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EUROPEAN FEDERATION OF ORGANISATIONS FOR MEDICAL PHYSICS

QUALITY CONTROL IN DIGITAL BREAST TOMOSYNTHESIS (DBT)

EFOMP PROTOCOL

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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 (van Engen et al., 2013) served as the starting point.

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 180° around the imaged volume (Dobbins 2009, Sechopoulos 2013).

This protocol is based on analyses of projection images and reconstructed DBT planes (typically with separation of 0.5 or 1.0 mm). This does not cover planar images synthetically created from the reconstructed planes. The algorithms used to create such images are based on the enhancement of clinical features, a recommendation of suitable tests is therefore not feasible.

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 the clinically used DBT mode and use the same exposure settings as used clinically in manual mode for dose and HVL measurements. Note that if the pre-exposure is not taken at zero degrees

in the clinically used AEC mode, this might introduce some differences in exposure between zero-degree angle stationary mode and the clinically used AEC mode.

The **unprocessed** projection images must be 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 images. 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 unprocessed projection images in zero-degree angle stationary mode should also be supplied with the 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 the assistance 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 baseline 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

Daily/weekly tests

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

- to check long term stability
- To check for (detector) artefacts and inhomogeneities

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, see Table 1.

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

QC tests	Acceptance	Routine	Daily/weekly	Repeat after
2 X-RAY SOURCE				
2.1 HVL and tube voltage	X	X		X-ray tube or filter replacement
2.2 X-ray beam alignment and collimation	X	X		X-ray tube or collimator blades replacement
2.3 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 changes
4.2 Long term stability	X	X	X	X-ray tube replacement detector replacement, relevant software changes
4.3 AEC performance	X	X		Detector replacement, relevant software changes
4.4 Local dense area	X	O		Detector replacement, relevant software changes
4.5 Exposure duration	X	O		Relevant software changes
4.6 AEC security cut-off	X	X		Relevant software changes
5 DETECTOR CHARACTERISTICS				
5.1 Response function	X	O[1]		Detector replacement, relevant software changes
5.2 Noise components analysis	X	O		Detector replacement, relevant software changes, degradation of image quality
5.3 Detector element failure	X	X		Detector replacement, relevant software changes
5.4 Uncorrected defective detector elements	X	X		Detector replacement, relevant software changes
5.5 System projection MTF	X (at all heights)	X (at 40 mm height)		X-ray tube replacement, Detector replacement, relevant software changes
6 TECHNICAL IMAGE QUALITY 3D				
6.1 Technical image quality of the reconstructed 3D image	X	X		Detector replacement, relevant software changes
6.2 MTF in the reconstructed image	O	O		Detector replacement, relevant software changes
6.3 Artefact spread function (ASF)	X	X		After relevant software changes
6.4 Geometric distortion	X	O		Relevant software changes
6.5 Missed tissue at chest wall side and at the top and bottom of the reconstructed image	X	X		X-ray tube replacement Detector replacement, relevant software changes
6.6 Image homogeneity and artefact evaluation	X	X	X	X-ray tube, filter or detector replacement, relevant software changes
7 DOSIMETRY				
7.1 Dosimetry	X	X		X-ray tube, filter or detector replacement, relevant software changes
Image Display				
8.1 Ambient light	X	X		
8.2 Geometric distortion[2]	X	X		
8.3 Contrast visibility	X	X		
8.4 Resolution	X	X		
8.5 Display artefacts	X	X		
8.6 Luminance ratio	X	X		
8.7 Greyscale display function	X	X		
8.8 Luminance uniformity	X	X		

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

2 CRT displays only

1.4 Definitions of action levels, limiting values and baseline values

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

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

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

Typical value
The typical value of a QC parameter is based on measured data, mostly by the members and consultants of the WG. For some currently available DBT systems, the amount of data to set typical values was limited, and in the future, other manufacturers and types of equipment will emerge on the market. Therefore, these values might need adaptation 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 ("old") breast dosimetry models. The new dosimetry model is explained in more detail in paragraph 1.8.

The limiting values for AGD using the new breast dosimetry are derived from the limiting values in the European Guidelines DM and EUREF DBT protocols (van Engen *et al.*, 2013, 2018) and the EFOMP DM protocol (Gennaro *et al.*, 2018). Using the x-ray spectra found in clinical practice for specific breast thicknesses for all major mammography unit manufacturers, the current ("old") limiting values for AGD have been converted to incident air kerma using the current ("old") dosimetry models. These incident air kerma values have been used as input to the new dosimetry model to obtain average AGD values using the same x-ray spectra as those at which the incident air kerma was calculated. This relationship between the AGD 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 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 more easily 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 somehow 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 this 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, not all the charge traps in the converter layer of the detector might have been cleared or there might be left-over charge in the detector elements due to incomplete readout. 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 very large exposures to the detector. This occurs particularly if there is a highly attenuating object in the beam, in that case the areas exposed to high intensity, like in areas with unattenuated x-ray beam, will be 'burnt' into the detector. This might also occur with repeated exposures of a similar type of object, e.g. a 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 (Marshall *et al.*, 2010) and some example results are shown in Mackenzie et al(Mackenzie *et al.*, 2017). A full quantification of the effect of lag and ghosting is difficult as the effect is dependent on the technology of the detector and both long term and recent exposure history of the detector. In the Tomosynthesis Mammographic Imaging Screening Trial (TMIST) quantification of ghosting was avoided by undertaking a qualitative examination of artefacts in the reconstructed planes (ACR, 2021). 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 currently no tests that are suitable for routine QC. The protocol does include a test to examine for artefacts in the reconstructed planes (6.6 Image homogeneity and artefact evaluation), partly due to the artefacts from lag and ghosting effects.

The test protocols must avoid that the QC tests generate ghosting and lag artefacts. For QC tests which do not require images, the detector should be protected with e.g. a metal plate. 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, or 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 3.

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

The most important aspect 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, unfortunately, these trials are very expensive and time consuming. Such studies were vital for demonstrating clinical acceptability but will not necessarily be practical for new versions of tomosynthesis systems. Alternative methods are therefore 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 should be a form of 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. Such 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
- an observer (human or mathematical) 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 in a homogeneous background relates to cancer detection in digital mammography (Warren *et al.*, 2012; Mackenzie *et al.*, 2016). Therefore, it was possible to create limiting values on the threshold gold thickness results for the acceptance of systems and monitor the quality of an individual 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 (completely) 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, in particular 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 and can be 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 artefact spread function measurements, to set baseline values that can be used to track changes in technical 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 audits 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 (International Atomic Energy Agency (IAEA), 2011). 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 phantoms must represent breast structures and lesion simulating targets is under investigation but it is expected that target detection results generated by phantoms 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 and images of 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 and breasts in a similar manner.

b) Use of the phantoms should facilitate assessment of the degree to which a DBT system suppresses background structures that surround a lesion which influence lesion detection. The phantoms should therefore have a structures 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 use in 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) Most existing 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 with very different appearances. There can be large differences in the appearance or texture of image noise, and artefact suppression algorithms can affect the artefact spread function. As a consequence, QC test outcome 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.

Currently, no validated task-based methods of measurement with accompanying anthropomorphic phantoms exist. Therefore, we recommend the use of readily available digital mammography phantoms. Due to the limitations mentioned above care should be taken in interpreting the results of these QC tests. However, performing QC tests with readily available phantoms may provide information about the stability of systems and on some quality aspects of the reconstructed tomosynthesis image.

1.8 New breast dosimetry model and phantom

The current ("old") breast dosimetry model commonly used in Europe was published in 1990 by Dance (Dance, 1990), the paper describing the method and conversion factors to estimate average glandular dose (AGD) 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 facilitated the estimation of AGD 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, following which the dose values associated with the radiation risk estimated for mammography (2D and DBT) will differ from values obtained with the current ("old") model. Note that this does not mean that the risk for the women undergoing mammography has changed, it is our estimation of the risk that changed.

The adaptation of the "old" dosimetry model was carried out by the joint EFOMP/AAPM Task Group 282, which also aimed at harmonizing the breast dosimetry models on both sides of the Atlantic.

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 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, all relevant QC test procedures in this protocol 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” method. If national or local QC protocols require a comparison between the AGD calculated by the system and by the medical physicist, it will be necessary to know which dosimetry model is used by the manufacturer.

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 if 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 are 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 or validate software for the QC tests in this protocol, but provide links to software by third parties. The links can be found on the webpage of the working group on the EFOMP website.

QC tests

2 X-ray source

2.1 HVL and tube voltage

Introduction

The x-ray beam's spectrum of radiant energy (radiation quality) is one of the primary factors influencing image quality and dose. X-ray generators used in digital mammography and digital breast tomosynthesis 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 are 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 and aluminium filters

Test frequency

- At acceptance and subsequent routine 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

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

Figure 1 Setup for the HVL measurement using a calibrated x-ray multimeter

- In practice, these measurements are performed simultaneously with tube output measurements for dosimetry (see section 2.3), therefore the compression paddle should be positioned as high as possible.
- Protect the detector using a radio-opaque sheet.
- Position the radiation sensor at the reference point (50mm from chest wall, centred laterally), see Figure 1.
- 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 foils to measure HVL

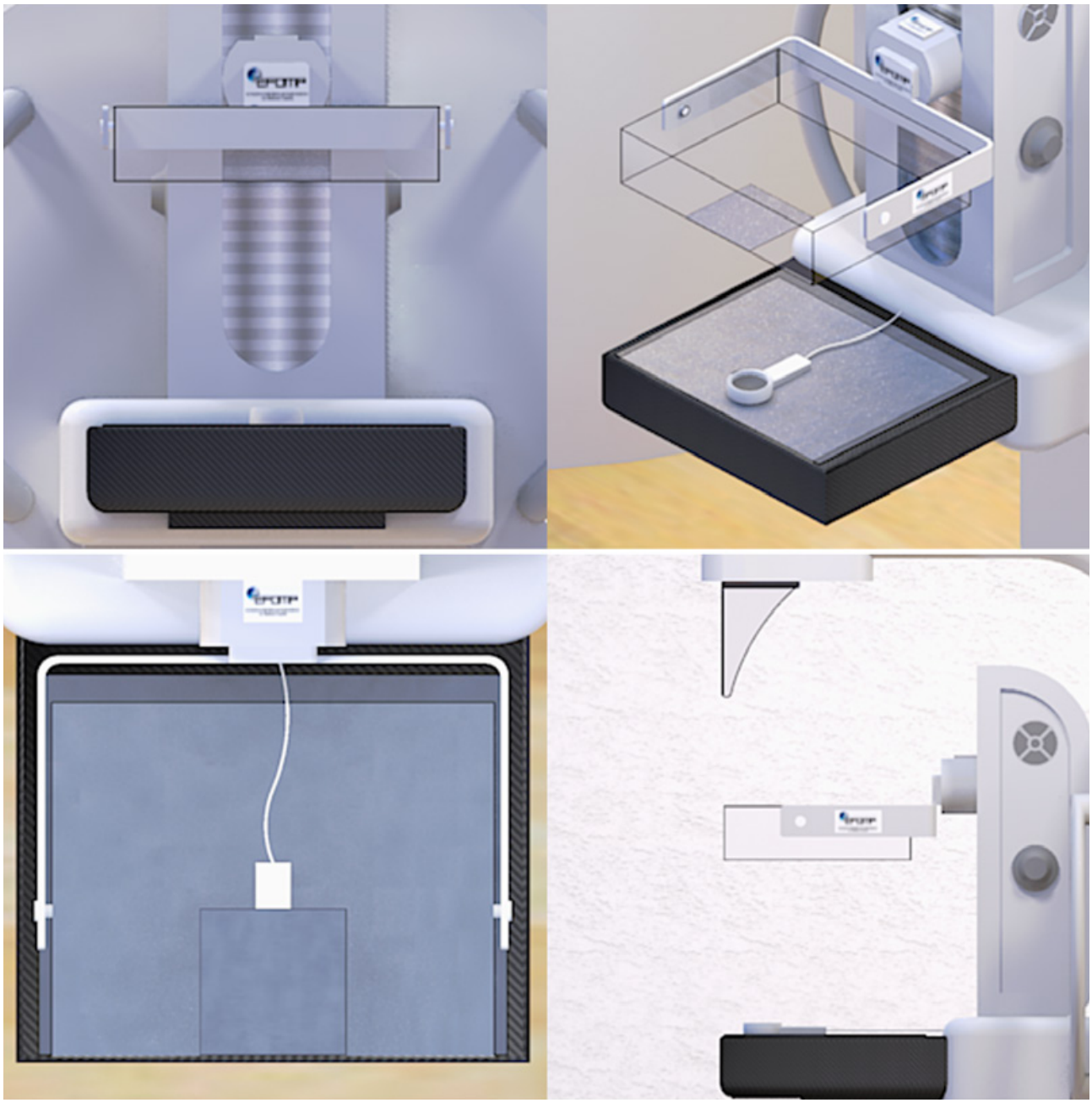

Figure 2 Setup for the HVL test using ion chamber and aluminium filters

- Protect the detector using a radio-opaque sheet.
- Position the radiation sensor at the reference point, see Figure 2.
- 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 aluminium foil.
- Determine HVL using the equation:

$$HVL = \frac{X_1 \cdot ln\left(\frac{2 \cdot Y_2}{Y_0}\right) - X_2 \cdot ln\left(\frac{2 \cdot Y_1}{Y_0}\right)}{ln\left(\frac{Y_2}{Y_1}\right)} \quad (1)$$

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: Target/filter combination 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 as filter thickness might be different.

Action levels

Tube voltage (kV) error should be ≤ 2kV

HVL is expected be within typical range, see Table 2. Some differences between systems exist due to different filter thickness or filter tilting.

Table 2 Typical HVL values

	HVL (mmAl) 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 ± .03	0.38 ± .03	0.37 ± .03		0.50 ± .05	0.51 ± .05	0.34 ± .05	0.44 ± .05
28	0.35 ± .03	0.42 ± .03	0.42 ± .03	0.46± .03	0.53 ± .05	0.58 ± .05	0.39 ± .05	0.49 ± .05
31	0.38 ± .03	0.45 ± .03	0.45 ± .03	0.51 ± .03	0.56 ± .05	0.61 ± .05	0.44 ± .05	0.55 ± .05
34	0.40 ± .03	0.47± .03	0.47 ± .03	0.55 ± .03	0.59 ± .05	0.64 ± .05	0.49 ± .05	0.61 ± .05
37				0.58 ± .03	0.64 ± .05	0.67 ± .05	0.53 ± .05	0.66 ± .05

2.2 X-ray beam alignment and collimation

Introduction

In x-ray imaging, the x-ray beam and image receptor should be aligned such that the x-ray beam coincides as much as possible with the image receptor. This reduces unnecessary dose to the women undergoing mammography and loss of clinical information due to parts of the detector being unexposed. This is particularly 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 or other suitable test instrument/recording media

Test frequency

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

Test procedure

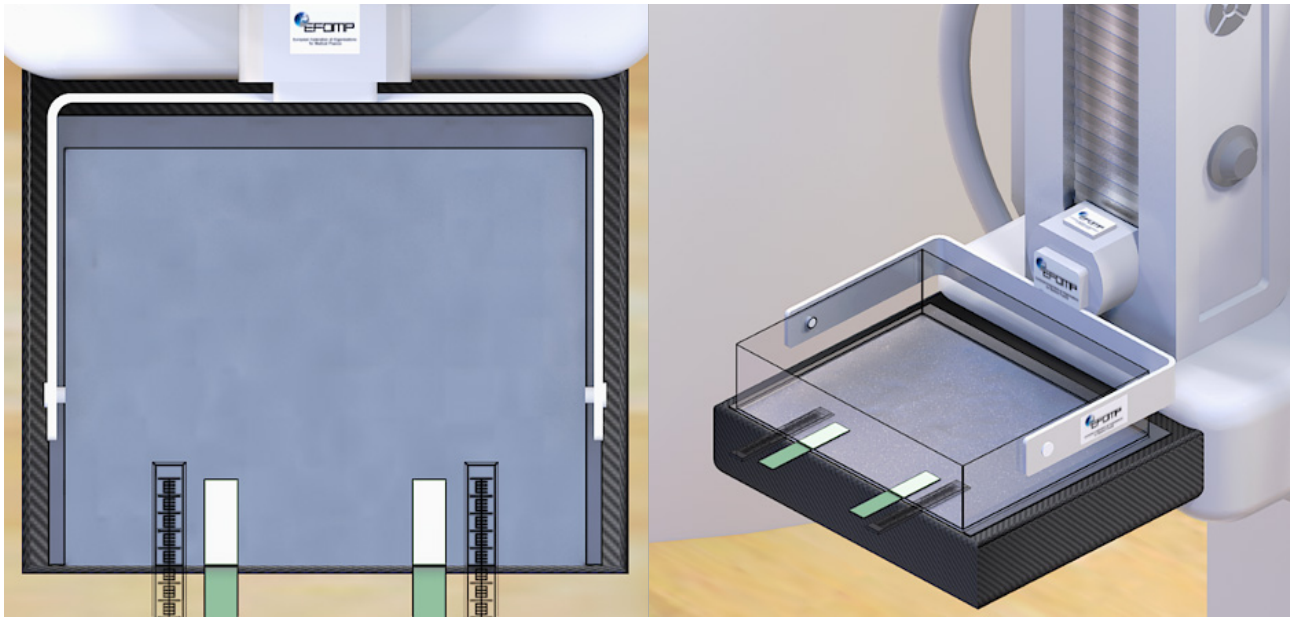

Figure 3 Setup for the x-ray beam alignment and collimation test

- Position lead rulers on the breast support table to mark the chest wall edge of the breast support table or the edge of the light field at chest wall side as shown in Figure 3.
- 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 (or edge of the breast support table) from the self-developing film, and the position of the light beam (or edge of the breast support table) 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.

Note: Dynamic collimation will, in general, improve the alignment of x-ray field in the individual projections to the image receptor.

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 chest wall side. At the lateral sides the x-ray field must not extend beyond the breast support table.

2.3 Tube output

Introduction

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

Tube output should be stable and consistent for all exposures.

Definitions

Tube specific output (mGy/mAs) is the incident air kerma per tube current-time product at the breast support table surface, including the attenuation of the compression paddle, which typically is corrected by the inverse square law to 1m distance from the focal spot (mGy/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 solid state x-ray dosimeter or ion-chamber dosimeter

Test frequency

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

Test procedure

Figure 4 Setup for the tube output test

- The compression paddle must be positioned as high as possible.
- The collimation of the system to produce the largest x-ray field shall be selected, and the tube fixed at the 'zero-degree' position.
- Protect the detector using a radio-opaque sheet, see Figure 4.
- 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. Tube current-time product should be chosen such, that the influence of switch-on effects in tube output is sufficiently reduced.

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.

The variation of tube output for subsequent exposures (short-term reproducibility) 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 is sufficient and that maximum compression force is limited to avoid excessive pain. Furthermore, any cracks and sharp edges on the compression paddle may cause unnecessary pain or injury to the women undergoing mammography.

Definitions

The compression force is the force applied to the breast to reduce the thickness and reduce breast movement during mammographic exposure. 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 tests

Test procedure

- Inspect all compression paddles for cracks, sharp edges, and damage.
- Position the compression force meter on the breast support table with the centre of the meter at the reference point.
- A PMMA slab or a steel plate may be used to protect the breast support table and compressible material may be used to protect the compression paddle. Beware of scratching the breast support table and/or compression paddle.
- Measure the maximum motorised compression force set by the system.
- Record any decrease in compression force from the maximum set by the system over 1 minute using maximum motorized compression.

Action levels

Maximum motorized compression force should exceed 150N.

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

The decrease over 1 minute in compression force from the maximum set by the system using motorized compression should not exceed 10N.

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

3.2 Displayed thickness

Introduction

The accuracy of the displayed compressed breast thickness is important:

(1) Most mammography systems use the displayed compressed breast thickness to determine the x-ray spectrum and the target image quality in fully automatic mode.

(2) For the assessment of clinical breast dose, compressed breast thickness is a factor in the calculation of glandular dose.

Definitions

The thickness displayed on the system and given in the DICOM header of the images is defined as the displayed thickness. It is acknowledged that the displayed thickness is dependent on the method of calibration by the manufacturers and that deviations between measured and displayed values might (partly) be attributed to the difference in methods of measurement between calibration and the QC 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 of 10 mm has been cut out, see Figure 5.
- Calliper, ruler or another appropriate device

Test frequency

- At acceptance and subsequent routine tests

Test procedure

- Position the block of compressible foam on the breast support table and apply a compression force of 100 N, see Figure 5.

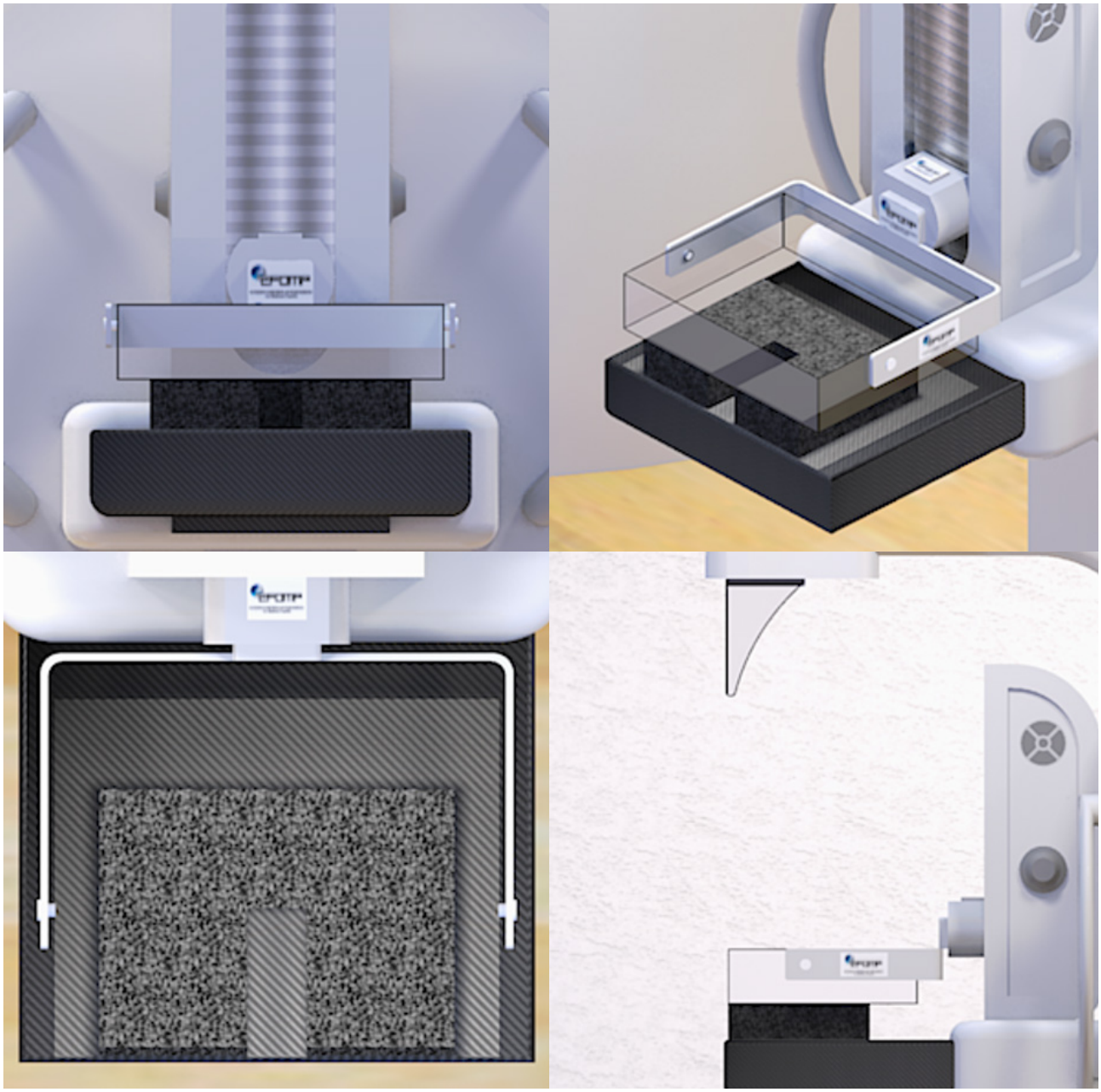

Figure 5 Setup for the displayed compressed breast thickness test

- Record the displayed thickness 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

Typically, the displayed and measured thickness deviate < 5 mm. For larger deviations, investigate the cause of the deviation.

4 Automatic exposure control

4.1 Short term repeatability

Introduction

In mammography, especially for 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 measure the signal and/or standard deviation on the image after a low dose pre-exposure and use a small detector area with lowest detector signal, lowest signal-to-noise ratio (SNR) or other internal image quality criteria 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 6.6).

Test equipment

- Standard test block

Test frequency

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

Test equipment

- Standard test block

Test frequency

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

Test procedure

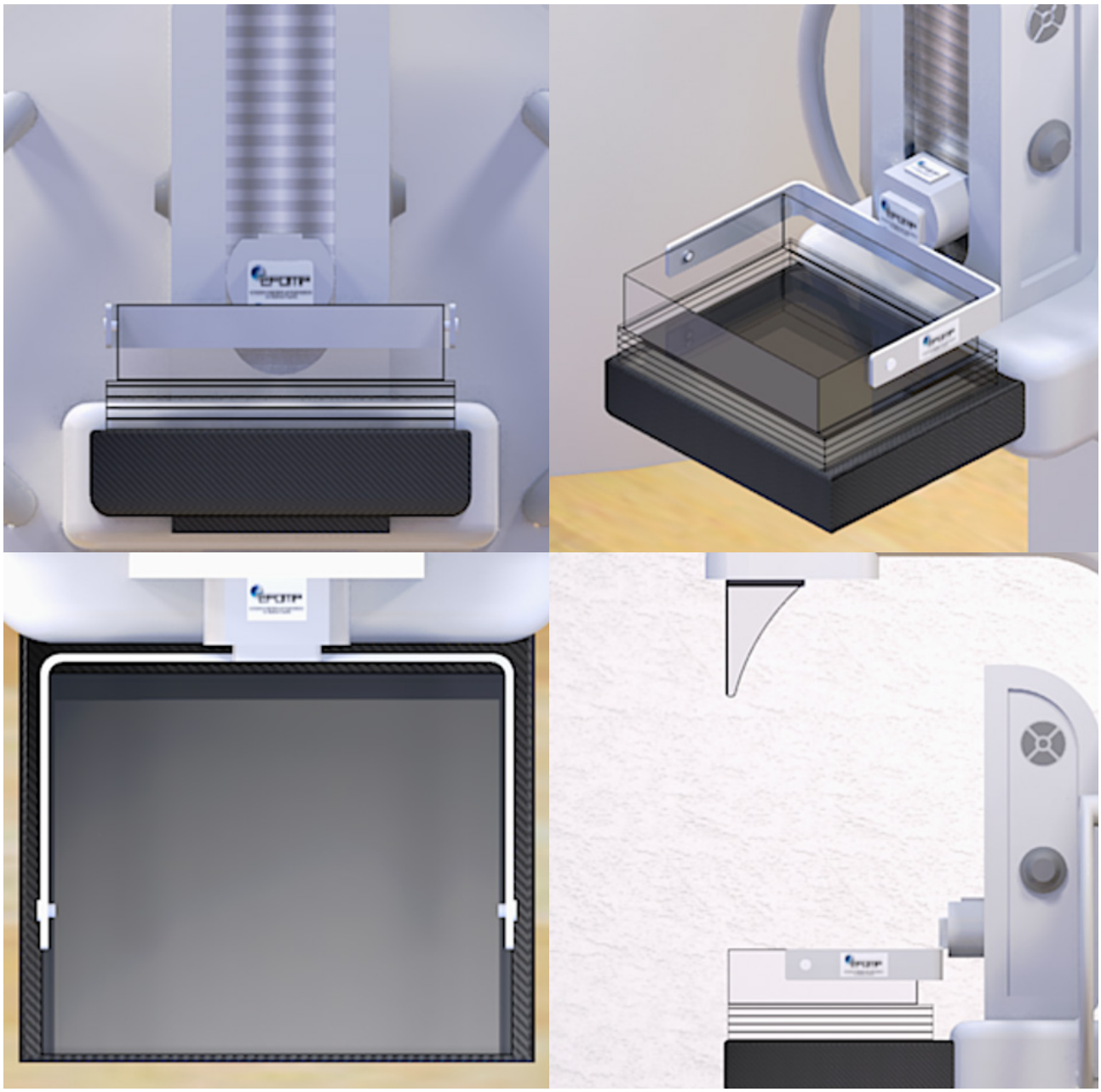

Figure 6 Setup for the short term repeatability test

- Position the standard test block on the breast support table, see Figure 6. 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 test 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. For systems using segmentation techniques in the clinically used AEC mode, this needs to be turned off.
- Record the exposure settings (target/filter combination, tube voltage, current–time product). Repeat this procedure 4 times.

Note: these images can also be used for artefact evaluation.

Analysis

- If the system has a non-linear response, the images need to be linearized.
- Measure the mean pixel value (MPV) and standard deviation (SD) in the reference ROI on the first projection image of the 5 scans, see Appendix 3.
- Calculate the SNR, defined as (MPV-pixel value offset)/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 mAs ≤ 5%
Variation in SNR ≤ 10%.

4.2 Long term stability

Introduction

In mammography, especially for 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 ageing 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 measure the signal and/or standard deviation on the image after a low dose pre-exposure and use a small detector area with lowest detector signal, lowest SNR or other internal image quality criteria 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 mAs) 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

Test frequency

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

- 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 tests 5.4 Uncorrected defective detector elements (when required) and 6.6 Image homogeneity and artefact evaluation

Test procedure

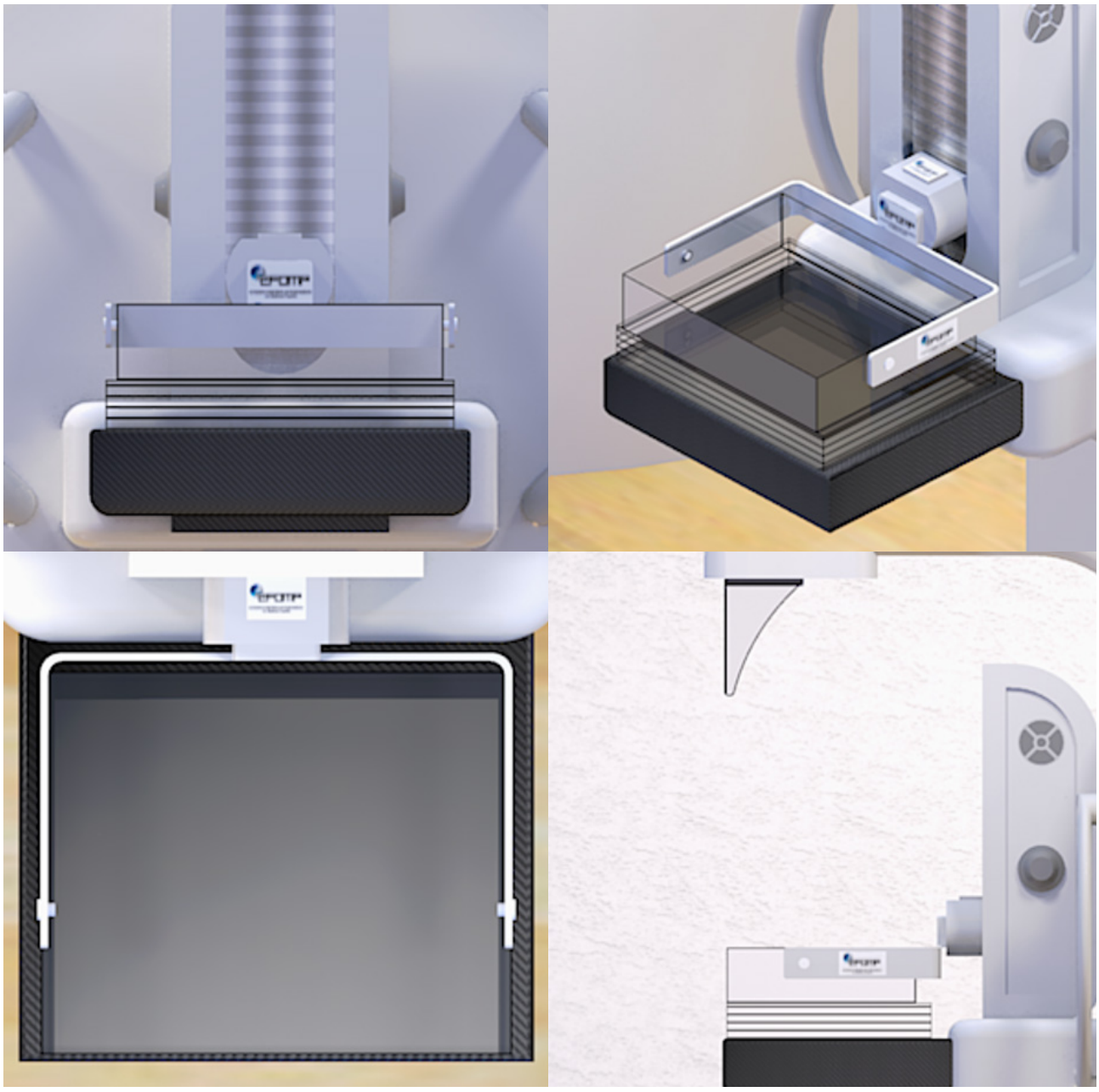

Figure 7 Setup for the long-term stability test

- Position the standard test block on the breast support table, see Figure 7. 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 test 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. For systems using segmentation techniques in the clinically used AEC mode, this needs to be turned off.
- Record the exposure settings (target/filter combination, tube voltage, current–time product).
- Repeat this procedure at least 4 times during a QC test.

Note: these images can also be used for artefact evaluation.

Analysis

- If the system has a non-linear response, the images need to be linearized.
- Measure the MPV and SD in the reference ROI on the first projection image of the scans, see Appendix 3.
- Calculate the SNR, defined as MPV/SD, in the first projection image of the scans.
- Calculate the average value of the 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%,
Investigate if the variation in current-time product between daily/weekly images ≥ ± 10%.

4.3 AEC performance

In mammography, especially for screening, it is important that clinical images are 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 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 technical 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 WG/TG 323 (Caballo *et al.*, 2022). Method 2 follows the procedure proposed for digital mammography systems in van Engen et al (van Engen *et al.*, 2013) 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 AGD for the three methods are described in section 7.1 Dosimetry.

Test equipment

Method 1: WG/TG 323 dosimetry phantom

- Aluminium sheet 10 mm x 10 mm, thickness 0.2 mm
- 1 base plate, thickness 20 mm, with an insert equivalent to 50th glandular tissue percentile
- 7 additional plates of thickness 10 mm simulating adipose tissue

Method 2: PMMA slabs and spacers

- Aluminium sheet 10 mm x 10 mm, thickness 0.2 mm
- 7 PMMA plates (density 1.19 gr cm-3) 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,10 mm x 10 mm, thickness 0.2 mm
- 5 PMMA plates (density = 1.19 gr cm-3) with thicknesses (in mm): 20.0, 27.5, 30.0, 32.5 and 35.0.
- 7 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
- At subsequent routine tests
- After detector replacement
- After relevant software changes

Test procedure

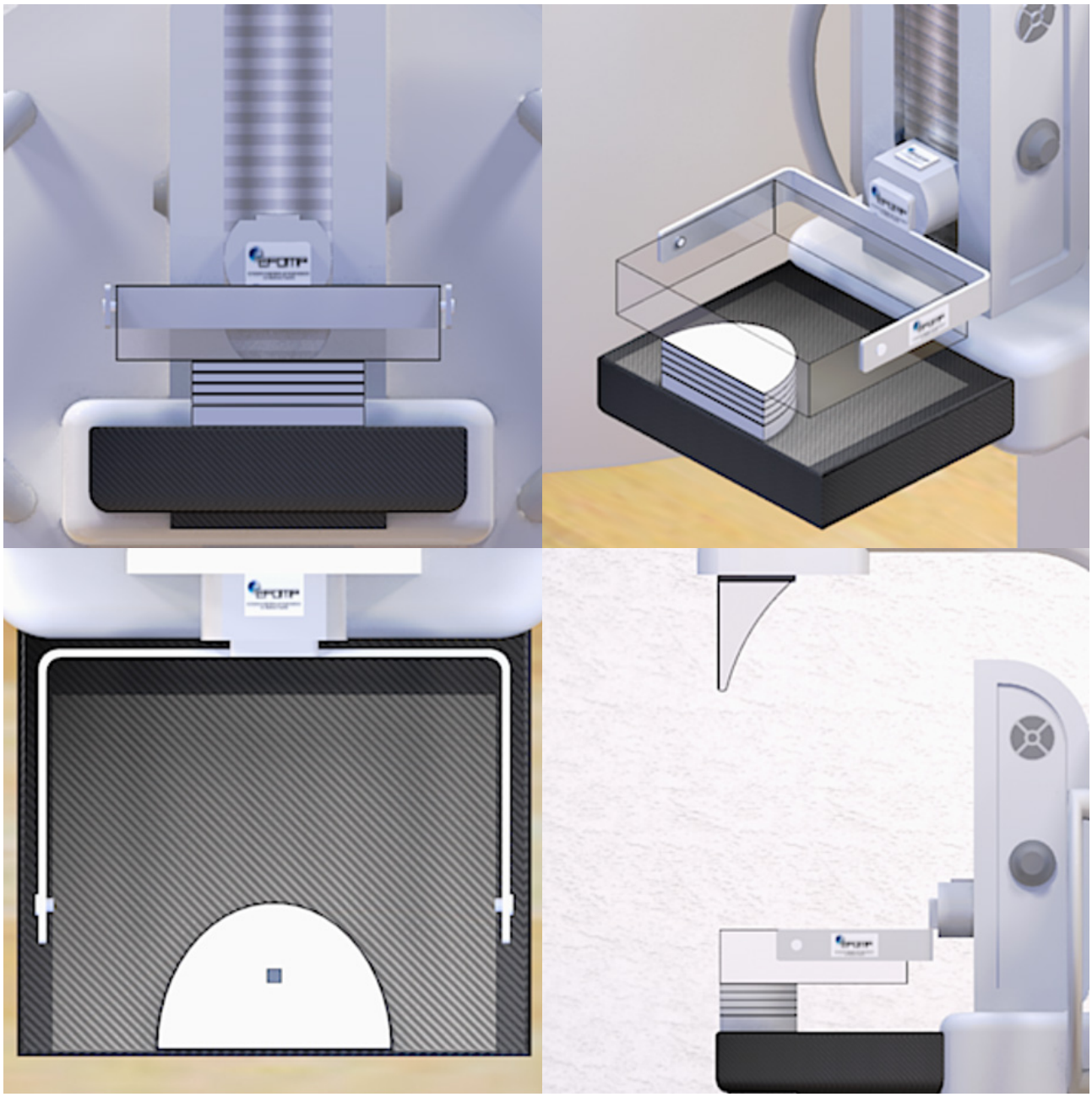

Figure 8 Setup for the AEC performance test, method 1

Method 1: WG/TG 323 dosimetry phantom

- Position the base slab with insert of 50th glandular tissue percentile on the breast support table.
- Position the aluminium sheet of dimensions 10 mm x 10 mm and thickness 0.2 mm at the reference position on top of the base slab, as shown in Figure 8.
- Place the compression paddle in contact with the base plate and apply a compression force of 100 N.
- Make a DBT exposure of the phantom in the clinically relevant AEC mode.
- Add a 10 mm thick adipose tissue plate and repeat the procedure. Continue adding adipose tissue plates until images have been made for thicknesses 20, 30, 40, 50, 60, 70, 80 and 90 mm.

Remark: If 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 plates and spacers

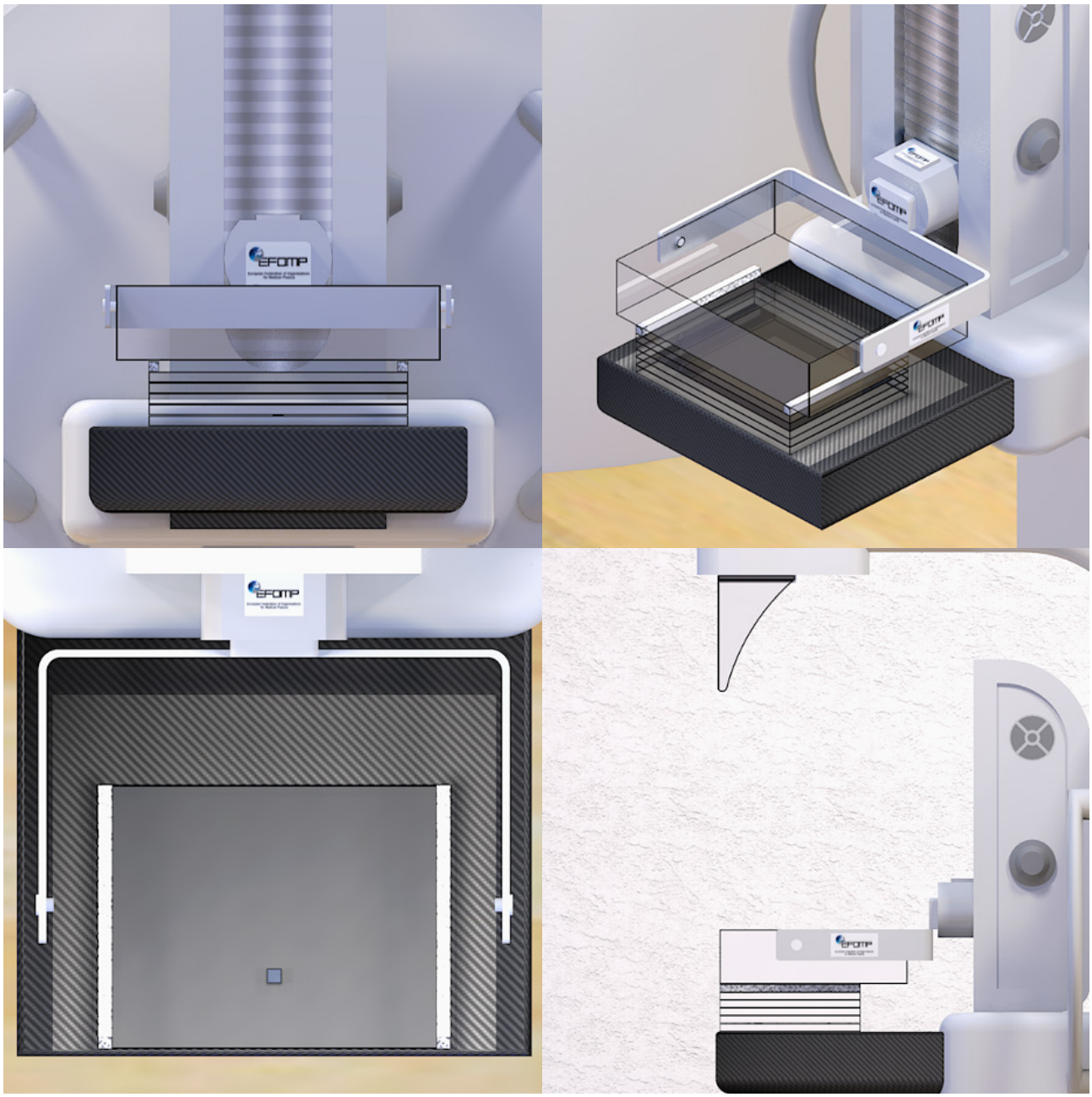

Figure 9 Setup for the AEC performance test, method 2

- Position one 10 mm thick PMMA plate on the breast support table. For some systems the phantom should not completely cover the FOV area. For these systems an area with full irradiation at the lateral and nipple sides is required for the clinical AEC mode to function properly, see Appendix 3s. In this case, the segmentation used in the clinical AEC mode, can be switched on.
- Position the aluminium sheet of dimensions 10 mm x 10 mm and thickness 0.2 mm at the reference position, as shown in Figure 9.

- Position a second 10 mm thick PMMA plate on top of the first plate, taking care not to displace the Al sheet, see Figure 9.
- 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.
- 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 plates of PMMA on top of the stack (Figure 9).
- The compression paddle should be positioned at the heights 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 9). Be aware of compression paddle tilting when spacers are placed at the back edge (nipple side) of the PMMA.

Remark: If 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 plates

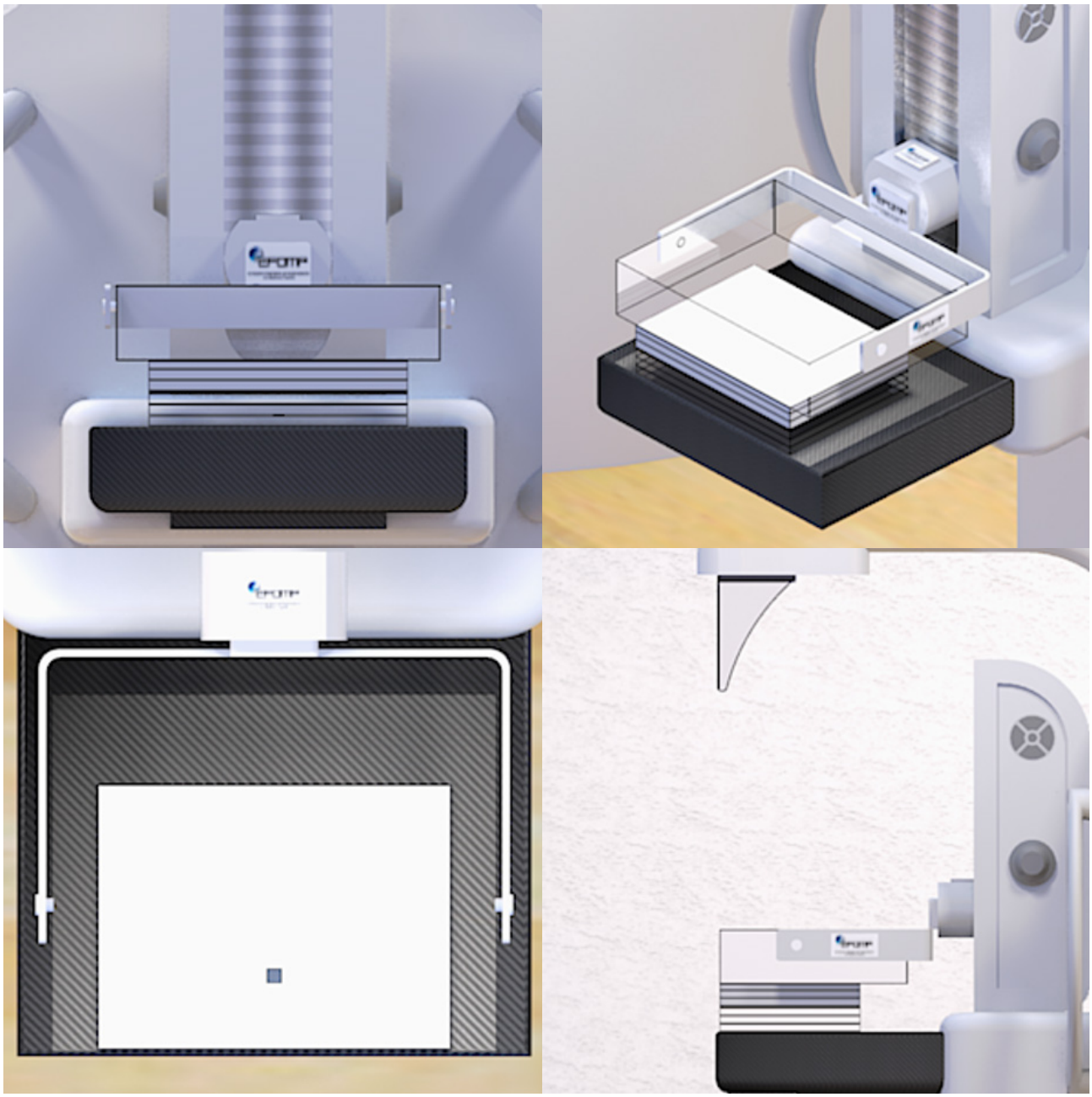

Figure 10 Setup for the AEC performance test, method 3

- Position one 10 mm thick PMMA plate on the breast support table. For some systems the phantom should not completely cover the FOV area. For these systems an area with full irradiation at the lateral and nipple sides is required for the AEC to function properly, see Appendix 3. In this case, the segmentation used in the clinical AEC mode, can be switched on.
- Position the aluminium sheet of dimensions 10 mm x 10 mm and thickness 0.2 mm 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.
- 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, positioning the PMMA and PE thicknesses according to Table 4. PMMA plates should always be at the bottom of the stack and PE plates should be on top of the PMMA stack (see Figure 10).

Remark: If 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

PMMA thickness (mm)	Height of the compression paddle (mm)	Spacer 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

Measurements are performed on DBT projections, not on the reconstructed planes.

- For each DBT acquisition, select the first projection image. Note that the projection image on which the measurements are made may be the first or the second one depending on the manufacturer (see Appendix 3 and remark).
- Position a 5 mm x 5 mm ROI in the centre of the image of the aluminium sheet (Figure 11).

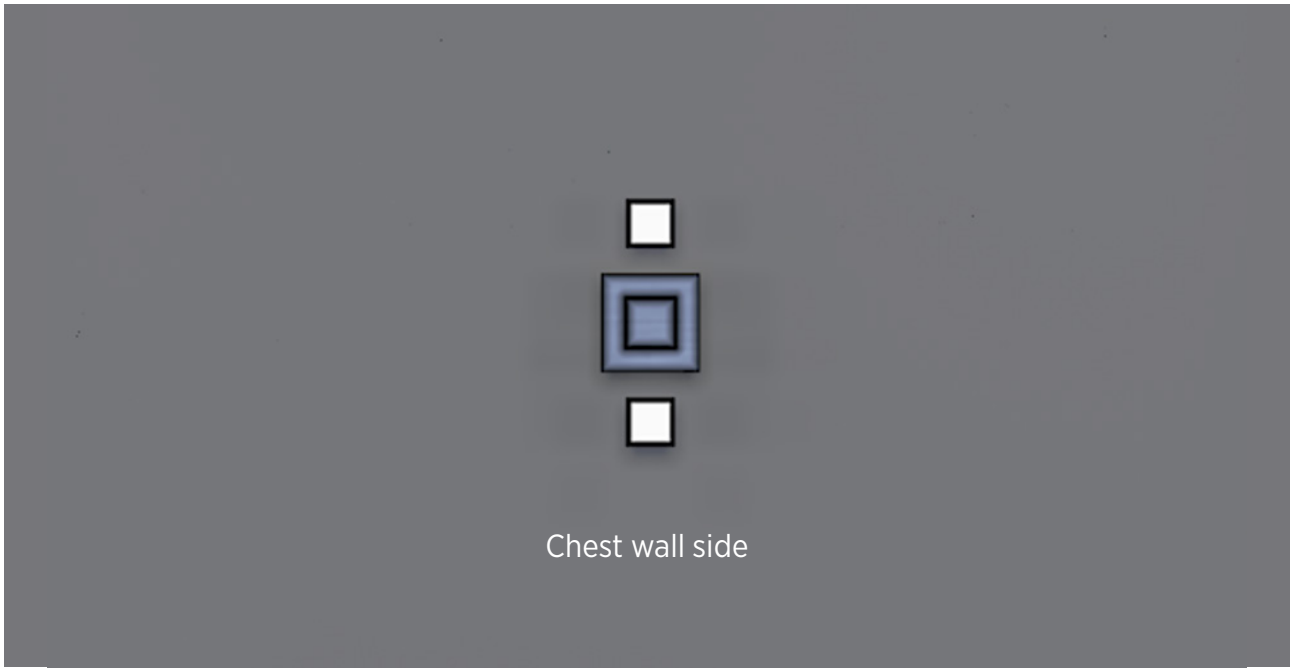

Figure 11 Position of the ROIs on the projection images. Nipple and chest wall sides are respectively at top and bottom of the image. The scan direction is perpendicular to the lateral sides of the image.

- Position two 5 mm x 5 mm ROIs in the background areas on the chest wall and nipple sides of the aluminium sheet (Figure 11). 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 1 mm x 1 mm elements and using the averages of the mean pixel values and standard deviations from the elements.
- Measure the MPV and SD at the three ROIs.
- If the system has a non-linear response, the images need to be linearized using the response function (see section 5.1).
- Calculate the MPV(background) and SD(background) according to:

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

$$\mathrm{MPV(background)} = \frac{\sum_1^2 \mathrm{MPV(ROI}_n\mathrm{)}}{2} \quad (3)$$

- Calculate the SDNR of the aluminium object:

$$\mathrm{SDNR} = \frac{|MPV(signal) - MPV(background)|}{\mathrm{SD(background)}} \quad (4)$$

Where MPV(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 is not ordered sequentially when saved. To identify the images, the projection angle can be found in the DICOM header. (Contact vendor for information on DICOM header tags).

Action levels
SDNR values should be within 15% of the baseline values set at acceptance. It is also possible to compare SDNR values between systems of the same brand, type, software version and AEC setting.

4.4 Local dense area

Introduction

Structures in breasts, e.g., the glandular structures, are not distributed homogeneously over the volume 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 to 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. In this QC test the approach in Bouwman et al (Bouwman et al., 2016) is followed in method 2 and a similar approach is followed for the phantoms used in method 1 and 3.

Definitions

A local dense area is an area of higher glandularity within the breast. The variation of SDNR and AGD on the first projection image of a series of tomosynthesis acquisitions 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 technical image quality level within the densest area of the breast. In this QC test the desired target technical image quality is represented by the SDNR of a simulated 50 mm thick fatty breast with 50% glandularity in the central region.

Test equipment

A phantom that mimics the attenuation of a 50 mm thick fatty breast (0% glandularity) and objects whichsimulate areas of higher glandularity (until about 100% glandularity), that can be obtained by using 3 different phantoms:

- Method 1: Dosimetry phantom
- Method 2: PMMA slab +small PMMA plates + spacers
- Method 3: PMMA slab + PE slab + small PMMA plates

Method 1: Dosimetry phantom

- Five series of base slabs of the new dosimetry phantom simulating different percentiles density (5^{th}, 25^{th}, 50^{th}, 75^{th} and 95^{th} percentile)
- Three 10 mm thick slabs simulating fatty tissue
- Aluminium object (10 mm x10 mm, 0.2 mm thickness)

Method 2: PMMA slab + small PMMA plates + spacers

- PMMA slab (dimensions 240 mm x 180 mm ×, 40 mm thick)
- 3 small PMMA plates (dimensions 20 mm × 40 mm, each one 4 mm thick)
- 2 spacers (10 mm thick) made of soft material in order not to influence the AEC choice
- Aluminium object (10 mm x10 mm, 0.2 mm thick)

Method 3: PMMA slab + PE slab + small PMMA plates

- PMMA slab (dimensions 240 mm x 180 mm ×, 20 mm thick)
- PE slab (Polyethylene density 0.94 g/cm3, dimensions 240 mm x 180 mm ×, 30 mm thick)
- 3 small PMMA plates (dimensions 20 mm × 40 mm, each one 4 mm thick)
- Aluminium object (10 mm x10 mm, 0.2 mm thick)

Test frequency

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

Test procedure

Method 1: Dosimetry phantom

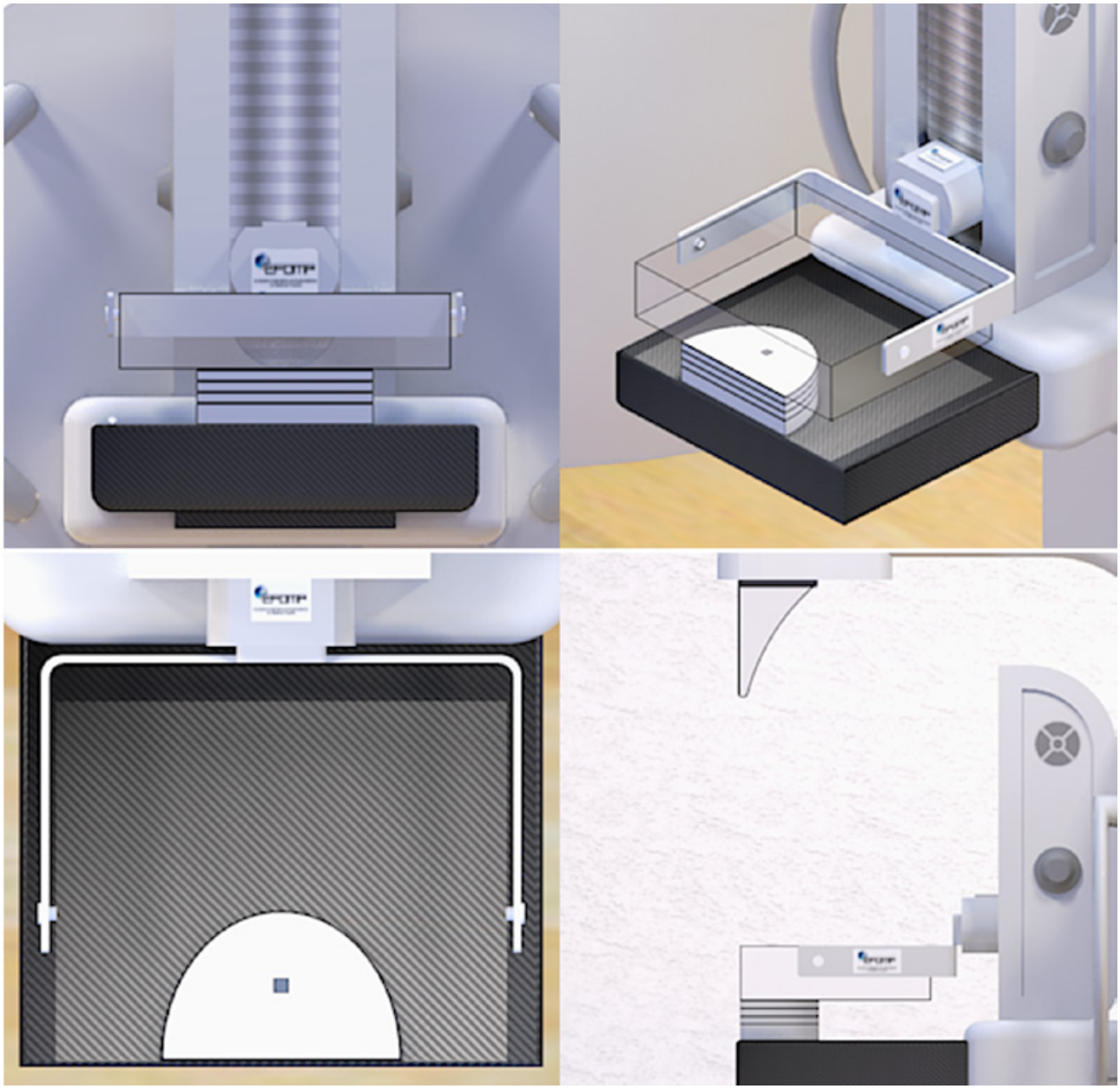

Figure 12 Setup for the local dense area test when using the dosimetry phantom

- Place the dosimetry phantom with the 5th percentile density (base slab) on the breast support table and add three 10 mm thick plates simulating fatty tissue, see Figure 12.
- Place the compression paddle in contact with the phantom, and apply a compression force of 100 N, if the system requires compression for the AEC to work correctly (see Appendix 3).
- Place the aluminium sheet on the compression paddle within AEC sensor area, in the central part of the detector, and 50 mm mm anterior to the chest wall edge of the breast support table.

  Tip: Disable the automatic paddle decompression mode (remember to enable this function at the end of the test).
- Perform a DBT exposure using the clinically relevant AEC mode and record the exposure factors (target/filter, kV, mAs, AGD).
- Replace the base slab with the 25th, 50th, 75th and 95th percentile density slabs and repeat the procedure for each base slab.
- The configuration with the three 10 mm thick plates simulating fatty tissue and the base slab with 50th percentile density slab corresponds to the reference glandularity for a breast of 50 mm thickness. The AGD and the SDNR relative to the base slab with 50th percentile density slab is defined as AGDref and SDNRref.

Analysis

- For each acquisition i, on the first "for processing" projection image (see Appendix 2), measure MPVi (signal) and SDi in the area of extra attenuation (corresponding to the glandularity area of the dosimetry phantom) within a ROI of 5 mm x 5 mm inside the aluminium sheet.
- Position two 5 mm x 5 mm ROIs in the background area, inside the simulated glandular area, perpendicular to the tube motion direction and measure MPV and SD.
- Calculate the MPV (background) i and SD (background) i according to:

$$\mathrm{SD(background)} = \frac{\sum_1^2 \mathrm{SD(ROI_n)}}{2} \qquad (5)$$

$$\mathrm{MPV(background)} = \frac{\sum_1^2 \mathrm{MPV(ROI_n)}}{2} \qquad (6)$$

- Calculate SDNRi for each tomosynthesis acquisition according to:

$$\mathrm{SDNR} = \frac{|\boldsymbol{MPV(signal) - MPV(background)}|}{\mathrm{SD(background)}} \qquad (7)$$

- Evaluate the percent deviation of the $SDNR_i$ of each acquisition with respect to the $SDNR_{ref}$, where $SDNR_{ref}$ is defined as the SDNR relative to the acquisition with the base slab with the 50th percentile density slab:

$$\boldsymbol{SDNR\_deviation_i(\%) = 100 \cdot \frac{(SDNR_i - SDNR_{ref})}{SDNR_{ref}}} \qquad (8)$$

- Compute the *Min Deviation SDNR (%) = min (SDNR_deviationi(%))*

- Evaluate the percentage deviation of the AGDi of each acquisition with respect to the AGDref, where AG-Dref is defined as the AGD relative to the acquisition with the base slab with the 50th percentile density slab:

$$AGD\_deviation_i(\%) = 100 \cdot \frac{(AGD_i - AGD_{ref})}{AGD_{ref}} \quad (9)$$

- Compute the *Max Deviation AGD (%) = max (AGD_deviationi(%))*

Test procedure

Method 2: PMMA slab + small PMMA plates + spacers

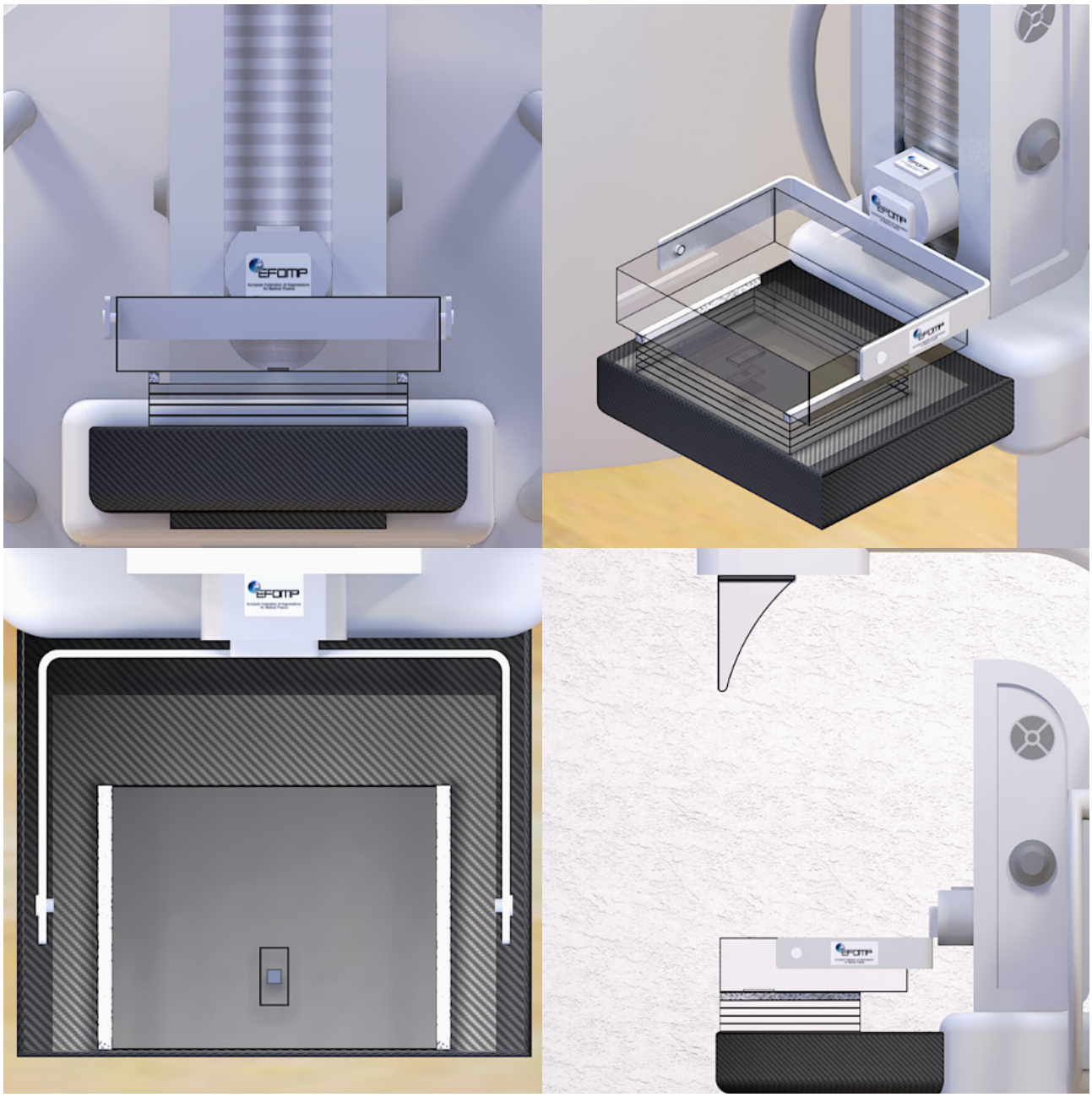

Figure 13 Setup for the local dense area test when using PMMA slab + small PMMA plates and spacers

- Place the 40 mm PMMA slab on the breast support table, make sure that the phantom does not completely cover the Field of View (FOV) area, see Figure 13.
- Position the compression paddle at 50 mm height.
  (If the mammographic equipment requires compression for the AEC to function: place the spacers at the nipple side, at least 19 cm away from the chest wall edge, or at lateral sides, at a distance to avoid any effects on the AEC system, and 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, and 50 mm anterior to the chest wall edge of the breast support table.

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

- Perform a DBT exposure using the clinically relevant AEC mode and record the exposure factors (target/filter, kV, mAs, AGD).
- Position the first 4 mm thick small PMMA plate over the aluminium sheet (see Figure 13). This configuration corresponds to the reference glandularity for a 50 mm thickness breast with 50% glandularity in the central region.
- Perform an exposure with the same AEC mode as above and record the exposure factors (target/filterref, kVref, mAsref, AGDref).
- 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.

Analysis

- For each acquisition i, on the first "for processing" projection image (see Appendix 2), measure MPVi (signal) and SDi in the area of extra attenuation (corresponding to the small PMMA plates or to the glandularity area of the dosimetry phantom) within a ROI of 5 mm x 5 mm inside the aluminium sheet.
- Position two 5 mm x 5mm ROIs in the background area, inside the simulated glandular area, perpendicular to the tube motion direction and measure MPV and SD.
- Calculate the PV (background) i and SD (background) i according to:

$$\mathrm{SD(background)} = \frac{\sum_1^2 \mathrm{SD(ROI_n)}}{2} \qquad (10)$$

$$\mathrm{MPV(background)} = \frac{\sum_1^2 \mathrm{MPV(ROI_n)}}{2} \qquad (11)$$

- Calculate SDNRi for each tomosynthesis acquisition according to:

$$\mathrm{SDNR} = \frac{|MPV(signal) - MPV(background)|}{\mathrm{SD(background)}} \qquad (12)$$

- Evaluate the percentage deviation of the $SDNR_i$ of each acquisition with respect to the $SDNR_{ref}$, where $SDNR_{ref}$ is defined as the SDNR relative to the acquisition with 4 mm added small PMMA plates:

$$SDNR\_deviation_i(\%) = 100 \cdot \frac{(SDNR_i - SDNR_{ref})}{SDNR_{ref}} \quad (13)$$

Compute the *Min Deviation SDNR (%) = min (SDNR_deviationi(%))*

Evaluate the percentage deviation of the AGD_i of each acquisition with respect to the AGD_{ref}, where AGD_{ref} is defined as the AGD relative to the acquisition with 4 mm added small PMMA plates:

$$AGD\_deviation_i(\%) = 100 \cdot \frac{(AGD_i - AGD_{ref})}{AGD_{ref}} \quad (14)$$

Compute the *Max Deviation AGD (%) = max (AGD_deviationi(%))*

Test procedure

Method 3: PMMA slab + PE slab + small PMMA plates

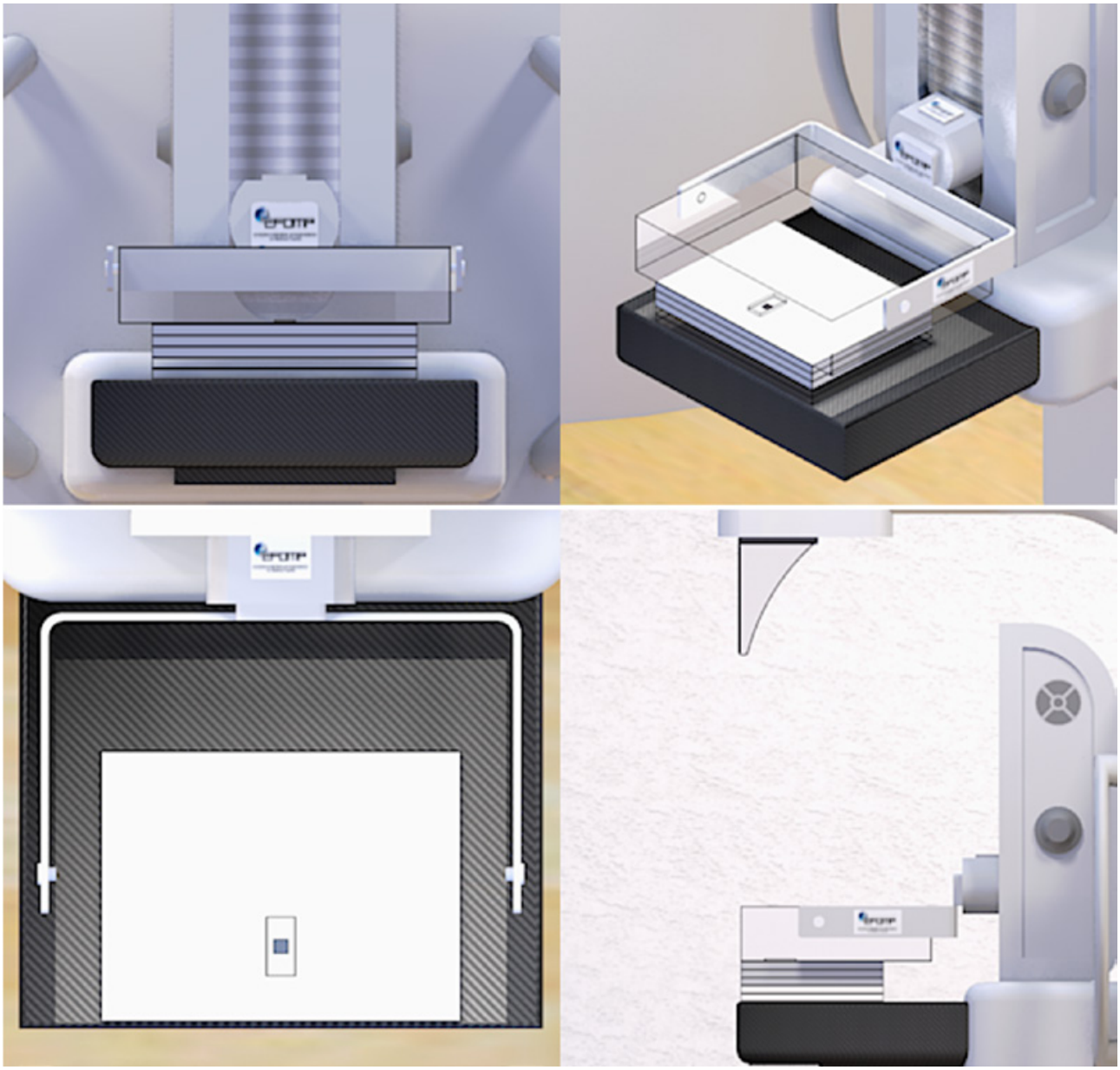

Figure 14 Setup for the local dense area test when using PMMA slab + PE slab + small PMMA plates

- Place a 20 mm PMMA slab and 30 mm PE slab on the breast support table and position the compression paddle at 50 mm height.
- Make sure that the phantom does not completely cover the Field of View (FOV) area, see Figure 14.
- Place the compression paddle in contact with the phantom, and apply a compression force of 100 N, if the system requires compression for the of the AEC to work correctly (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).

- Perform a DBT exposure using the clinically relevant AEC mode and record the exposure factors (target/filter, kV, mAs, AGD).
- Position the first 4 mm thick small PMMA plate over the aluminium sheet (see Figure 13). This configuration corresponds to the reference glandularity for a breast of 50 mm thickness.
- Perform an exposure with the same AEC clinical mode and record the exposure factors (target/filterref, kV_{ref}, mAs_{ref}, AGD_{ref}).
- 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.

$$\mathrm{SD(background)} = \frac{\sum_1^2 \mathrm{SD(ROI_n)}}{2} \quad (15)$$

$$\mathrm{MPV(background)} = \frac{\sum_1^2 \mathrm{MPV(ROI_n)}}{2} \quad (16)$$

- Calculate SDNRi for each tomosynthesis acquisition according to:

$$\mathrm{SDNR} = \frac{|MPV(signal) - MPV(background)|}{\mathrm{SD(background)}} \quad (17)$$

- Evaluate the percentage deviation of the $SDNR_i$ of each acquisition with respect to the $SDNR_{ref}$, where $SDNR_{ref}$ is defined as the SDNR relative to the acquisition with 4 mm added small PMMA plates:

$$SDNR\_deviation_i(\%) = 100 \cdot \frac{(SDNR_i - SDNR_{ref})}{SDNR_{ref}} \quad (18)$$

- Compute the Min Deviation SDNR (%) = min (SDNR_deviationi(%))
- Evaluate the percentage deviation of the AGD_i of each acquisition with respect to the AGD_{ref}, where AGD_{ref} is defined as the AGD relative to the acquisition with 4 mm added small PMMA plates:

$$AGD\_deviation_i(\%) = 100 \cdot \frac{(AGD_i - AGD_{ref})}{AGD_{ref}} \quad (19)$$

Compute the *Max Deviation AGD (%) = max (AGD_deviationi(%))*

Action levels
The Min deviation SDNR ≥ - 30% and Max deviation AGD> 0 (no negative variation in AGD is allowed).

Min Deviation SDNR (%) and Max Deviation AGD (%) should be within ± 20% of the baseline. If not, investigate the cause.

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 source moves with respect to the imaged object while the x-ray tube is emitting radiation, exposure time per projection influences the degree of blurring in the projection images due to the effective x-ray source 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 exposure time per projection, as this is a source of blurring for systems where the x-ray source moves with respect to the breast during exposure. As part of this test, the accuracy of the exposure time for an x-ray projection is assessed. This test also quantifies the total scan time, as the potential for patient motion artefacts increases with increasing total scan time.

Test equipment
- Suitable exposure time meter.
- Radiopaque sheet
- The projection images from the AEC performance test (Section 4.3)

Test frequency
- At acceptance
- Optional at subsequent routine tests
- After relevant software changes

Test procedure

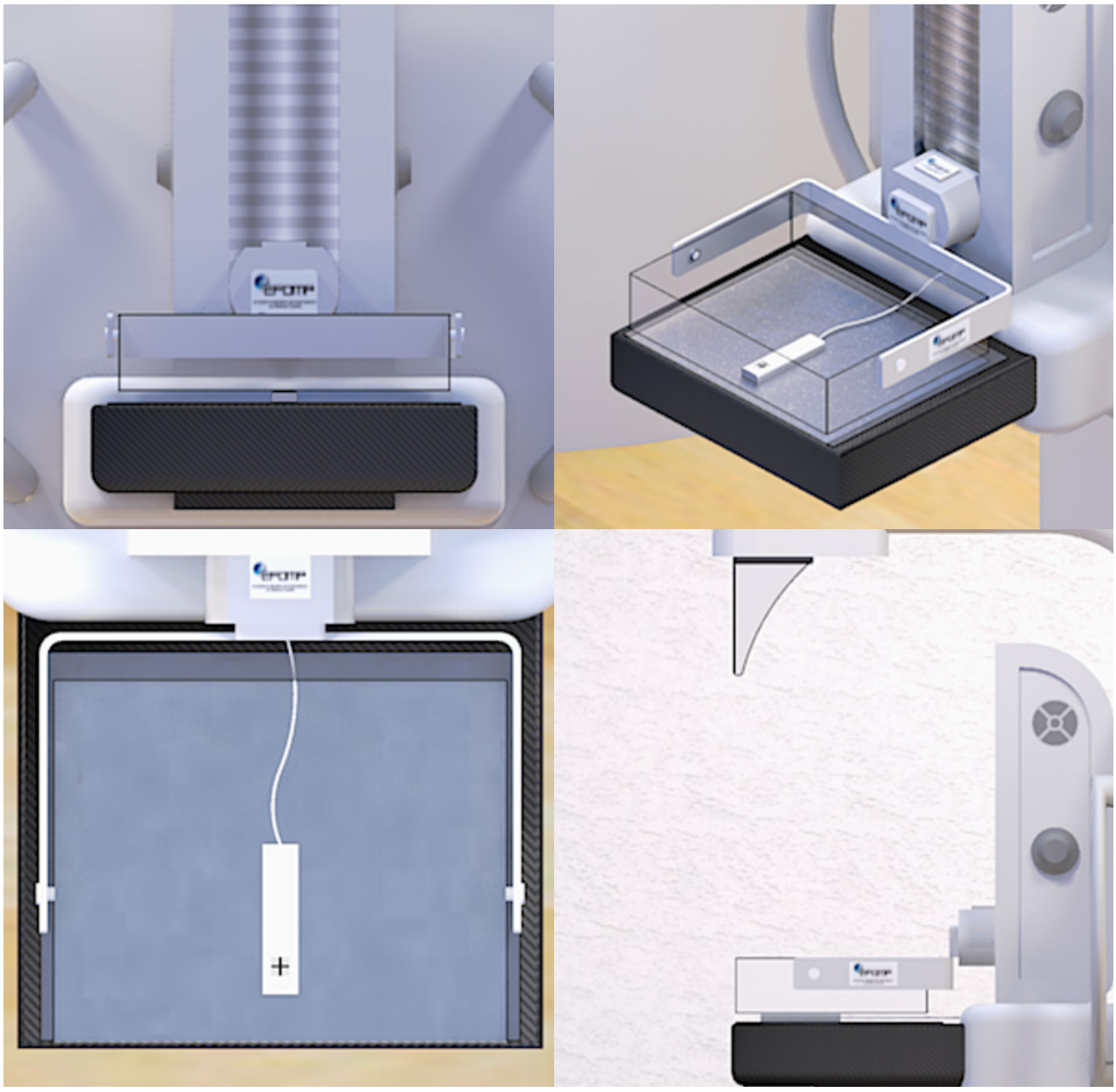

Figure 15 Setup for the exposure duration test

- Cover the x-ray detector with a radiopaque sheet and position the meter at the reference point, see Figure 15.
- Set the zero-degree angle stationary mode and manually set the technique factors by the clinically used AEC mode for 45 mm breast equivalent thickness.
- 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.
- Obtain the projection images for the scan and extract the exposure time per projection.

Analysis

- For the scan acquired with the dosimeter, calculate the percentage difference between the Exposure Time recorded in the DICOM header tag and the measured exposure.
- Using the projection images acquired for the AEC performance test (section 4.3), extract the exposure time per projection for all the breast equivalent thicknesses assessed. For a given thickness, compare the current measured projection time to the baseline value measured at the Acceptance test.

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.

For the AEC image data, investigate changes in exposure time >20% compared to the baseline values, for a given thickness. It may be that the system is selecting a different tube voltage/target/filter combination.

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. If the measured exposure time per projection is regarded as long or if total scan time is regarded as 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 AEC security cut-off

Introduction

AEC security cut-off 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.

Purpose

To check the correct functioning of the security cut-off

Test equipment

- Suitable high attenuating object e.g., radiopaque sheet

Test frequency

- At acceptance and subsequent routine tests
- After relevant software changes

Test procedure

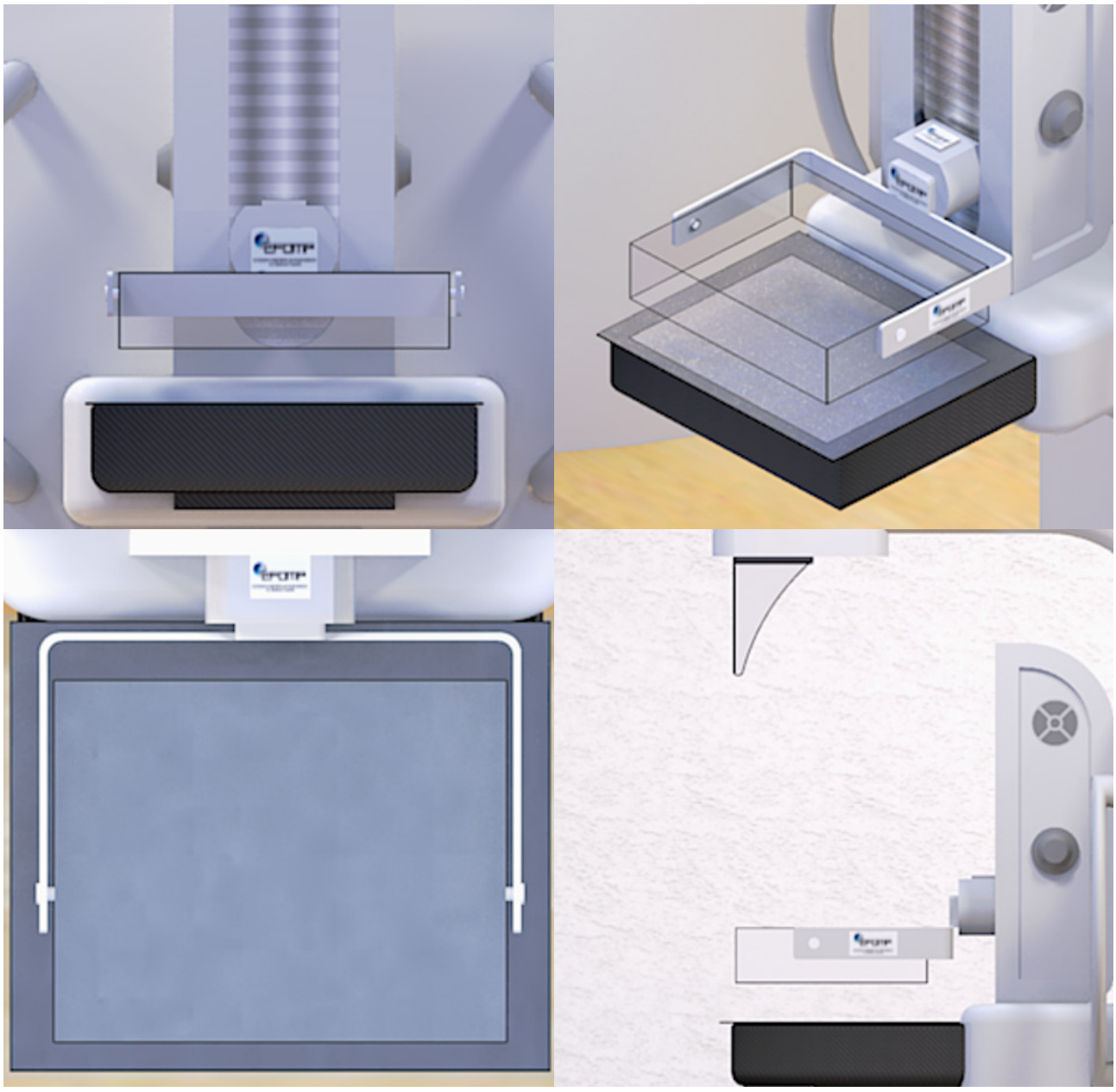

Figure 16 Setup for the security cut-off test

- Position the highly attenuating object on the breast support table covering the detector or the AEC sensor area of the detector, see Figure 16.
- Position the compression paddle at a height of 50 mm. If the system requires a minimum compression to produce images in the clinically used AEC mode, position the standard test block on the high attenuating object and apply a compression of 100 N.
- Perform an exposure at the clinically used AEC mode and record whether the exposure is terminated. For systems using segmentation techniques in the clinically used AEC mode, this needs to be turned off.

Analysis

- Verify that the mAs value is consistent with the pre-exposure value (typically in the range 2-15 mAs).

Warning: To avoid excessive mAs, consult the user manual for maximum permitted exposure time.

Action levels

The exposure should be terminated after the pre-exposure (typically in the range 2-15 mAs).

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 pixel value 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 air kerma levels expected for the DBT system. The detector air kerma/projection (K) will vary between DBT devices and will depend on system design parameters such as number of projections, angular range, beam quality and total dose for a scan.

The response function is characterized by a model function that is fitted to the data. This is typically linear, although other functions such as a logarithmic function 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 the 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 the breast support table (K), for a given beam quality.

Purpose

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

Test equipment

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

Remark: for some DBT systems, it will not be possible to achieve detector air kerma levels similar to those in clinical practice with a 2 mm Al attenuator in place. For these systems, the use of a 3 mm thick aluminium attenuator is suggested, see appendix 3.

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 changes

Test procedure

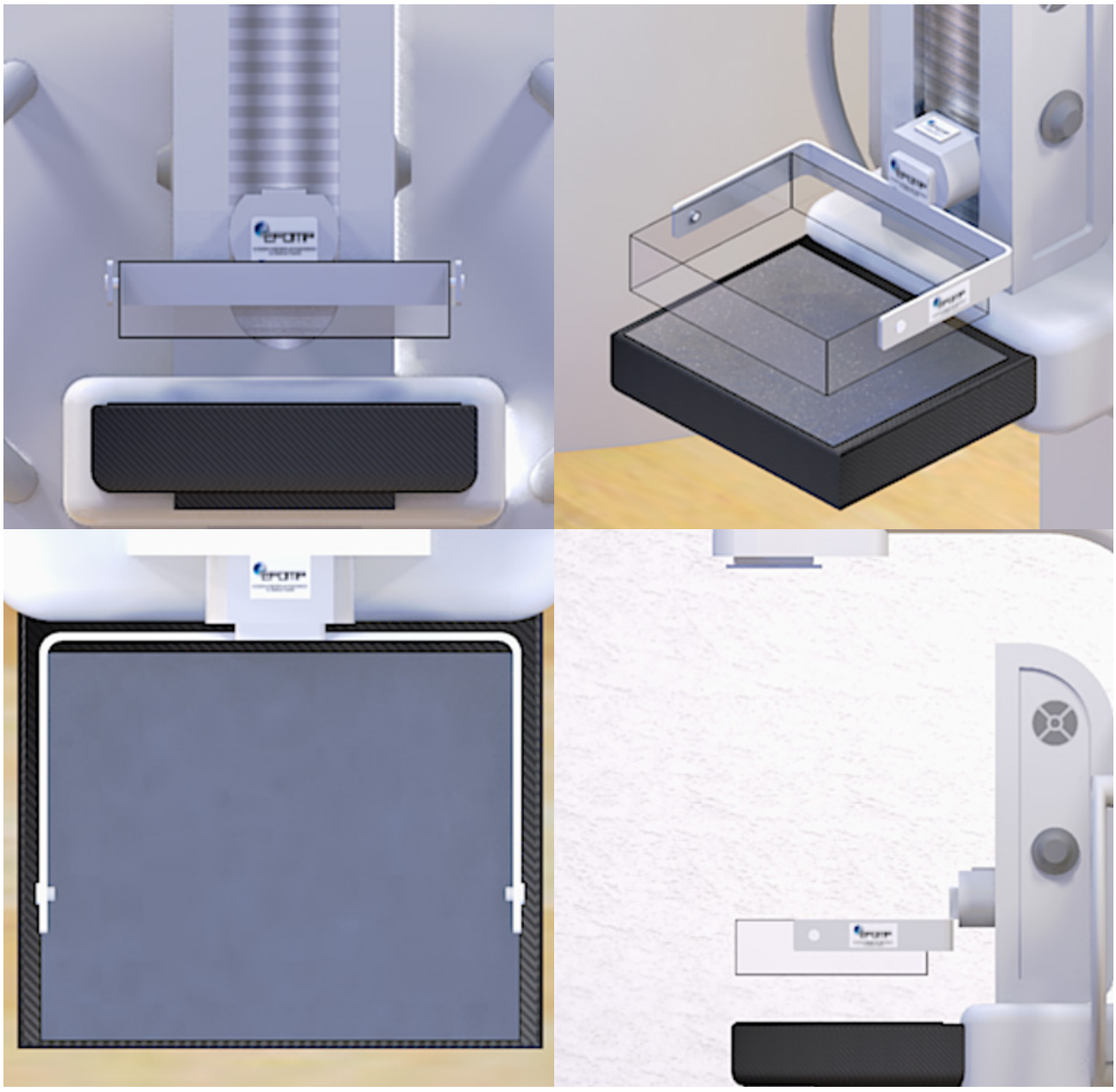

Figure 17 Setup for the response function QC test

- 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, see Figure 17, and select zero-degree angle stationary DBT exposure mode.
- Set the target/filter combination and tube voltage selected by the clinically used AEC mode for the standard test block.
- Acquire DBT scans at a range of mAs values and measure air kerma/projection. Calculate the K using an inverse square law correction to obtain an estimate of air kerma/projection at the detector input plane (do not correct for breast support table cover transmission).

- Before acquiring the scans used to acquire the response function images, the antiscatter grid should be removed; for systems where the antiscatter grid must be in position for DBT scans to be made, see the remark below.
- Remove the radiopaque sheet and acquire the DBT scans at a range of mAs values, starting from the minimum mAs that can be set on the system up to a mAs that gives an air kerma/projection value of ~100 µGy/image. The mAs (and air kerma) between each step should change by a factor of approximately 1.4. The minimum and maximum MPV in the response function measurement should bracket the typical clinical MPVs found in the AEC performance test (Section 4.3).
- Obtain the 'For Processing' projection images for analysis.
- Repeat the measurement for all clinically used target/filter combinations using a tube voltage chosen by the AEC for that filter in the AEC performance test (section 4.3).

Analysis

- Measure the MPV 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.
- To obtain the response function, plot MPV against K and fit an appropriate model function (linear, logarithmic or power) to the MPV data. Record the fit coefficients and the correlation coefficient.
- Use the fit coefficients 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

The response function should match the specification of the manufacturer.
Investigate cases where $R^2 \leq 0.98$ for the response function curve fit (i.e., fit of MPV vs K).

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:

$$\sigma^2 = e + qK + sK^2 \qquad (20)$$

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 (Bouwman *et al.*, 2009). The curve fit is performed using variance that is weighted by the inverse of the air kerma, as this improves curve fit consistency (Monnin *et al.*, 2014).

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

- The analysis for this test is performed on the images acquired for the detector response function (see Section 5.1).
- Spreadsheet to calculate the response function and perform the noise component analysis.

Remark: for some DBT systems, it will not be possible to achieve detector air kerma levels similar to those in clinical practice with a 2 mm Al attenuator in place. For these systems, the use of a 3 mm thick aluminium attenuator is suggested.

Test frequency

- At acceptance
- Optional at subsequent routine tests
- After detector replacement
- After relevant software changes
- After degradation of image quality

Test procedure

- Use the images made in section 5.1 Response function.

Analysis

- Use the response function images (Section 5.1).
- Linearize the images to air kerma using the response function.
- Measure variance in the reference ROI, positioned in the first projection image of the response function images.
- Plot variance against the detector incident air kerma/projection.
- Fit the polynomial curve in equation (20); weight the variance at a given air kerma by that air kerma and record the fitted noise coefficients.
- 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 levels, use the measured pixel value from the AEC performance test (section 4.3). Linearize the MPV in the projection images via the response function to give an approximate clinical detector air kerma/projection for each thickness.
- Estimate the fraction of quantum noise at these air kerma levels.
- For the 45 mm thickness, 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 at clinical detector air kerma levels.

Track the fitted values of the noise coefficients over time (optional).

For a given model of x-ray detector, similar values are expected for the percentage of electronic, quantum and structure noise. The coefficients could also be used to compare performance between systems using the same model of x-ray detector.

Remark: The test described here uses data acquired in zero-degree angle stationary mode, where the K/projection is constant over all projections (this is the case for the DBT devices currently available). The noise evaluation is therefore not performed using a moving tube, as would be the case for the clinical mode. This is considered acceptable for constancy testing, where comparisons are made against baseline data. The test could also be performed using projections acquired with a moving tube to examine the clinical mode, for example if additional noise measurements are made as part of a trouble shooting step. If this is done, it should be noted that K/projection will change with projection angle in the oblique projections and interpretation of results could be more complex.

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. Utilising 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'. The map is likely to be very similar to that for the 2D image, but there may be differences for the DBT acquisition.

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 tests
- After detector replacement
- After relevant software changes

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”. During the routine QC test, manufacturers should provide access to the user to obtain the "bad pixel map".

Analysis
- The bad pixel map obtained during the routine QC tests should be compared to previous maps.

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
If the bad pixel map obtained during the routine QC test significantly differs from previous maps, the service engineer should be called to investigate and it should be determined whether corrective actions should be taken.

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 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’.

Note: Elements in the beam path like dust particles can resemble bad pixels on the image. It is advisable to accurately clean all the equipment parts before performing this test.

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

Test frequency

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

Note: for daily or weekly QC this test can be combined with tests 4.2 Long term stability and 6.6Image homogeneity and artefact evaluation

Test procedure

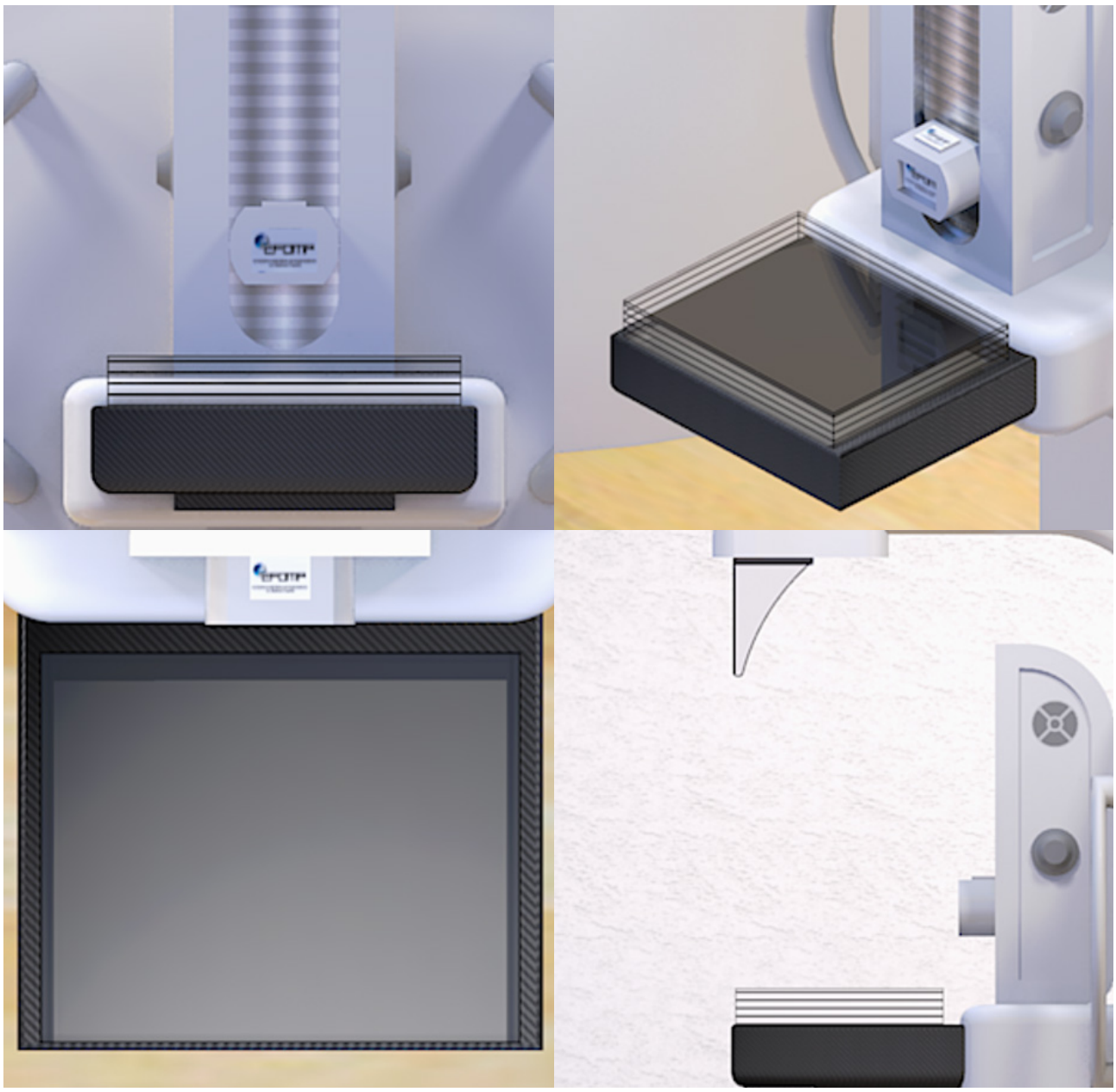

Figure 18 Setup for the uncorrected defective elements test

- The uncorrected defective detector elements test is performed on projection images acquired in tomosynthesis mode.
- Make an exposure of the standard test block in manual mode without the compression paddle, using the exposure setting from AEC performance test 4.3, see Figure 18. If exposures cannot be made without the compression paddle or without compression, position the paddle in contact with the standard test block and apply a compression of 100 N.

Analysis

- Add all projection images to one image to obtain an image which is less noisy.
- If the system has a non-linear response, linearize the image.
- On this image 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.

Remark: There is a benefit doing the analysis on projection images acquired in tomosynthesis mode, since the coordinates of defects will remain stationary projection to projection. If defects such as dust, particles are present in a plane different from the detector they will move angle to angle. This acquisition mode will allow elimination of false alarms. The analysis of projections acquired in zero-degree angle stationary mode would not highlight this difference.

Remark: A first qualitative assessment can be done comparing all the projections with a narrow contrast window and detect stationary anomalies. If the same defect is present in all projections at the same coordinates, it can then be quantified.

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 breast support table. The MTF measurement is sensitive to vibration and may therefore be useful for detecting changes in the mechanical stability of the gantry.

Hence, a system MTF in the projection images should be measured at a number of positions above the breast support table, 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 mm2 suitable for the measurement of the MTF.
- 2 mm thick aluminium plate
- Appropriate MTF calculation software
- Low contrast supports, 20 mm, 40 mm and 70 mm thick, to support the edge phantom at different heights above the breast support table. Expanded polystyrene blocks or small plastic blocks can be used

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 at all heights and at 40 mm height for subsequent routine tests
- After relevant software changes involving the acquisition scheme
- After detector and tube replacement

Test procedure

Figure 19 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. If a compression paddle is required, then position it in contact with the edge.
- 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 breast support table 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 19. 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 manually setting the x ray factors selected by the AEC for 20 mm, 40 mm and 70 mm breast, respectively. The MTF edge should be supported on low contrast supports, positioned underneath the edge such that they do not influence the area used for MTF analysis.

Note: Measuring MTF at 0 mm, 20 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°. Re-bin the MTF data at 0.10 mm-1 spatial frequency intervals. Find the spatial frequency for MTF values of 0.5 (MTF50).

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 MTF50 point should be > 90% of the baseline value set at acceptance

Investigate when there is more than 10% difference in the MTF50 point from the baseline value.

Remark: If a change in MTF is suspected, then additional steps should be taken to determine the origin of the change: for example, is the change a result of degradation in the detector or in the AEC technique factors? For systems without binned DBT projections, examine the MTF measured for DM (2D) mode or measure the MTF with the tool on the breast support platform, to establish whether there is a change in blurring in the detector. If the change in MTF only occurs at positions above the breast support, then the problem is likely a result of changes to AEC programming i.e. longer pulse lengths for projection images.

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 baseline 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 baseline values for technical image quality.

At subsequent routine tests: To compare test result with the established baseline 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 tests
- After detector replacement
- After relevant software changes

Test procedure

Option 1: CDMAM phantom

- Position the phantom in the middle of a 40 mm stack of PMMA and on the breast support table.
- Apply a compression of 100 N.
- Make an exposure 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 (van Engen, R. E. et al., 2013).
- Compare the score to the baseline 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 Thijssen, 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 filtered 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

- Position the phantom on top of a 30 mm stack of PMMA and on the breast support table.
- Apply a compression of 100 N.
- Make an exposure using automatically selected exposure factors.
- Carry out a visual assessment of the reconstructed tomosynthesis image of the TORMAM phantom. For this assessment it is necessary to use a diagnostic display 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 baseline 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.

- Position the phantom on the breast support table.
- Apply a compression of 100 N.
- 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.
- Carry out an appropriate assessment of the reconstructed tomosynthesis image.
- Compare the score to the baseline 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.

- Position the phantom on the breast support table.
- Apply a compression of 100 N.
- 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.
- Carry out an appropriate assessment of the reconstructed tomosynthesis image
- Compare the score to the baseline value.

Action levels

Option 1: CDMAM phantom

The measured threshold contrast values at acceptance can be used as a baseline 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 baseline 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 baseline 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 baseline 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 one of the parameters 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 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 tool, 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 probability these structures will be detected is determined to some extent by the blurring that occurs at different stages within the DBT system and therefore a quantitative measure of 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 changes

Test procedure

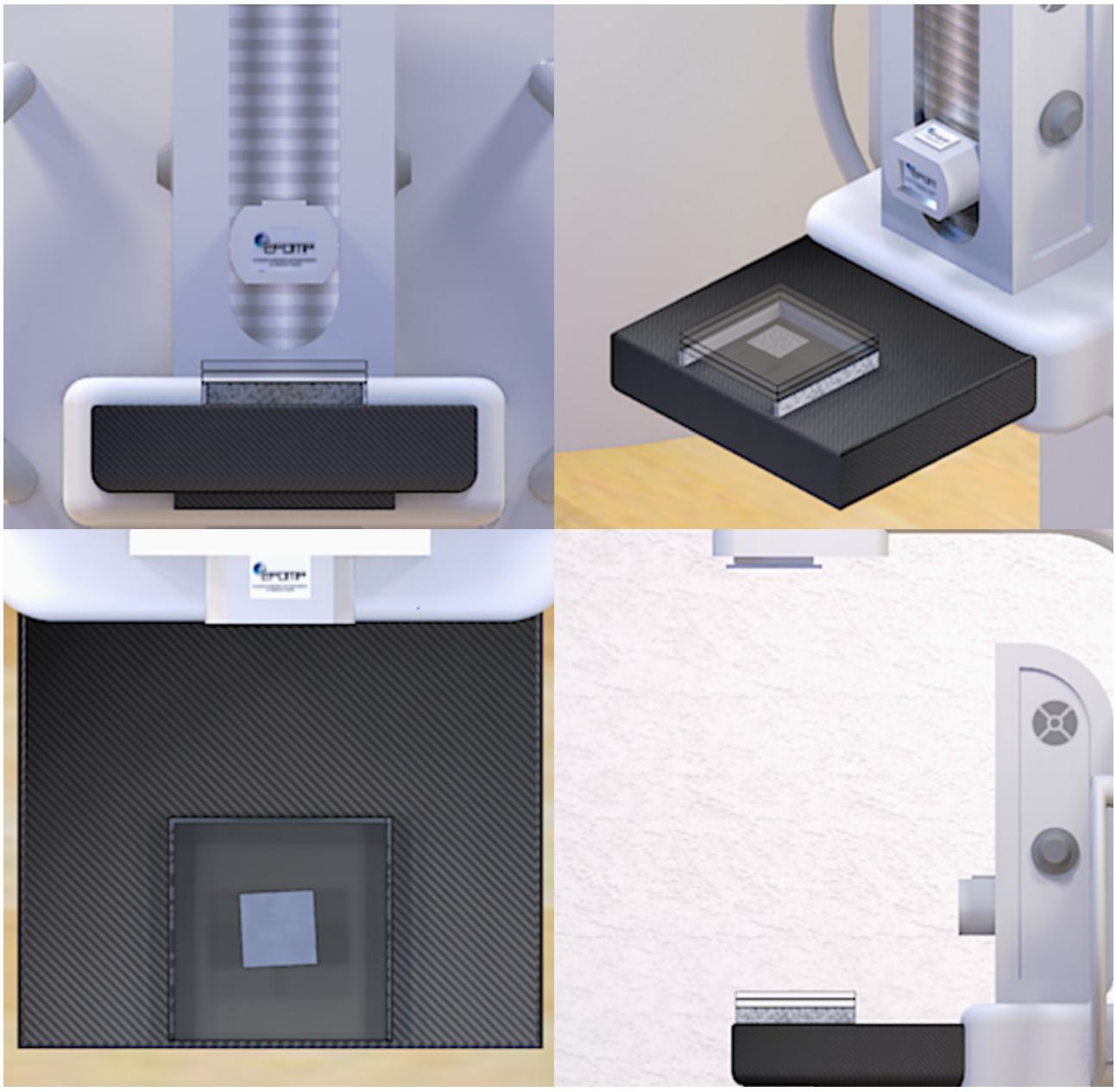

Figure 20 Setup for the MTF in the reconstructed image test using a low contrast edge as the MTF test tool

- Position the MTF phantom such that the wire or edge is held 40 mm above the breast support table. This can be done using small plastic blocks placed at the phantom edge. To measure the MTF in the ortho-scan 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 20.
- It is vital that the wire or edge is held parallel to the detector and therefore remains entirely within a given reconstructed plane.

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.

- The phantom must not be vibrating or moving as this will degrade the measured MTF.
- Manually set the techniques factors found in the AEC test for 40 mm breast simulating material (section 4.3) and acquire a DBT scan, using the standard clinical reconstruction algorithm.
- Change the test object position to measure the MTF in the tube-travel direction. Rotate the MTF phantom 90°, so the wire or edge is centred left-right and is orthogonal to the tube-travel direction (but aligned ~3° to reconstruction matrix). The wire or edge should be positioned at the midline of the detector in the left-right direction.
- Manually set the techniques factors for 40 mm breast simulating thickness and acquire a DBT scan using the standard clinical reconstruction algorithm.
- Obtain the in-focus plane with of the wire or edge.

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 (MTF0.5).

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 (Monnin *et al.*, 2020) 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 MTF0.5 value from the baseline value set at acceptance should be investigated.

With care, the MTF0.5 value can be used as a reference level to compare DBT units of the same model, using the same imaging mode. This can only be done if the same reconstruction algorithm, imaging mode and image processing factors are used for both sets of measurements.

6.3 Artefact spread function (ASF)

Introduction

Due to the limited angle and limited number of projections, the reconstructed tomosynthesis volume is under-sampled. 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. It is useful to quantify the magnitude of this signal spread between planes in the z-direction (i.e., between planes). 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 in-plane localization of objects 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:

$$ASF(z) = \frac{\overline{MPV}_{artefact}(z) - \overline{MPV}_{bkg}(z)}{\overline{MPV}_{object}(z_0) - \overline{MPV}_{bkg}(z_0)} \qquad (21)$$

Here, z_0 is the plane containing the real feature, z is the location of a plane containing the artefact of the feature, $\overline{MPV}_{object}(z_0)$ and $\overline{MPV}_{bkg}(z_0)$ are the mean pixel values measured respectively in the object and background in plane z_0, and $\overline{MPV}_{artefact}(z)$ and $\overline{MPV}_{bkg}(z)$ 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-planes spread of structures that might obscure objects of interest. The ASF is used to quantify this signal spread between planes.

Test equipment

A 5 mm thick PMMA slab containing a number of 1.0 mm diameter spheres composed of Al. Thin discs could also be used, with a diameter in the range 0.25 to 0.5 mm, and with a thickness giving a projected contrast equivalent to ~0.5 mm Al.

The objects should be spaced 2 cm or further apart in an array.

One object must be positioned and imaged on the midline of the detector in the left-right direction.

Note: the thickness and composition of the objects will determine the contrasting signal generated by the objects 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.

6 PMMA slabs of 10 mm thickness

Software to calculate FWHM

Test frequency

At acceptance and subsequent routine tests

After relevant software changes

Test procedure

Remark: Images acquired using the geometric test phantom (section 6.4) may be used for this purpose, enabling the two tests to be combined.

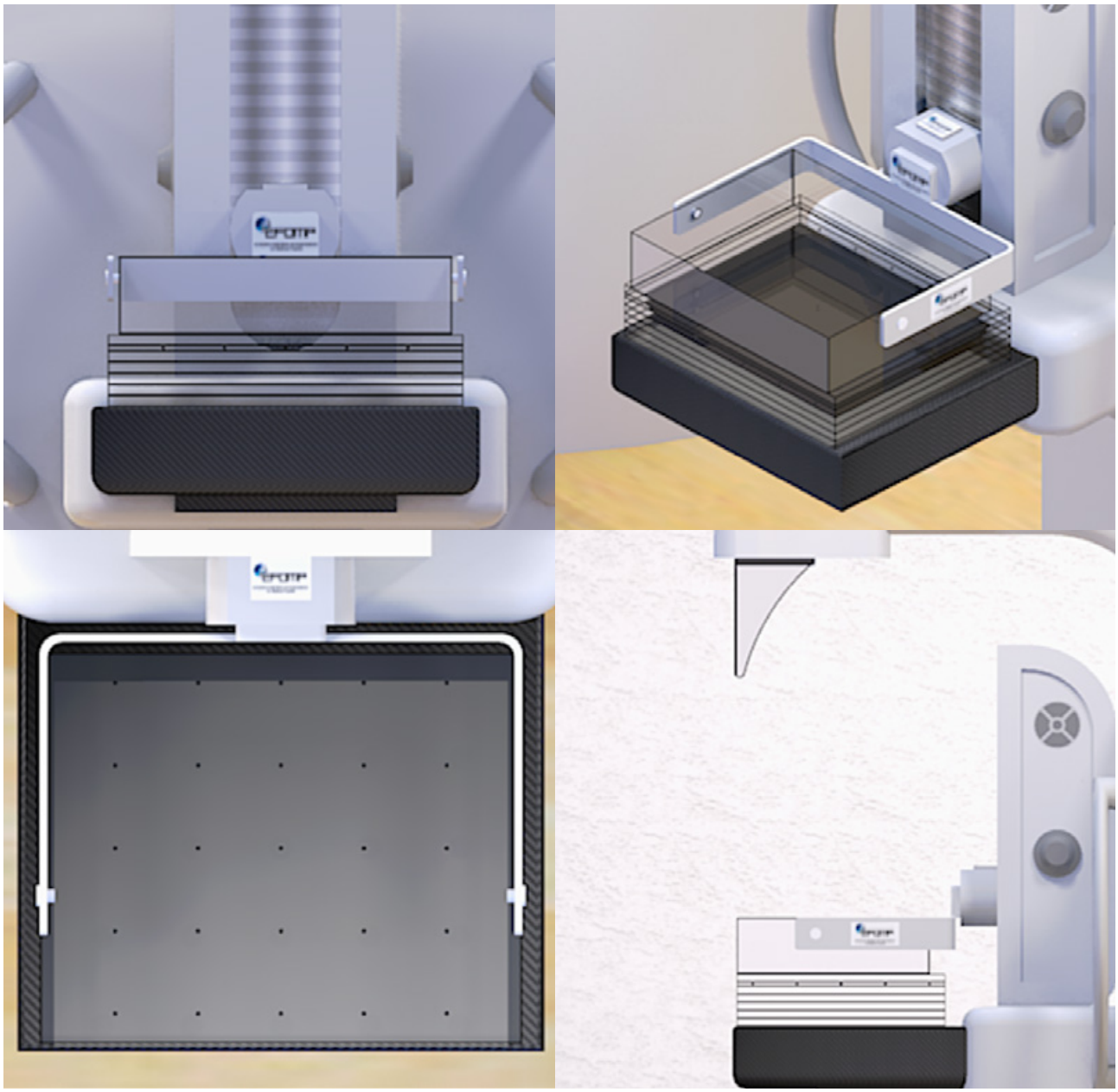

Figure 21 Example of setup for the artefact spread function test (other phantoms may be used)

Position five 10 mm thick slabs of PMMA on the breast support table, followed by the phantom containing the stimuli and then another sheet of 10 mm thick PMMA.

For the Siemens Inspiration and Revelation DBT systems, small spacers (≤5x5mm^2 area) of thickness 2 mm must be positioned at the chest wall edge to ensure that the test object is parallel to the x-ray detector.

Make an exposure using the clinically used AEC mode and standard clinical reconstruction algorithm, see Figure 21. 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 (21). Normalize the curve to a maximum of 1.0 as follows: subtract the background value from the curve using the average value of $\overline{MPV}_{bkg}(z)$, 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.

Repeat for an array of spheres near the chest wall and take an average of the measured ASFs.

If different plane spacing or slabbing options are available on the system, then the ASF for 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 linked to 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:

$$(x', y', z) = (xM, yM, z) \qquad (22)$$

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 (22) is the height above the detector, while z in equation (21) 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 (21).

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

Investigate the cause if the FWHM value ≥ 15% difference with the baseline values established at the acceptance test.

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.

Note: It is worth undertaking this test before any measurements of technical image quality (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 22). 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

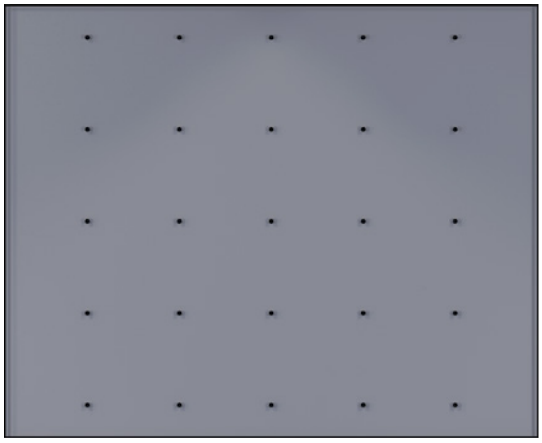

Figure 22 Example of the geometric distortion phantom

Test frequency

- At acceptance
- Optional at subsequent routine tests
- After relevant software changes

Test procedure

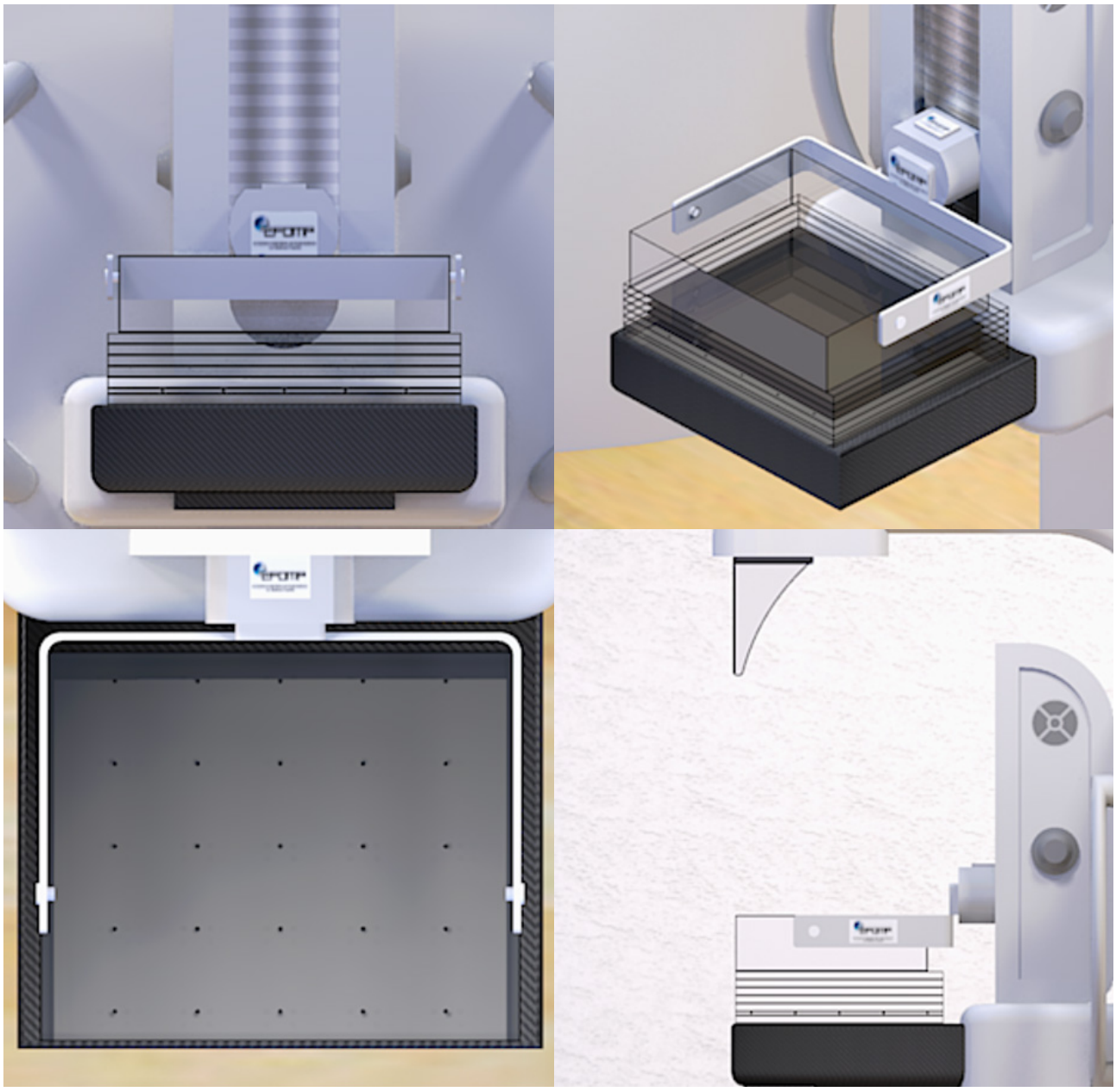

Figure 23 Setup for the geometric distortion test

- The geometric distortion phantom is imaged within the total of 60 mm stack of PMMA, see Figure 23. 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, see Appendix 1 it may be necessary to use small 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 all 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 webpage of the working group on the EFOMP 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, see section 6.3.
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 is important.

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

Introduction

Due to the design of the breast support table, compression device, relative position of the x-ray tube and position of the detector in the breast support table, 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 the breast tissue between the breast support table 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 table 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 potentially missed tissue at the 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 x-ray tube replacement
- After detector replacement
- After relevant software changes

Test procedure

Missed tissue at chest wall side

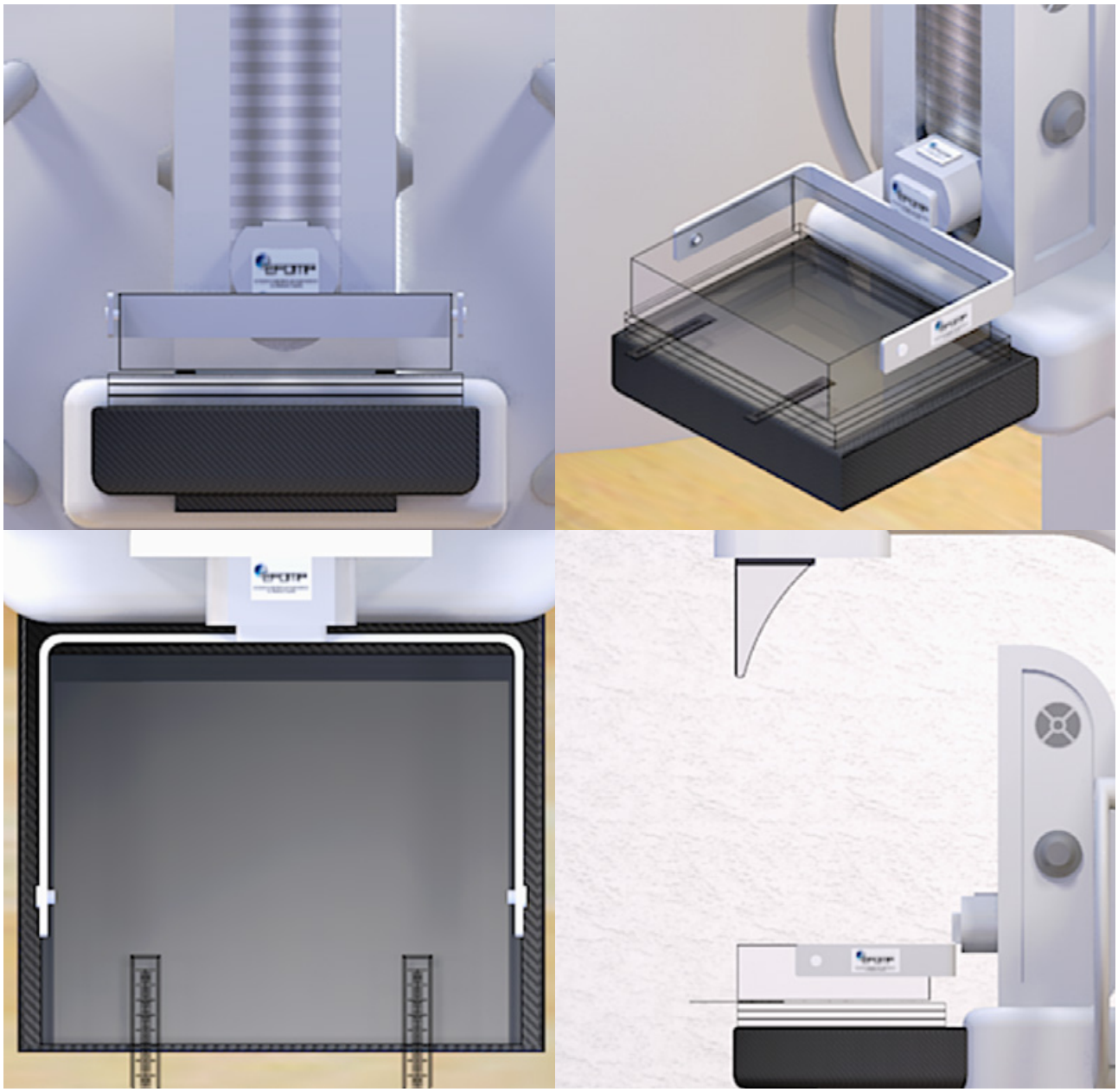

Figure 24 Setup for the missed tissue at chest wall side test

- Position the standard test block on the breast support table
- 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 24.

- Acquire a DBT image in manual mode using the exposure factors for the standard test block in clinical AEC mode.

Analysis

- Evaluate the amount of missed tissue, i.e., the amount of tissue between the chest wall edge of the breast support table and the chest wall edge of the reconstructed focal plane. At acceptance this measurement should also be performed at 30 mm and 60 mm height above the compression paddle.

Test procedure

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

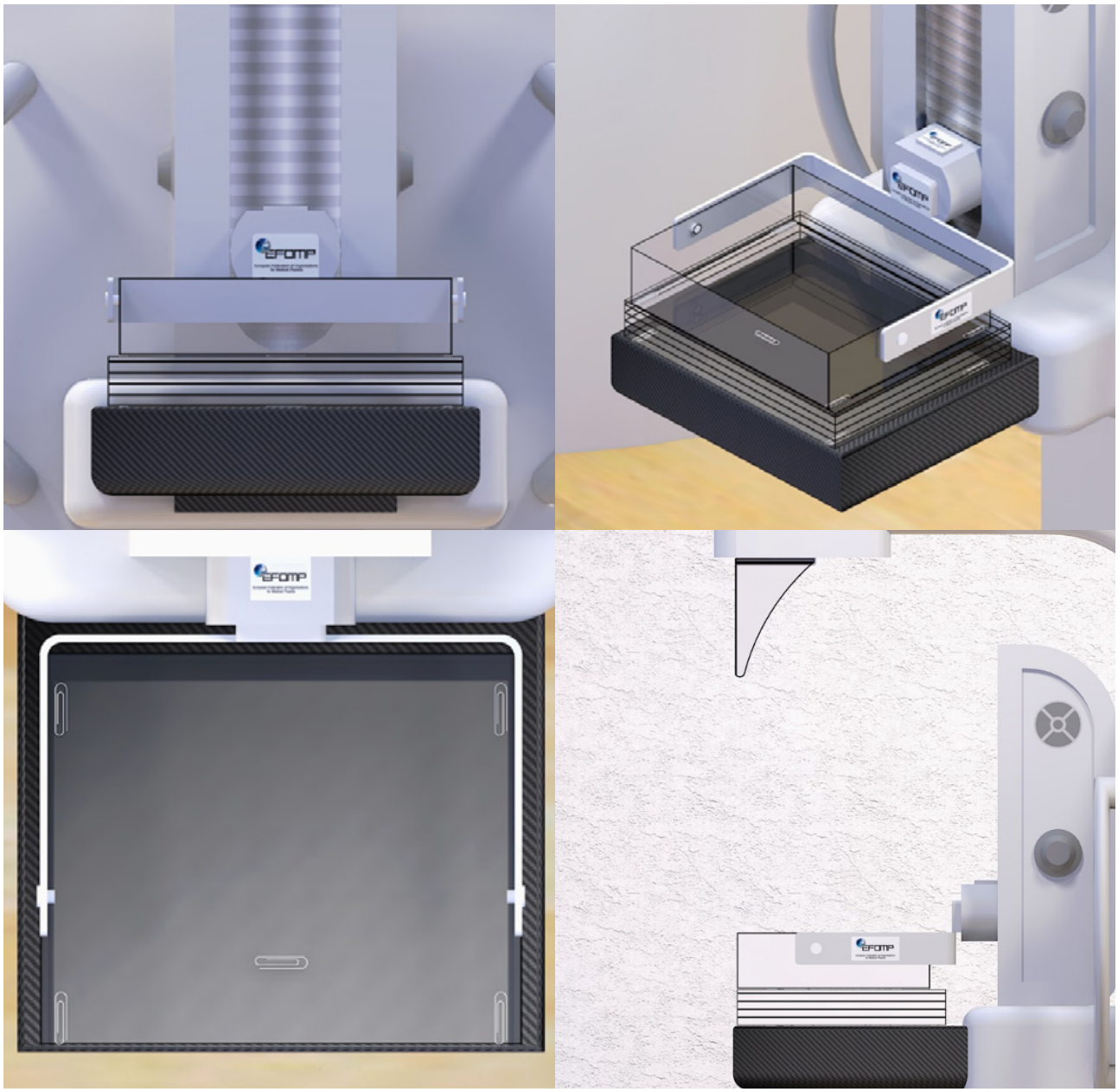

Figure 25 Setup for the missed tissue at the top and bottom of the reconstructed DBT image

- Position some small high contrast objects on the breast support table surface such that they are positioned at the edges of the imaging field, see Figure 25. To prevent scratching, wrap some adhesive tape around the high contrast objects.
- Carefully position the standard test block on the breast support table.
- Position the compression paddle such that the paddle is just above the phantom surface. Do not compress.
- Acquire a tomosynthesis image setting in manual mode using the exposure factors for the standard test block.
- 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 breast support table 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.

Test frequency

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

- 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

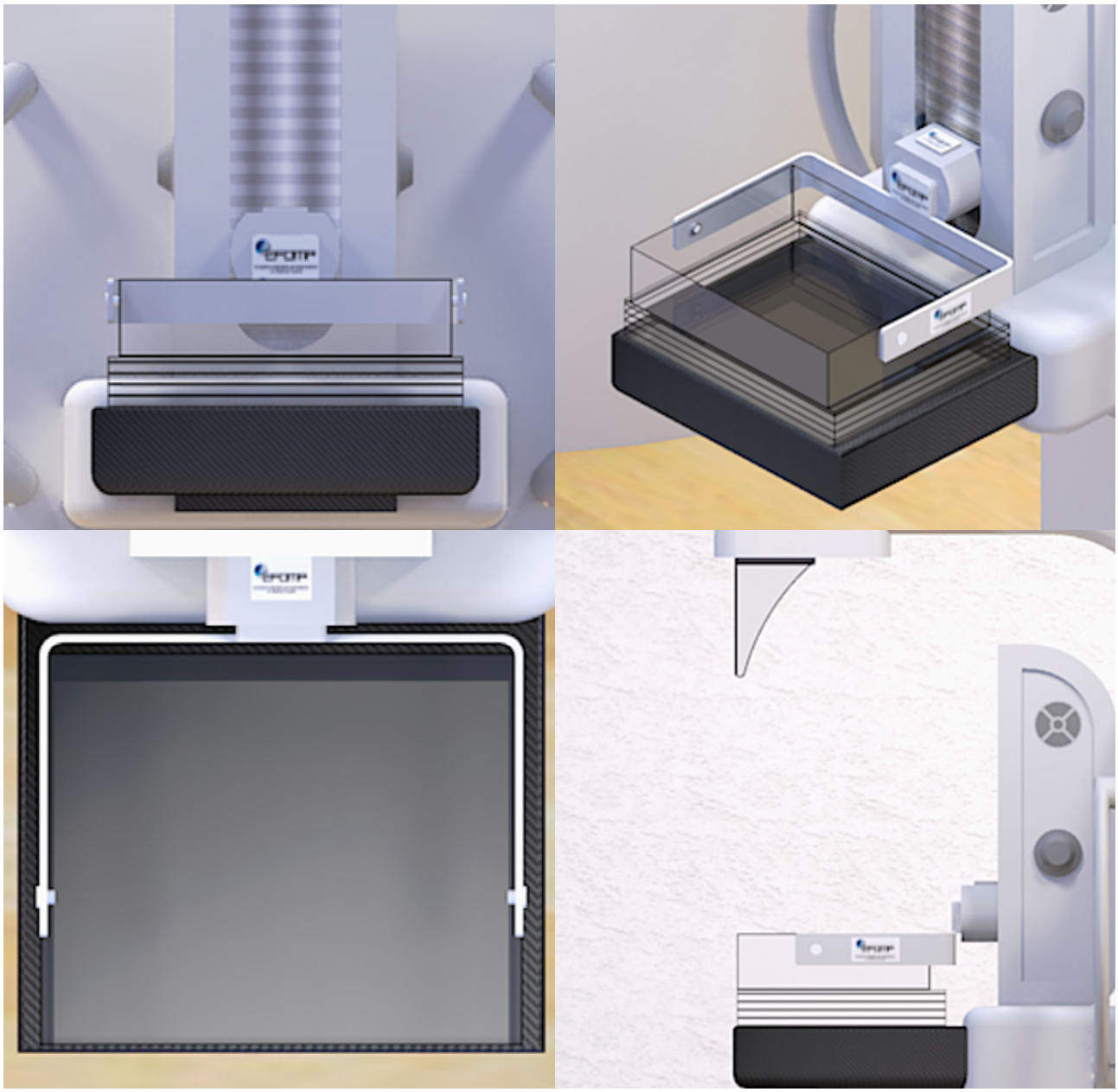

Figure 26 Setup for the image homogeneity and artefact evaluation test

- Position the standard test block on the breast support table, see Figure 26.
- Apply a compression of 100 N.
- Acquire a DBT image in the clinically used AEC mode. 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 and reconstruction parameters in the clinically used AEC mode.

Analysis
- Add all projection images and inspect the resulting image for detector artefacts.
- Visually inspect all focal planes of the reconstructed tomosynthesis image for artefacts and inhomogeneities.

Action levels
No disturbing artefacts and or clinically relevant inhomogeneities should be present.

7 Dosimetry

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 from the air kerma at the reference point are provided here.

Definitions
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. Breast density values to be evaluated are described in terms of percentiles, not percentage, density.

In breast tomosynthesis, the average glandular dose is the sum of the doses received from individual projections.

Purpose
To estimate the AGD to model breasts using phantoms representing breasts of several thicknesses.

Test equipment
- Suitable dose meter
  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 shall be made.

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 tests
- After x-ray tube replacement

- After filter replacement
- After detector replacement
- After relevant software changes

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 mAs.

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

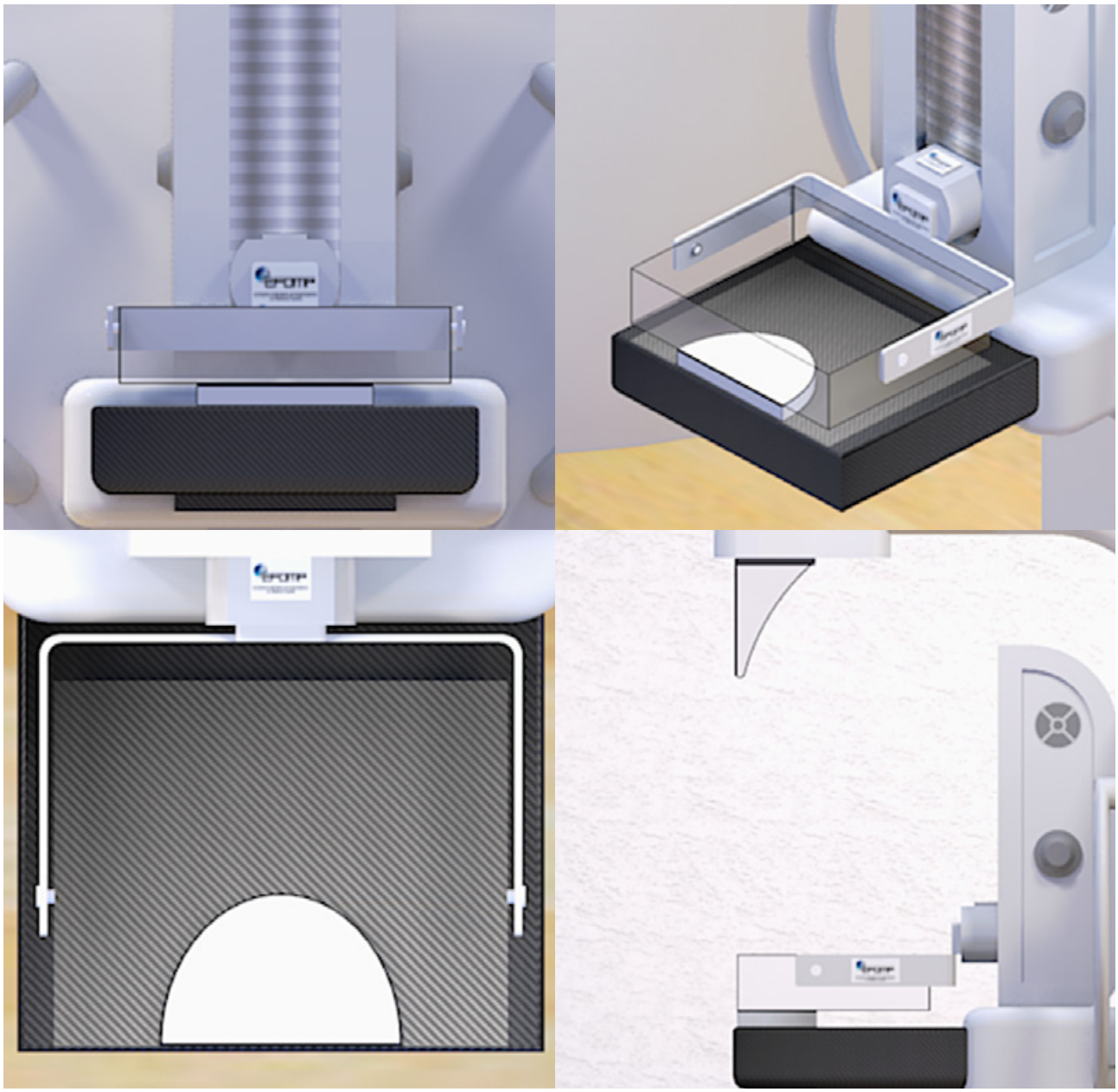

Figure 27 Setup for estimating glandular dose using the WG/TG 323 phantom

- Position the base slab with 50th percentile density on the breast support table.
- Place the compression paddle in contact with the base slab and apply a compression force of around 100 N, see Figure 27.
- 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 the compression paddle heights indicated in Table 5: 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 5 Dosimetry phantom thickness, height of the compression paddle, and hence thickness of the modelled compressed breast using the 50th percentile density base slab.

Dosimetry phantom thickness (mm)	Height of the compression paddle (mm)	Height of the compression paddle Equivalent volumetric breast density for the 50th percentile density base slab (%)
20	20	17
30	30	14
40	40	10
50	50	7
60	60	6
70	70	5
80	80	4
90	90	4

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

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 compressed breast thickness. In addition, for systems that require compression to determine the exposure factors in fully automatic mode (see Appendix 3), 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.

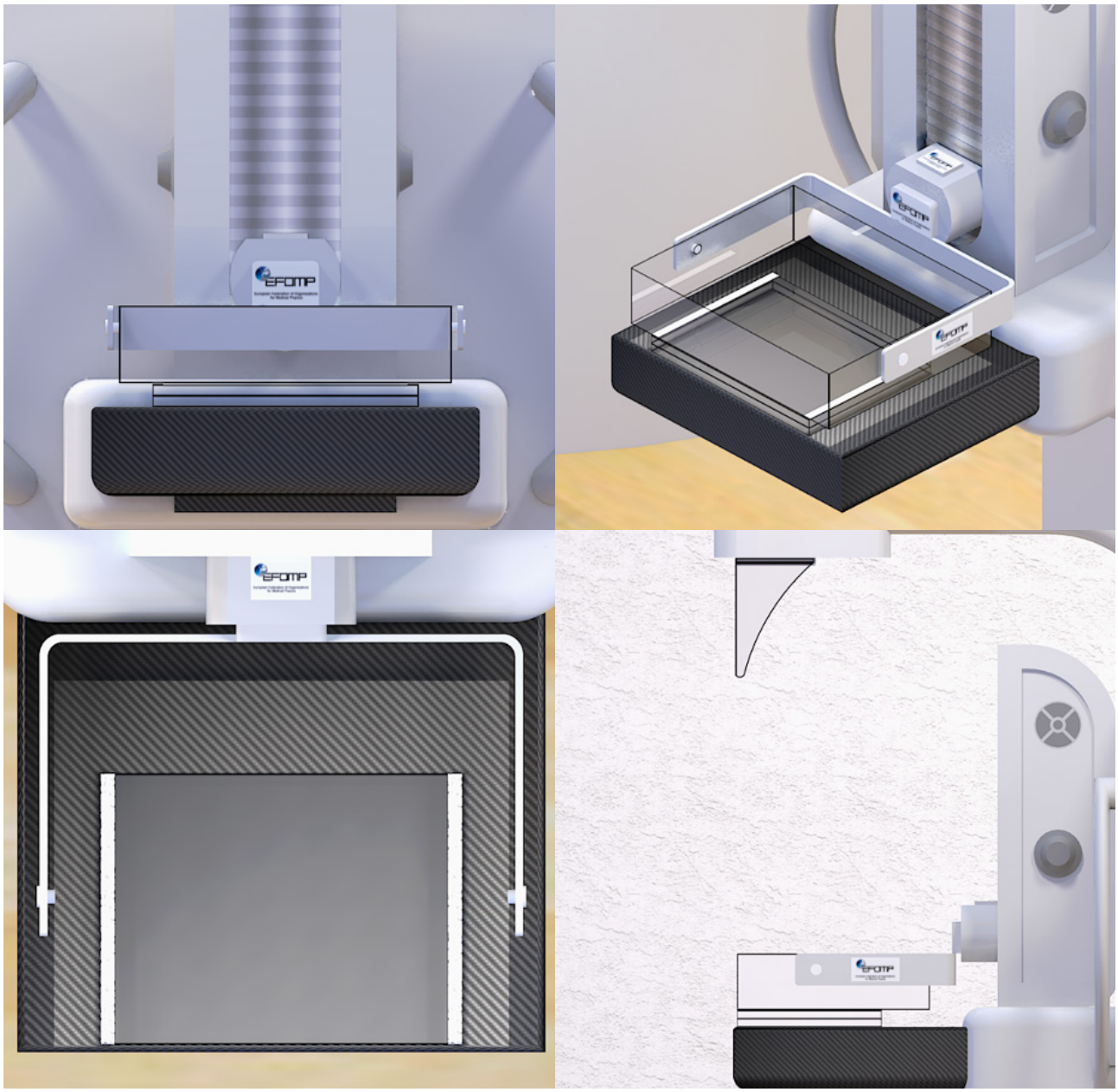

Figure 28 Setup for estimating glandular dose using PMMA slabs

- Position a 20 mm thick PMMA slab on the breast support table.
- Place the compression paddle at the height given in Table 6 for 20 mm of PMMA to obtain the thickness of the equivalent breast with similar attenuation, see Figure 28. This can be achieved by leaving an air gap between the PMMA plates and the compression paddle. For systems that require compression to determine the exposure factors in fully automatic mode, place the compression paddle in contact with the PMMA slab and apply a compression force of around 100 N. Use spacers if necessary. Position spacers so that they do not reduce the transmission of x rays through the central and chest wall regions of the image at any tube angle, for example along the nipple side of the PMMA or at the far lateral sides of the image receptor.
- Make a DBT exposure in the clinically relevant AEC mode. For some systems a specific phantom acquisition mode may need to be selected.
- Add additional slabs of PMMA and repeat the procedure, continue adding PMMA slabs until images have

been made at the compression paddle heights indicated in Table 6.

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

Table 6 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.

Table 6 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).

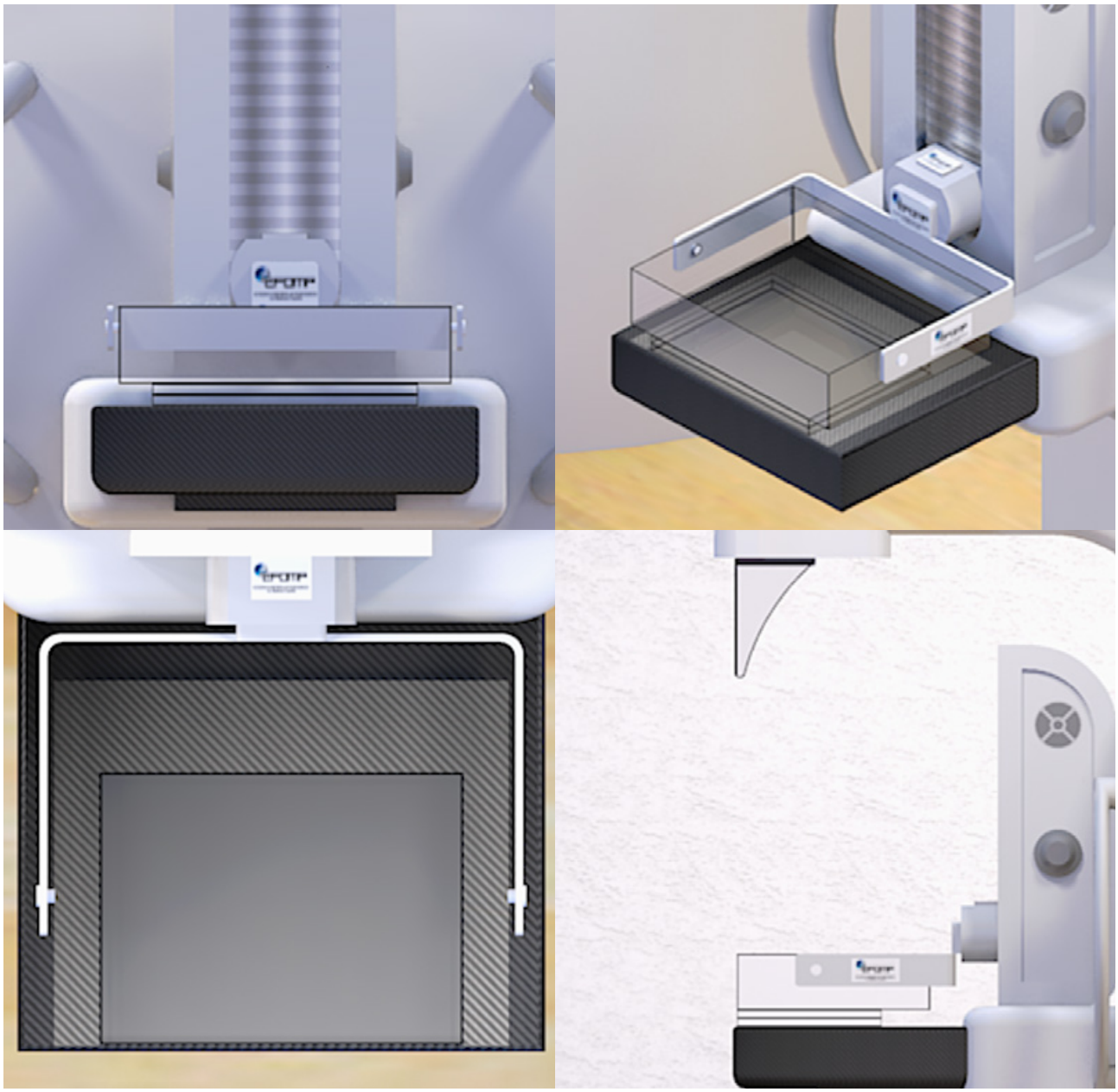

Figure 29 Setup for estimating glandular dose using PMMA and PE slabs

- Position a 20 mm thick PMMA plate on the breast support table
- 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, see Figure 29. For systems that require compression to determine the exposure factors in fully automatic mode, place the compression paddle in contact with the PMMA slab and apply a compression force of around 100 N.
- Make a DBT exposure in the clinically relevant AEC mode. For some systems a specific phantom acquisition mode may need to be selected.

- Add additional slabs of PMMA and PE and repeat the procedure, continue adding PMMA and PE slabs until images have been made at the compression paddle heights indicated in Table 7. PMMA slabs should always be at the bottom of the stack and all PE slabs on top of the PMMA stacks (see Figure 29).
- Record the exposure factors for each simulated breast thickness.
- Measure the air kerma in the zero-degree angle stationary mode in the reference point using the method given below and the recorded exposure factors.

Table 7 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

Method 1, 2 and 3

This procedure applies to all three options described above for estimation of the AEC-selected exposure factors. Although Γ (see appendix 5) 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.

- The dosimeter shall 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 30).
- The compression paddle shall be left in the beam but positioned as close to the x-ray tube as possible. The collimation of the system to produce the largest x-ray field shall be selected, and the tube fixed at the 'zero-degree' position.
- It is recommended that when performing these measurements the radiopaque sheet (e.g., steel plate, etc.) be placed on the breast support table, underneath the dosimeter to avoid ghosting issues.

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 30 Schematic showing the setup for the measurement of K_m.

- Measure the air kerma using this setup in zero-degree angle stationary mode for a given reasonable mAs, e.g., 50 mAs, for each of the set of other exposure parameters determined in the previous step using the phantoms.
- Scale the measured air kerma to the actual mAs set by the AEC for each corresponding exposure to obtain K_m.
- 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 2.1 and 2.3.

Estimation of average glandular dose for the AEC-selected exposures

Use the WG/TG 282 software to estimate the AGD to the evaluated breast models as would result from acquisition with the AEC-selected exposures. Consult the User's Guide of the WG/TG 282 provided software for details on its use.

Action levels

Table 8 a Average glandular dose limiting values for PMMA + spacers phantoms

Breast thickness (mm)	Average glandular dose Limiting value (mGy)
21	1.1
32	1.25
45	1.7
53	2.1
60	2.5
75	3.7
90	5.1

Table 8b Average glandular dose limiting values for PMMA + PE phantoms

Breast thickness (mm)	Average glandular dose Limiting value (mGy)
20	1.1
30	1.2
40	1.5
50	1.9
60	2.5
70	3.2
80	4.0
90	5.1

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

Table 8c Average glandular dose limiting values for the WG/TG 323 phantom

Breast thickness (mm)	Average glandular dose Limiting value (mGy)
20	To be determined, see website
30	
40	
45	
50	
60	
70	
80	
90	

Assessing clinical breast doses

It is also encouraged to estimate the AGD for a series of breast examinations performed on each mammography system. The procedure can be found in Appendix 7: Auditing clinical breast doses. The action levels given for phantoms do not apply to clinical breast doses.

8 Image display

The QC tests in this section are based upon the work of American Association of Physicists in Medicine (AAPM) on the "Assessment of Display Performance for Medical Imaging systems" by Task Group 18 (AAPM, 2005; Samei *et al.*, 2005) and "Display Quality Assurance" by AAPM TG270 (AAPM, 2019; Bevins *et al.*, 2020). The TG18 test patterns described in this section can be downloaded from: https://deckard.duhs.duke.edu/~samei/samei_tg18/. The TG270 test patterns can be downloaded from the TG wiki on the AAPM website

Some general remarks:
- Display the test patterns at full resolution (exactly one display pixel for each pixel in the digital image).
- The displays should be tested as used clinically (e.g. third display on, ambient light conditions as in clinical practice, etc.).
- The display should be calibrated according to the ambient conditions as used clinically.
- Dedicated mammography image displays typically have two 5MP portrait monitors or one large (at least 10 MP) landscape monitor.
- When viewing a sequence of images in cine-mode at high frame rate, like the reconstructed DBT image in cine mode, it is possible that not all focal planes are shown on the display. It might also be possible that the image on the display does not reach full resolution and that individual pixels on the display may not have reached the correct luminance level due to the response time of the display.

8.1 Ambient light

Introduction
The ambient light in a reading room decreases the luminance range of the display. It is therefore important that illuminance levels are sufficiently low.

Note: Very low illuminance levels might increase eye fatigue.

Definitions
Ambient illuminance is the available light in an environment on the display. Ambient luminance is the ambient light reflecting from a display's surface when the display is off. The ambience ratio is the ambient luminance divided by the minimum luminance.

Purpose
To quantify the amount of ambient light and (optional) the ambient ratio

Test equipment
- TG270-sQC test pattern
- Suitable illuminance meter
- Telescopic luminance meter (optional)

Test frequency
- At acceptance and subsequent routine tests

Test procedure

- Turn off the display.
- Position the illuminance meter at the centre of the display with the light meter facing outwards and measure ambient illuminance.
- Optional: Measure the ambient luminance with a telescopic luminance meter and calculate the ambience ratio by dividing the ambient light by the minimum luminance (from section 8.6).
- Display the TG270-sQC test pattern, see figure 32b.
- Evaluate the visibility of the low contrast features in the darkest region of the test pattern.

Action levels

Ambient light < 20 lux for diagnostic display devices.

The low contrast features in the darkest regions on TG270-sQC should be visible.

Optional: ambience ratio ≤ 1/4

8.2 Geometrical distortion (CRT displays only)

Introduction

In CRT displays electron beams are deflected to a phosphorescent screen, which forms the image. This deflection and the curvature of the screen introduce geometrical distortion in the image on the screen, which is corrected for. If this correction is not correct, the image will be geometrically distorted.

Definitions

Geometrical distortion is measured evaluating the 'straightness' of linear lines of a test image.

Purpose

To check geometrical distortion.

Test equipment

- TG18-QC test pattern

Test frequency

- At acceptance and subsequent routine tests

Test procedure

Figure 31 TG18-QC test pattern

- Display the TG18-QC image (see figure 31) on the display.
- The image should be centred on the display.
- Inspect the linear lines and borders of the test image for geometrical distortion.

Action levels
Borders should be completely visible, lines should be straight.

8.3 Contrast visibility

Introduction
It is important that images are displayed such that the human visual system can appreciate contrast in the light and in the dark parts of images.

Definitions
Contrast visibility is defined as the ability to distinguish small differences in driving levels over the full range of luminance levels.

Purpose
To evaluate contrast visibility.

Test equipment
- TG18-QC test pattern or TG270-sQC pattern

Test frequency
- At acceptance and subsequent routine tests

Test procedure

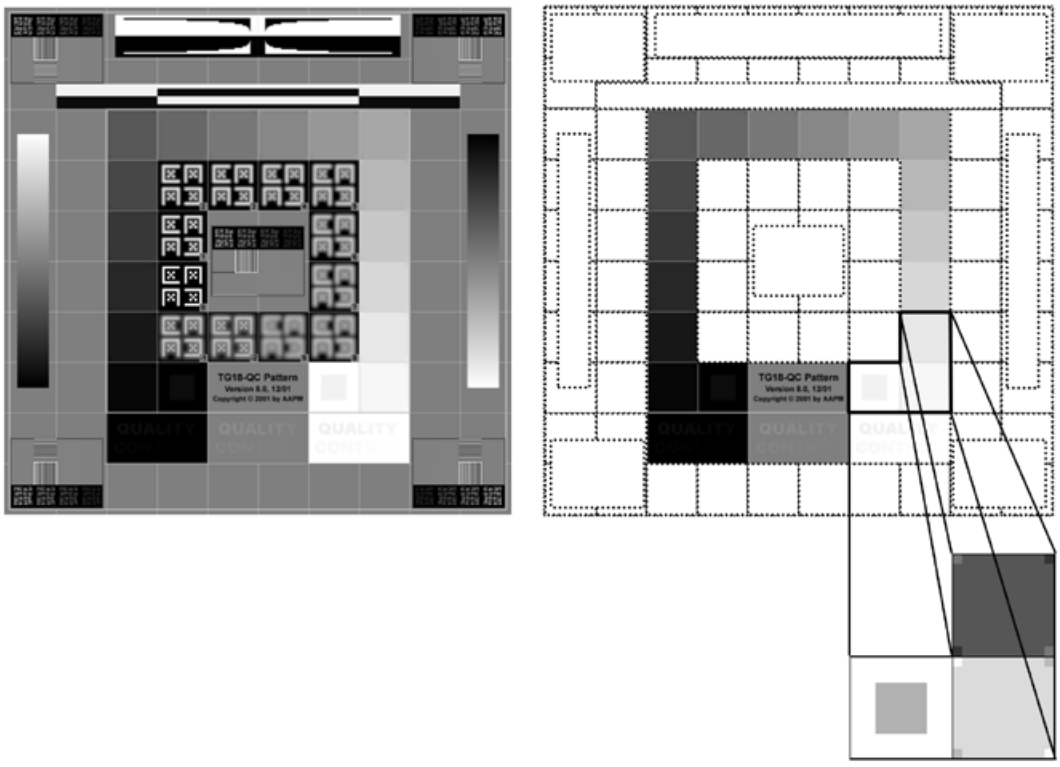

Figure 32a Contrast visibility test items in TG18-QC test pattern

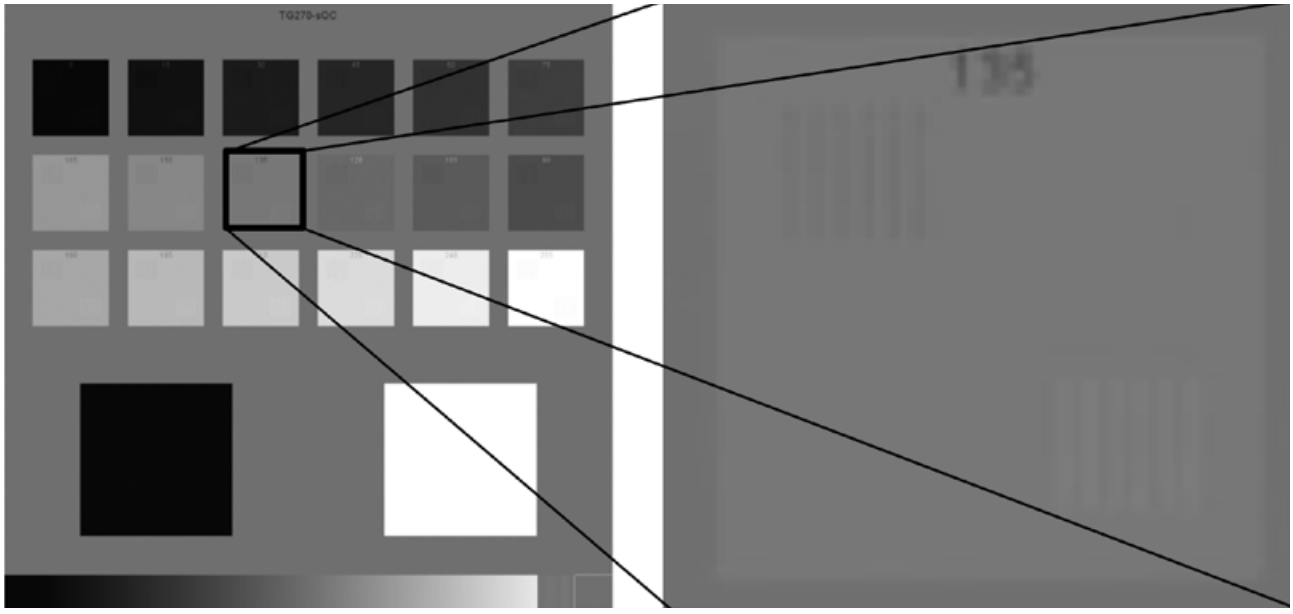

Figure 32b Contrast visibility test items in TG270-sQC pattern

Display the TG18-QC test pattern or the TG270-sQC test pattern. These patterns have luminance patches, in each of which low contrast objects can be found (see figure 32).

- Evaluate the visibility of all low contrast objects.
- In TG18-QC the two patches in the bottom with minimum and maximum pixel value, surrounding the test pattern name, contain a centre square with a pixel value of 5% and 95% of the maximal grey level respectively. Evaluate the visibility of these centre squares.
- In TG18-QC the letters “QUALITY CONTROL” in the three rectangles below these patches are displayed with decreasing contrast to the background. Record the letters which are visible for all three rectangles and compare against baseline.

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

Action levels
All low contrast objects should be visible. In the TG18-QC test pattern the 5% and 95% pixel value squares should be clearly visible and the number of letters, which are visible should not decrease over time.

8.4 Resolution

Introduction
In mammography, it is required to visualize small and low contrast structures. The display should be able to show these structures.

Definitions
Resolution is defined as the ability to visualize lines with alternating luminance levels.

Purpose
To evaluate resolution on the display.

Test equipment
- TG18-LPH10, -LPH50, -LPH89 and TG18-LPV10, -LPV50, -LPV89 test patterns or TG270-sQC test pattern

Test frequency
- At acceptance and subsequent routine QC tests

Test procedure
- Display the TG18-LPH10, (figure 33) or the TG270-sQC test pattern (figure 32b).
- Evaluate the visibility of the lines in the test pattern
- When using the TG18 images, repeat the procedure for the TG18-LPH50, TG18-LPH89, TG18-LPV10, TG18-LPV50 and TG18-LPV89 test patterns

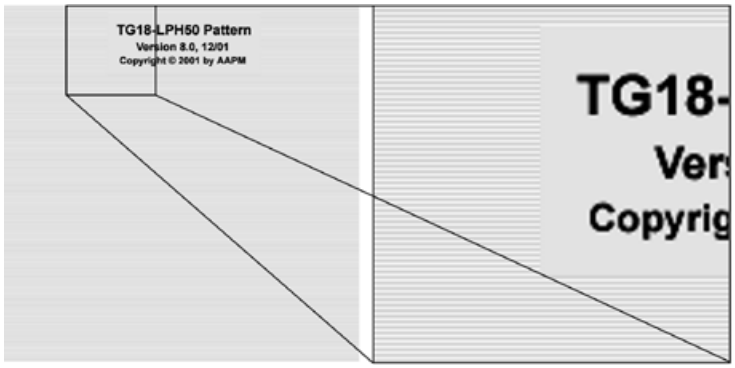

Figure 33 The TG18-LPH50 test pattern

Action levels
The line patterns should be discernible in all test patterns

8.5 Display artefacts

Introduction
Artefacts may hinder the visibility of structures on the display and should therefore not be present.

Definitions
An artefact is a difference in luminance level due to imperfections in the image display.

Purpose
To evaluate the presence of display artefacts

Test equipment
- TG18-QC test pattern

Test frequency
- At acceptance and subsequent routine QC tests

Test procedure
- Display the TG18-QC test pattern, alternatively TG18-UNL10 and/or TG18-UNL80 test patterns can be used.
- Check the displayed image for defect pixels and lines
- Check the display of the steps in the black-to-white and white-to-black ramp bars
- Check the displayed image for artefacts near the black-to-white and white-to-black transitions.
- Check the displayed image for temporal instability (flicker) and spatial instability (jitter).

Action levels
No disturbing artefacts should be present.

8.6 Luminance ratio

Introduction
It is important that the luminance range on a display is sufficiently large, so that the number of visible contrasts for a human observer. The luminance range is an indicator of luminance contrast response capabilities of the display.

Definitions
Luminance ratio is defined as the maximum luminance divided by the minimum luminance of a display.

Purpose
To evaluate the luminance range of a display

Test equipment
- TG18-LN12-01 to TG18-LN12-18 or TG270-ULN test patterns
- (Telescopic) Luminance meter

Test frequency
- At acceptance and subsequent routine QC tests

Test procedure
- Display the test patterns TG18-LN12-01 and TG18-LN12-18 or the maximum and minimum luminance test patterns of TG270-ULN.
- Measure the maximum and minimum luminance of the display device, preferably with a telescopic luminance meter as this meter includes the influence of ambient light.
- Repeat the measurement for all displays.
- Calculate the luminance range as the ratio of maximum and minimum display luminance.

Action levels
Luminance ratio >350 for diagnostic display devices, or >100 for modality display devices. The difference of maximum luminances between displays belonging to one displaying station should not exceed 5% of the lowest.

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

Remark: Masking of implants is recommended to prevent blinding of the radiologist, especially if high luminance displays are used (Luminance > 1000 cd/m^2).

8.7 Greyscale Display Function

Introduction
It is important that the perception of clinical images is similar on all displays. This means that the mapping from greyscale values to display luminance level or optical density should be consistent and according to the DICOM Greyscale Standard Display Function (GSDF).

Definitions
The greyscale display function maps the greyscale values of an image to luminance levels on a display.

Purpose
To evaluate whether a greyscale display function of a display complies to the DICOM Greyscale Standard Display Function (GSDF).

Test equipment
- Luminance test patterns TG18-LN12-01 to -18 or the series of TG270-ULN.
- (Telescopic) luminance meter.

Test frequency
- At acceptance and subsequent routine QC tests

Test procedure
- Make sure that the ambient conditions in the room are equal to clinical practice.
- Display the luminance test patterns. The test patterns should be displayed full screen.
- Measure the luminance of each test pattern, preferably with a telescopic luminance meter.
- The measured values can be inserted into a spreadsheet to automatically determine GSDF conformance.

Action levels
The calculated contrast response should fall within 10% of the GSDF contrast response for diagnostic class displays.

Remark: The acquisition workstation display is excluded from this test. This display should only be used to check positioning techniques, not for diagnosis and image quality checks.

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

8.8 Luminance uniformity

Introduction
It is important the luminance a display is sufficiently uniform.

Definitions
Uniformity is defined as the maximum luminance deviation of a display.

Purpose
To evaluate luminance uniformity of a display.

Test equipment

- TG18-UNL10 and TG18-UNL80 test patterns or TG270 ULN test patterns
- (Telescopic) luminance meter

Test frequency

- At acceptance and subsequent routine QC tests

Test procedure

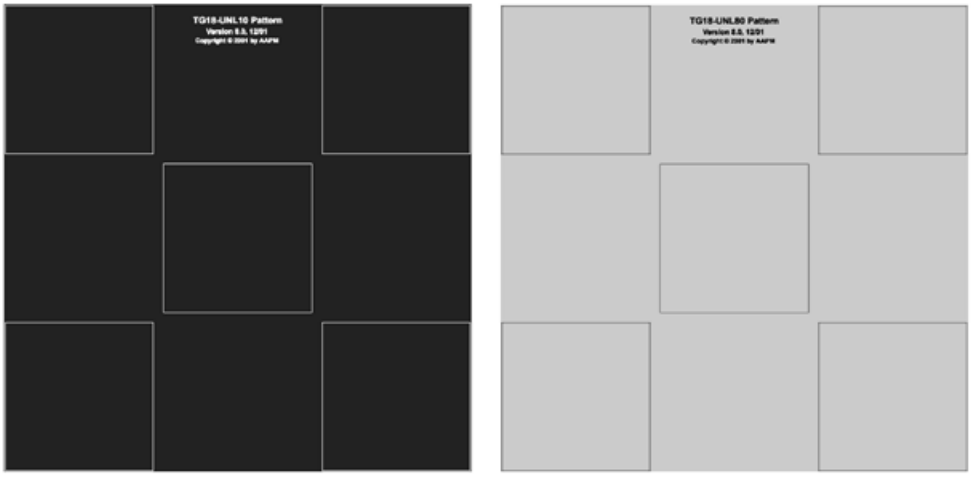

Figure 34a Test patterns TG18-UNL10 and TG18-UNL80

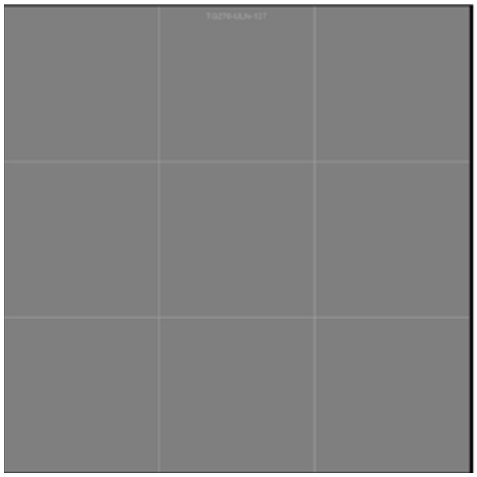

Figure 34b Test pattern TG270 ULN-127

- Display the test patterns TG18-UNL10 and TG18-UNL80 or the series of TG270-ULN see figure 34.
- Measure luminance at in the centres of the squares in the test patterns.
- Calculate the maximum luminance deviation of a display:

(Lmax-Lmin)/Lcentre

Action levels

Maximum luminance deviation of a display device < 30%.

9 Glossary

AEC	Automatic Exposure Control.
Acceptance test	QC tests performed after installation of the system, determines the acceptability of an individual system and sets baseline values for subsequent 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 the 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.
Baseline 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.
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 length	The duration of the x-ray exposure for a projection image.
Filtered Back Projection mode (FBP)	Mode on a DBT system in which the 3D reconstruction is performed using a back projection 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 display 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 the centreline of the imaging detector along the chest wall, and 50 mm anterior to the chest wall edge of the breast support table. Note that in previous protocols the reference point was at 60 mm from chest wall side.
Reference ROI	A 5 mm x 5 mm ROI with its centre positioned at the reference point.
Reference ROI (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.
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.

$$\mathrm{SDNR} = \frac{|MPV(signal) - MPV(background)|}{\mathrm{SD(background)}} \quad (23)$$

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.

$$\mathrm{SNR} = \frac{\mathrm{MPV - PVoffset}}{\mathrm{SD}} \quad (24)$$

Standard test block PMMA test object of 45 mm thickness covering the full detector 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 $\frac{min - max}{mean} \times 100\%$ (25)

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	A stationary mode at zero-degree angle which produces projection images in which stationary mode 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 9 Specifications and geometry of the breast tomosynthesis systems of some major manufacturers (based on Sechopoulos 2013, EUREF 2018 and subsequent information from manufacturers).

DBT System	GE Healthcare SenoClaire	GE Healthcare Pristina	Hologic Selenia Dimensions	Hologic 3 Dimensions	IMS Giotto Class	Metaltronica Helianthus DBT	Planmed Clarity3D	Siemens Mammomat Inspiration[1]	Siemens Revelation[1]	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	684
Focal plane pixel size (µm)	100	100	Standard: 95 or 117[2] High resolution: 70	Standard: 95 or 117[2] High resolution: 70	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	Continu-ous	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: 500 µm	Rh: 60 µm Ag: 75 µm	Rh: 50 µm	Rh: 50 µm	Al: 700µm
Angular range (°)	25	25	15	15	30[3]	15/24/50	30	50	50	15/40
Number of projection images	9	9	15	15	11	11/13/24	15	25	25	15
Source to detector distance (mm)	660	660	700	700	690	660	650	655	655	650
Distance between detector and centre of rotation (mm)	40	40	0	0	40	22	41	47	47	46

1 The detector and breast support table are slightly angulated.

2 The pixel size in standard resolution is appr. 95 microns for the small compression paddle and appr. 117 microns for the large compression paddle. The pixel size for high resolution is appr. 70 microns for both compression paddles. The exact pixel spacing depends on the height in the breast.

3 The projection images may not be equally spaced and may not have the same exposure factor.

4 Hexagonal shaped detector elements.

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

Table 10 Overview of the acquisition 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 HVL and tube voltage	Zero-degree mode	n.a.	Tube voltage error ≤ ± 2 kV. HVL should be within typical range.
2.2 X-ray beam alignment and collimation	Manual tomosynthesis mode	Reconstructed DBT image	At chest wall side 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.
2.3 Tube output	Zero-degree mode	n.a.	Variation ≤ 5%.
3 COMPRESSION			
3.1Compression 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 > 5 mm, investigate the cause of the deviation.
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 stability	Clinical AEC mode	1st projection image	Variation in the reference ROI: pixel value ≤ ± 10%, SNR ≤ ± 10%, Investigate if the variation between the incident air kerma between daily/weekly images ≥ ± 10%.
4.3 AEC performance	Clinical AEC mode	1st projection image	SDNR values within 15% of the baseline values
4.4 Local dense area	Clinical AEC mode	1st projection image	The Min deviation SDNR ≥ - 30% and the Max deviation AGD> 0 Min Deviation SDNR (%) and Max Deviation AGD (%) should be within ± 20% of baseline. If not, investigate the cause.
4.5 Exposure duration	Clinical AEC mode	n.a.	The exposure time for a projection in the DICOM header should be within 15% of the measured value. Investigate if exposure time > ±20% compared to the baseline values
4.6 AEC 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.	If the bad pixel map differs from previous maps, the service engineer should be called to investigate.
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 in ROI.
5.5 System projection MTF	Manual tomosynthesis mode	1st projection image	MTF50 point should be > 90% of the baseline value

6 TECHNICAL IMAGE QUALITY 3D

6.1 Technical image quality of the reconstructed 3D image	Clinical AEC mode	Reconstructed DBT image	Compared with the baseline value
6.2 MTF in the reconstructed image	Manual tomosynthesis mode	Reconstructed DBT image	≤ 20% difference with baseline value
6.3 Artefact spread function (ASF)	Clinical AEC mode	Reconstructed DBT image	≤ 15% difference with baseline value. 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 and at the 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 Image homogeneity and artefact evaluation	Clinical AEC mode	Reconstructed DBT image	No disturbing artefacts and or clinically relevant inhomogeneities should be present

7 DOSIMETRY

7.1 Dosimetry	Zero-degree mode	n.a.	See table 8a, b and c

8 IMAGE DISPLAY

8.1 Ambient light	n.a.	n.a.	Ambient light < 20 lux for diagnostic display devices, low contrast features in the darkest regions on TG270-sQC should be visible, optional: ambience ratio ≤ 1/4
8.2 Geometric distortion (CRT only)	n.a.	n.a.	Borders should be completely visible, lines should be straight.
8.3 Contrast visibility	n.a.	n.a.	All low contrast objects should be visible
8.4 Resolution	n.a.	n.a.	The line patterns should be discernible in all test patterns
8.5 Display artefacts	n.a.	n.a.	No disturbing artefacts should be present.
8.6 Luminance ratio	n.a.	n.a.	Luminance ratio >350
8.7 Greyscale display function	n.a.	n.a.	Within 10% of the GSDF
8.8 Luminance uniformity	n.a.	n.a.	Maximum luminance deviation < 30%.

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

Table 11 Compression requirements, requirements on fully irradiated area and projection image to be used for QC measurements in clinical fully automatic AEC mode for current versions of different brands of system (in 2022).

Brand	Compression required in clinical AEC mode	Fully irradiated area at lateral and nipple side required	(Recorded) Projection image on which QC measurements need to be performed
Fujifilm	No	No	First
GE[1]	Yes	No	First
Hologic	No	No	First
IMS	Yes	No	Second
Metaltronica	Yes	No	First
Planmed	No1	No	First
Siemens[2]	Yes	Yes	Second

1 For this system a 3 mm instead of 2 mm thick aluminium attenuator might be used in some QC tests to obtain photon fluencies as in clinical practice

2 Compression thickness reading < 120 mm

3 Segmentation should be turned off if phantoms are used which do not resemble a breast sufficiently, like homogeneous phantoms.

Appendix 4: Test equipment

	Material	Dimensions	thickness	purity
Dosemeter				
kV meter				
Base slabs AAPM/EFOMP dosimetry phantoms (5th, 25th, 50th, 75th, and 95th percentile densities)	Materials simulating the attenuation of glandular and fatty tissue	Appr. 160 x 100 mm[1]	20±0.1mm	
7 slabs for the AAPM/EFOMP dosimetry phantom	Material simulating fatty tissue	Appr. 160 x 100 mm	10±0.1mm	
4 PMMA slabs	PMMA, density = 1.19 g mm^{-3}	≥ 240mm x 180 mm	10±0.1mm	
7 PMMA slabs	PMMA, density = 1.19 g mm-3	Covering the whole detector		
1 PMMA Slab	PMMA, density = 1.19 g mm^{-3}	Covering the whole detector	5±0.1mm	
Standard test block2	PMMA, density = 1.19 g mm^{-3}	Covering the whole detector	45±0.1mm	
Set of spacers		appr. 180mm x appr. 10 mm	2±0.1, 5±0.1, 10±0.1, 20±0.1 mm	
PE Slabs	PE, density = 0.94 g mm^{-3}	≥ 240mm x 180 mm	2±0.1 mm 5±0.1 mm 10±0.1mm	
SDNR sheet	Aluminium	10±1 mm x 10±1 mm	0.200±0.002 mm	99%
Small spacers for systems with an angle between detector and breast support table		≤ 5 x 5mm[2]	2±0.1mm	
ASF and geometric distortion phantom	PMMA with Aluminium spheres, density PMMA = 1.19 g mm^{-3} (or similar)	PMMA: 240 mm x 300 mm (or similar)	PMMA: 5±0.1 mm; aluminium spheres: 1.00± 0.03 mm (or similar)	
Aluminium sheet	Aluminium	Covering the whole X-ray beam	2 mm	99%
MTF phantom (projection images)	Stainless steel	> 50 mm x 50 mm	1 mm	
Low contrast supports, 20 mm 40mm and 70 mm thick, to support the edge phantom at different heights above the breast support table ~~bucky~~ (Section 5.5)				
MTF phantom (reconstructed image)	Aluminium	> 50 mm x 50 mm	0.2 mm	
MTF wire	Tungsten	Length > 50mm	25 µm diameter	
Radiopaque sheet	e.g. Stainless steel	covering the whole image receptor	e.g. 3 ± 1 mm	
Self-developing film	Sensitive for mammography x-ray spectra			
Block of foam	Density: 30±5 kg/m3, 5.0±1.0 kPa at 40% deformation	240 mm x 180 mm		
X-ray rulers				
AAPMTG18 and/or TG270 test patterns				
Phantom for assessment of technical image quality				

[1] AAPM/EFOMP TG 323 report.

[2] It is also possible to use 4 slabs of 10 mm + one slab of 5 mm thickness as standard test block.

Appendix 5: Details of the breast dosimetry method

Dosimetry for tomosynthesis systems is 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. 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 31. 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 side, by a 1.5 mm layer of skin.

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.

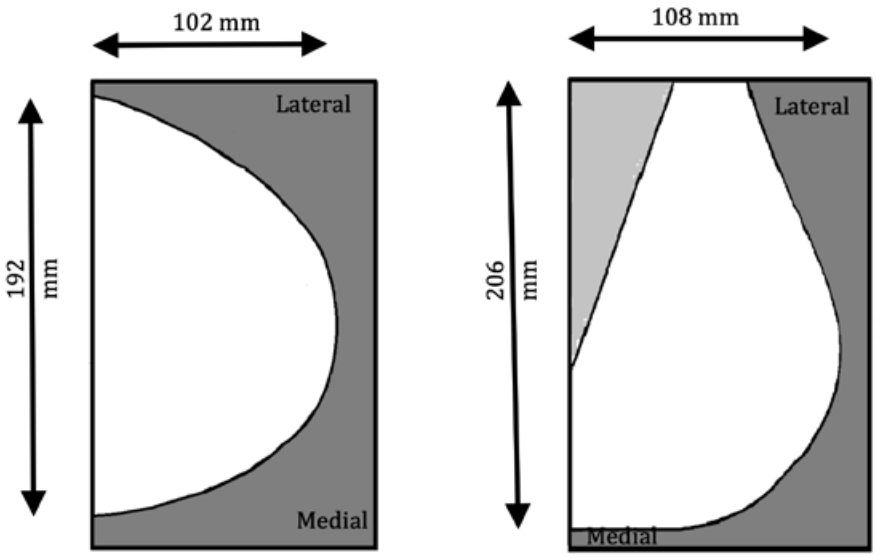

Figure 31 Examples of the models of the compressed breasts for the (left) CC and (right) MLO views used for the dosimetry estimates. These breast models are the ones that represent compressed breast thicknesses of 58 mm.

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.

To estimate the average glandular dose D_g, the following equation is used:

$$D_g = K_{ref}\,\Gamma \qquad (26)$$

In this expression Kref 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 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:

$$\Gamma = \frac{\sum_{a=A_{min}}^{A_{max}} \sum_{e=E_{min}}^{E_{max}} \psi(e) \left(\frac{\mu_{tr}}{\rho}\right)_{air} (e)\gamma(t,g,e,a)}{N_a \sum_{e=E_{min}}^{E_{max}} \psi(e) \left(\frac{\mu_{tr}}{\rho}\right)_{air} (e)} \qquad (27)$$

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, ψ(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, *γ(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. The reports of WG/TG 282 and WG/TG 323 may be consulted for more detailed information.

Appendix 6: EFOMP/AAPM Breast dosimetry 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 50th percentile insert-containing slab is used, together with as many adipose slabs to be able to represent the desired compressed breast thickness.

Appendix 7: Auditing clinical breast doses

It is encouraged to use the WG/TG 282 software (ref) to estimate the AGD 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 31. 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 mAs 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 Km for the used 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.

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