube rotates, and by which the breast is only partially irradiated at each position of the x-ray tube. Due to the design of the system and continuous readout from the detector, individual projection images might not exist.

SDNR Signal Difference to Noise Ratio. If calculated from projection images, these images must first be linearized.

$$\mathrm{SDNR} = \frac{PV(signal) - PV(background)}{\mathrm{SD(background)}} \qquad (14)$$

sequence of images Full series of images on a DBT system between and including pre-exposure and/or first projection image and the last projection image.

SNR Signal-to-Noise Ratio: In DM imaging SNR is calculated as follows for a specific ROI. If calculated from projection images, these images must first be linearized

$$\mathrm{SNR} = \frac{\mathrm{PV - PVoffset}}{\mathrm{SD}} \qquad (15)$$

Standard test block PMMA test object of 45 mm thickness to represent a typical load for the system. The block may consist of several thinner slabs.

Straight through position

The position of the focal spot in which the focal spot line equals the zero-degree line.

Threshold contrast The contrast of an object at a given detectability. Detectability can be determined using human or machine scoring.

Unprocessed image A digital image after flat-fielding and detector corrections but before other image processing has been applied. In the DICOM header the value of the element Presentation Intent Type (0008,0068)is 'FOR PROCESSING'. Sometimes unprocessed images are referred as 'raw data'

Unprocessed projection image

A projection image without clinical image processing.

Variation

$$\frac{\min - \max}{mean} \text{ x } 100\% \qquad (16)$$

Z-direction

On DBT systems, the z-direction is perpendicular to the reconstructed planes.

Zero-degree projection

A projection in which a line through the focal spot and centre of rotation is perpendicular to the breast support table surface.

Zero-degree angle stationary mode

A stationary mode at zero-degree angle which produces projection images in which the exposures of all projection images is given without movement of the x-ray tube. In this mode it must be possible to choose similar x-ray spectra as in standard DBT mode. AEC should be working as for a moving tube DBT scan. Projection images should have the same corrections (e.g. gain, flat fielding, etc.) as for the moving tube DBT scan.

For dose, HVL and tube voltage measurements a stationary mode at the zero-degree angle is required giving the same exposure in the clinically used AEC mode(s) as in DBT mode but without the tomosynthesis movement. All DBT systems must have this mode available

Zero-degree line

line connecting the centre of the rotation and the source when the tube is in the nominal 0° position

Appendix 1: Specifications and geometry of common breast tomosynthesis systems

Table 12 Specifications and geometry of the breast tomosynthesis systems of some major manufacturers (based on Sechopoulos 2013, EUREF 2018 and subsequent information from manufacturers). Updates can be found on the EFOMP website.

DBT System	GE Healthcare SenoClaire	GE Healthcare Pristina	Hologic Selenia Dimensions	Hologic 3Dimensions	IMS Giotto Class	Metaltronica Helianthus DBT	Planmed Clarity3D	Siemens Mammomat Inspiration	Siemens Revelation	Fujifilm Amulet Innovality
Detector material	CsI-Si	CsI-Si	a-Se	a-Se	a-Se/ CsI-Si	a-Se/ CsI-Si	CsI-Si	a-Se	a-Se	a-Se
Detector element pitch (µm)	100	100	70	70	85/83	85/85	83	85	85	68[3]
Focal plane pixel size (µm)	100	100	95-117[1]	95-117[1]	90/?	85	83/166	85	85	50-100/ 100-150
x-ray tube motion	Step-and shoot	Step-and shoot	Continuous	Continuous	Step-and-shoot	Continuous	Continuous Sync-and-Shoot	Continuous	Continuous	Continuous
Target	Mo/Rh	Mo/Rh	W	W	W	W	W	W	W	W
Filter	Mo: 30µm Rh: 25 µm	Mo: 30µm Ag: 30µm	Al: 700 µm	Al: 700 µm	Ag: 50 µm	Al: 700 µm	Rh: 75 µm Ag: 60 µm	Rh: 50 µm	Rh: 50 µm	Al: 700 µm
Angular range (°)	25	25	15	15	30[2]	15/24/50	30	50	50	15/40
Number of projection images	9	9	15	15	11	11/13/19	15	25	25	15
Source to detector distance (mm)	660	660	700	700	690	?	650	655	655	650
Distance between detector and centre of rotation (mm)	40	40	0	0	40	?	4.4	47	47	46

[1] The pixel size in the focal planes change with height above the breast support table.

[2] The projection images may not be equally spaced and may not have the same exposure factor.

[3] Hexagonal shaped detector elements.

Appendix 2: Overview of testing modes, type of images for analysis and limiting values

Table 13 Overview of the acquistion mode, type of image for analysis and limiting values for all QC tests

	Acquisition mode	Type of images used in QC test	Limiting values
2 X-RAY SOURCE			
2.1 Focal spot motion	Clinical AEC mode	n.a.	The focal spot motion length should not change > 20% compared to the reference value.
2.2 Tube voltage accuracy HVL and tube voltage	Zero-degree mode	n.a.	Tube voltage error ≤ ±1kV. HVL should be within typical range.
2.3 X-ray beam alignment and collimation checks	Manual tomosynthesis mode	Reconstructed DBT image	The x-ray field must not extend more than 5 mm beyond the edge of the image receptor and the reconstructed tomosynthesis image. At the lateral sides the x-ray field should not extend beyond the breast support table.
2.4 Tube output	Zero-degree mode	n.a.	Within typical range. Variation ≤ 5%.
3 COMPRESSION			
3.1 Compression force	n.a.	n.a.	Maximum motorized compression force between 150 N and 200 N. Decrease in compression force within 1 minute ≤ 10 N. No damage, sharp edges and cracks on compression paddle.
3.2 Displayed breast thickness value	n.a.	n.a.	If the displayed and measured thickness deviate > 2 mm, correction factors need to be applied when determining clinical breast dose
4 AUTOMATIC EXPOSURE CONTROL			
4.1 Short term repeatability	Clinical AEC mode	1st projection image	Variation in total current–time product (mAs) ≤ 5%.

			Variation in SNR ≤ 10%.
4.2 Long term AEC stability	Clinical AEC mode	1st projection image	Variation in incident air kerma (or current-time product) ≤ ± 10% Variation in pixel value ≤ ± 10%. Variation in SNR ≤ ± 10%.
4.3 AEC performance	Clinical AEC mode	1st projection image	SDNR values within 15% of the reference values and within 15% of the values of systems of the same brand, type and software version.
4.4 Local dense area	Clinical AEC mode	1st projection image	Dose should increase with higher simulated glandularity. Max deviation in SDNR ≤ 15% (provisional limiting value)
4.5 Exposure duration	Clinical AEC mode	n.a.	The exposure time for a projection in the DICOM header should be within 15% (provisional value) of the measured value
4.6 Guard timer/security cut-off	Clinical AEC mode	n.a.	The exposure should be terminated after the pre-exposure.
5 DETECTOR CHARACTERISTICS			
5.1 Response function	Manual tomosynthesis mode	1st projection image	$R^2 > 0.98$. The response function model must match the specification of the manufacturer
5.2 Noise components analysis	Manual tomosynthesis mode	1st projection image	Quantum noise must be the largest noise component over the clinical detector air kerma range.
5.3 Detector element failure	n.a.	n.a.	Manufacturer's limiting values, see appendix 4.
5.4 Uncorrected defective detector elements	Manual tomosynthesis mode or zero-degree mode	1st projection image or zero-degree image	Uncorrected dels should be not visible. No pixel value should deviate > 20% from the average value an ROI.
5.5 System projection MTF	Manual tomosynthesis mode	1st projection image	Change MTF_{50} < 20% from the reference value.
6 IMAGE QUALITY 3D			
6.1 Technical	Clinical AEC mode	Reconstructed DBT	Compared with the reference

image quality 3D		image	value
6.2 MTF in the reconstructed image	Manual tomosynthesis mode	Reconstructed DBT image	≤ 20% difference with reference value
6.3 Artifact spread function	Clinical AEC mode	Reconstructed DBT image	≤ 10% difference with reference value (provisional). The FWHM values of different systems of the same brand, type and software version should be similar.
6.4 Geometric distortion	Clinical AEC mode	Reconstructed DBT image	Within manufacturers specifications
6.5 Missed tissue at chest wall side/at top and bottom of the reconstructed image	Clinical AEC mode	Reconstructed DBT image	Width of missed tissue at chest wall side ≤ 5 mm. All high contrast objects at the breast support table and underneath the compression paddle should be brought into focus in the reconstructed tomosynthesis image
6.6 homogeneity and artefact evaluation	Clinical AEC mode	Reconstructed DBT image	The mean pixel value and SNR of each ROI should be < 3% of the values in adjacent ROIs. Deviation in mean pixel value of each ROI should be < ± 10% of the mean pixel value in all ROIs. Deviation in SNR of each ROI should be ≤ ± 50% of the mean SNR in all ROIs. If variance in an ROI is > 30% higher than the variance in neighbouring ROIs, the image should be investigated visually for an artefact on this position. No disturbing artefacts should be present.
7 DOSIMETRY			
7.1 Dosimetry	Zero-degree mode	n.a.	Under construction.

Appendix 3: Compression requirements in clinical AEC mode and projection images for QC measurements for different brands of systems

Table 14 Compression requirements, requirements on fully irradiated area and projection image to be used for QC measurements in clinical fully automatic AEC mode for different brands of systems. Updates can be found on the EFOMP website.

Brand	Compression required in clinical AEC mode	Fully irradiated are at lateral and chest wall side required	Projection image on which QC measurements need to be performed
Fujifilm	No	No	First
GE	Yes	No	First
Hologic	No	No	First
IMS	Yes	No	Second
Metaltronica	Yes	No	First
Planmed	No	No?	?
Siemens	Yes	Yes	Second

Appendix 4: Pixel map criteria and manufacturer limits

The content of this appendix will be discussed with each manufacturer separately before inclusion in this protocol.

Appendix 5: Auditing clinical breast doses

It is encouraged to use the WG/TG 282 software (ref) to estimate the average glandular dose for a series of examinations (> 200 cases) performed on real breasts on each mammography system. Note that although the acquisition conditions of actual patient imaging are used, the results of these estimates are NOT patient doses. This is because the average glandular dose is still estimated for the simplified model breasts exemplified by those in Figure XX. For real patient dose estimates, the magnitude and distribution of the glandular tissue in the actual patient breasts would have to be known and considered.

To estimate the average glandular dose to the model breasts based on patient exams, the DICOM header of the acquisition being investigated needs to be analysed to obtain the source target/filter combination, tube voltage, and current-time product used, in addition to the measured breast thickness under compression. If not already available for the tube voltage and target/filter combination used, it is recommended that the 1st half-value layer be measured. Optionally, the dosimetry software can develop a standard x-ray spectrum model without refinement for the actual 1st half-value layer of the used spectrum. In addition, the tube output needs to be known to calculate the K_m for the used current-time product (mAs). The breast density input in the dosimetry software can be either 50th percentile, or, if available, the volumetric breast density (in percent) obtained from quantitative analysis of the image. Various research and commercial software packages perform this type of quantitative analysis to estimate volumetric breast density from mammographic or tomosynthesis images.

References

Badal, A., Clark, M. and Ghammraoui, B. (2018) 'Reproducing two-dimensional mammograms with three-dimensional printed phantoms', *Journal of Medical Imaging*, 5(03), pp. 033501-1–9. doi: 10.1117/1.jmi.5.3.033501.

Bliznakova, K. (2020) 'The advent of anthropomorphic three-dimensional breast phantoms for X-ray imaging', *Physica Medica*. Elsevier Ltd, 79(December), pp. 145–161. doi: 10.1016/j.ejmp.2020.11.025.

Bouwman, R. W. (2013) 'Phantoms for quality control procedures in digital breast tomosynthesis : dose assessment', 4423. doi: 10.1088/0031-9155/58/13/4423.

Cockmartin, L. *et al.* (2017) 'A structured phantom for detection performance comparison between breast tomosynthesis and digital mammography', *Physics in Medicine & Biology*, 15(62), pp. 758–780. doi: 10.1088/1361-6560/aa5407.

Dance, D. R. (1990) 'Monte Carlo calculation of conversion factors for the estimation of mean glandular breast dose.', *Physics in medicine and biology*, 35(9), pp. 1211–9. Available at: http://www.ncbi.nlm.nih.gov/pubmed/2236205.

Dance, D. R., Skinner, C. L., *et al.* (2000) 'Additional factors for the estimation of mean glandular breast dose using the UK mammography dosimetry protocol', *Physics in Medicine and Biology*, 45(11), pp. 3225–3240. doi: 10.1088/0031-9155/45/11/308.

Dance, D. R., Thilander Klang, A., *et al.* (2000) 'Influence of anode/filter material and tube potential on contrast, signal-to-noise ratio and average absorbed dose in mammography: A Monte Carlo study', *British Journal of Radiology*, 73(874), pp. 1056–1067. doi: 10.1259/bjr.73.874.11271898.

Dance, D. R. and Young, K. C. (2014) 'Estimation of mean glandular dose for contrast enhanced digital mammography : factors for use with the UK , European and IAEA breast dosimetry protocols', *Phys. Med. Biol.*, 59, pp. 2127–2137. doi: 10.1088/0031-9155/59/9/2127.

Dance, D. R., Young, K. C. and van Engen, R. E. (2009) 'Further factors for the estimation of mean glandular dose using the United Kingdom, European and IAEA breast dosimetry protocols.', *Physics in medicine and biology*, 54(14), pp. 4361–72. doi: 10.1088/0031-9155/54/14/002.

Dance, D. R., Young, K. C. and Van Engen, R. E. (2011) 'Estimation of mean glandular dose for breast tomosynthesis: Factors for use with the UK, European and IAEA breast dosimetry protocols', *Physics in Medicine and Biology*, 56(2), pp. 453–471. doi: 10.1088/0031-9155/56/2/011.

Glick, S. J. and Ikejimba, L. C. (2018) 'Advances in digital and physical anthropomorphic breast phantoms for x-ray imaging', *Medical Physics*, 45(10), pp. e870–e885. doi: 10.1002/mp.13110.

Hernandez, A. M. *et al.* (2017) 'Generation and analysis of clinically relevant breast imaging x-ray spectra', *Medical Physics*, 44(6), pp. 2148–2160.

Karssemeijer, N. and Thijssen, M. A. O. (1996) 'Determination of contrast-detail curves of mammography systems by automated image analysis', in *Digital Mammography*. Amsterdam: Elsevier, pp. 155–160.

Maki, A. K., Mainprize, J. G. and Yaffe, M. J. (2016) 'Considerations for robust measurement of the slice-sensitivity profile in tomosynthesis mammography for quality control', *Medical Physics*, 43(8), pp. 4803–4807. doi: 10.1118/1.4959539.

Rossman, A. H. *et al.* (2019) 'Three-dimensionally-printed anthropomorphic physical phantom for mammography and digital breast tomosynthesis with custom materials, lesions, and uniform quality control region', *Journal of Medical Imaging*, 6(02), pp. 021604-1–8. doi: 10.1117/1.jmi.6.2.021604.

Schopphoven, S. *et al.* (2019) 'Breast phantoms for 2D digital mammography with realistic anatomical structures and attenuation characteristics based on clinical images using 3D printing', *Physics in Medicine and Biology*. IOP Publishing, 64, p. 215005 (12pp). doi: 10.1088/1361-6560/ab3f6a.

Veldkamp, W. J. H., Thijssen, M. a. O. and Karssemeijer, N. (2003) 'The value of scatter removal by a grid in full field digital mammography', *Medical Physics*, 30(7), p. 1712. doi: 10.1118/1.1584044.

Young, K. C. (2006) 'Comparison of software and human observers in reading images of the CDMAM test object to assess digital mammography systems', *Proceedings of SPIE*. Spie, 6142, pp. 614206-614206–13. doi: 10.1117/12.653296.