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Routine quality control tests for breast tomosynthesis (physicists)

NHS Breast Screening Programme Equipment Report 1407

December 2015

NHS Cancer Screening Programmes

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Public Health England
Wellington House
133-155 Waterloo Road
London SE1 8UR
Tel: 020 7654 8000
www.gov.uk/phe
Twitter: @PHE_uk
Facebook: www.facebook.com/PublicHealthEngland

Lead authors: A Burch, R Loader, B Rowberry, C Strudley, D Whitwam

For queries relating to this document, contact Mary Greatorex at mary.greatorex@phe.gov.uk

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Contents

Executive summary

Guidance is provided on routine quality control tests for tomosynthesis systems to be carried out by medical physics services. These should be carried out in addition to the 2D tests described in the IPEM Report 89 and NHS Breast Screening Programme (NHSBSP) Equipment Report 0604. The tests are used to ensure that the equipment performs as expected and meets the appropriate NHSBSP standards.

The tests covered comprise:

- tests performed at equipment commissioning
- six monthly performance tests

1. Introduction

1.1 Background

Quality control (QC) testing of full field digital mammography systems by medical physics services in the NHSBSP is described in IPEM Report 89[1] and NHSBSP Equipment Report 0604.[2] This protocol addresses the additional tests to be performed in tomosynthesis mode and employs the terminology used in Equipment Report 0604.

The tests and the limiting values (remedial levels and suspension levels) are based on current experience of testing breast tomosynthesis systems. They are likely to be revised in the light of further experience and developments in technology. The protocol is not intended to provide a method for the complete evaluation or comparison of tomosynthesis systems.

A related publication describes the QC tests to be performed by radiographers.[3]

1.2 Breast tomosynthesis

Full field digital mammography represents a three dimensional object in a two dimensional image. This results in superposition of tissue (or anatomical noise) that can mask low contrast objects or can mimic architectural distortion or lesions.[4] Full field digital imaging has enabled the development of advanced imaging techniques which were not possible with film imaging, such as breast tomosynthesis. This technique aims to improve the visibility of lesions by acquiring a limited number of projections over a

narrow angular range. These projections are then reconstructed to produce a series of images in closely spaced focal planes parallel to the detector surface. The spatial resolution between focal planes, that is, in the direction perpendicular to the detector, is mainly determined by the angular range and number of projections. It is much less than the spatial resolution in the focal planes parallel to the detector, which is mainly determined by the detector pixel size or re-binned detector pixel size. This 3D data set may allow improved visualisation of lesions within a plane by removal (or blurring) of the overlying and underlying tissue.

Different manufacturers of digital mammography systems have developed their own methods of producing tomosynthesis images. The two most common reconstruction methods are filtered back projection and iterative reconstruction. A full discussion of current methods of tomosynthesis acquisition, together with a review of reconstruction processes, has been published by Sechopoulos.[5, 6]

The introduction of tomosynthesis brings some new challenges, including issues with data transfer and storage, reporting times for the increased volume of data, increased clinical image acquisition times (compared with standard mammograms) and increased time for radiographer QC and for medical physics testing.

Radiation dose is an important factor in the introduction of new X-ray technologies. For tomosynthesis, the radiation dose per projection is a fraction of the dose required to produce a 2D mammogram. The resulting total dose for a single tomosynthesis acquisition has been found to be approximately one to two times that of a single 2D exposure.[7, 8]

1.3 Current systems

The features of currently available breast tomosynthesis systems are summarised in Table 1, which is based on work by Sechopoulos[5] and EUREF.[1]

Table 1. Specifications and geometry of breast tomosynthesis systems currently available

DBT System	*GE Healthcare SenoClaire*	*Hologic Selenia Dimensions*	*IMS Giotto Tomo*	*Siemens Mammomat Inspiration*	*Fujifilm Amulet Innovality*
Type of geometry	Full-field	Full-field	Full-field	Full-field	Full-field
Detector type	Energy integrating	Energy integrating	Energy integrating	Energy integrating	Energy integrating
Detector material	CsI-Si	a-Se	a-Se	a-Se	a-Se
Detector element size (µm)	100	70	85	85	68[c]
Focal plane pixel size	100	95-117[a]	85	85	100/150
X-ray tube motion	Step-and-shoot	Continuous	Step-and-shoot	Continuous	Continuous
Target	Mo/Rh	W	W	W	W
Filter	Mo: 30µm Rh: 25µm	Al: 700µm	Rh: 50µm Ag: 50µm	Rh: 50µm	Al: 700µm
Angular range (°)	25	15	40[b]	50	15/40
Number of projection images	9	15	13	25	15
Source to detector distance (mm)	660	700	680	655	650
Distance between detector and centre of rotation (mm)	40	0	20	47	46
Reconstruction method	Iterative	Filtered back projection	Iterative	Filtered back projection	Filtered back projection

[a] The pixel size in the focal plane changes with height above the breast support table.
[b] The projection images are not equally spaced and do not have the same exposure factors.
[c] Hexagonal shaped detector elements

1.4 Contributory sources of information for this protocol

The authors made use of the following sources of information:

EUREF tomosynthesis QC protocol[9]
TOMMY Trial QA protocol[10]
NCCPM tomosynthesis evaluation protocol[11]

A number of scientific papers, including those by Sechopoulos[5, 6], Marshall et al[12], Bouwman et al[13], and Hu et al[14] were also reviewed and considered in the preparation

on this document; the reader should refer to these for more detailed discussion of various aspects of breast tomosynthesis.

1.5 Future development

Ideally, QC protocols for imaging systems should be evidence-based and reflect clinical priorities. The authors are conscious that this protocol falls short of this ideal. Specific questions to be addressed in any future update may include:

- clinical experience – equipment performance and key performance criteria
- image quality test objects – ideally to include non-uniform backgrounds to test the ability of the system to reduce the effects of overlying structures
- equipment reliability – common and/or important faults that can occur on tomosynthesis systems
- lag and ghosting – testing may be more important in tomosynthesis than in planar imaging because the detector is not necessary cleared between exposures
- “system MTF” – this might be measured as an alternative to limiting spatial resolution, to detect effects due to tube movement
- image display – additional tests could be carried out on display monitors, to check that adequate image quality is maintained when scrolling rapidly through a set of tomosynthesis planes

2. Testing methodology

This section explains the methodology behind the testing protocols outlined in Section 3. It gives some background information about differences in both the testing methodology and the expected performance parameters for tomosynthesis systems, as compared with 2D digital mammography systems. The reader is assumed to be familiar with the testing procedures for 2D digital mammography systems.

Quantitative measurements are needed to evaluate the performance of digital mammography systems in accordance with the recommendations of this protocol.

These may be carried out using the relevant tools on a review workstation or by exporting images in a DICOM format for remote analysis.

Most of the tomosynthesis tests are similar to tests carried out for 2D systems, using the same test objects. It may therefore be convenient to carry out the tomosynthesis testing in conjunction with the 2D testing.

Some tomosynthesis systems allow a 2D image to be produced during the same compression as the 3D tomosynthesis image acquisition. The quality of this 2D image may be different to that achieved in standard 2D mammography mode, for example, if a different grid and/or different beam quality is used, or if the image is synthesised from projection images. In such cases, additional tests should be carried out to confirm that the image quality and dose for this type of 2D image meet NHSBSP standards.

2.1 Alignment

Alignment checks are carried out to ensure that when the system is operating in tomosynthesis mode the boundaries of the X-ray beam are suitably restricted, and that all of the target tissue is adequately represented within the reconstructed tomosynthesis image.

2.1.1 Alignment of the X-ray beam to the image and detector

For tomosynthesis the most important X-ray beam alignment measurement is at the chest wall edge of the reconstructed image in the same way as for 2D.

In acquiring a tomosynthesis image there are partially irradiated volumes at the sides, which may or may not be included in the reconstructed image, and are difficult to quantify. Depending on the tomosynthesis geometry, it may be possible to detect the lateral edges of the irradiated volume using self-developing film at the height of the centre of rotation (if the collimation is fixed) or at the surface of the breast support table (if the system uses dynamic collimation to restrict exposure to the edges of the detector). The position of the edge of the X-ray beam may be compared to the edges of projection images, where available, or to the edges of the reconstructed focal plane in which the markers are in focus. The edges of the X-ray beam should not extend excessively beyond the dimensions required to produce the tomosynthesis image. Also, any primary beam overlapping the edges of the detector should be intercepted and suitably attenuated by the breast support structure.

2.1.2 Alignment of the imaged volume to the target volume

The target volume is defined by the chest wall edges of the breast support table and compression paddle, the underside of the compression paddle, the surface of the breast support table and the nipple and lateral edges of the light beam. A measurement is

made of any missed tissue which is not included or not brought into focus within the reconstructed volume. Missed tissue at the chest wall edge is measured as for 2D. In assessing whether all the tissue at the top or bottom of the image is brought into focus, it should be noted that the breast support table and compression paddle may not be horizontal and parallel to each other, particularly when compression is applied using a tilting compression paddle.

2.2 Tube output and HVL

If the tomosynthesis mode does not use the same range of tube voltage settings and target/filter combinations as the 2D mode, additional measurements of tube output and half-value layer (HVL) should be made for the purpose of dose calculation. The tube voltage should not be affected by the selection of a different filter in tomosynthesis mode, so the measurements of voltage accuracy made in 2D mode should suffice, provided the range of voltage checked is appropriate.

For most tomosynthesis systems it is should be possible to measure air kerma at the clinically selected kV and target/filter combinations for the 0° central projection, with the tomosynthesis specific paddle raised at least 50mm above the dosemeter, as described in IPEM Report 89.[1] For some scanning systems, the significantly reduced collimation may make this method inappropriate and an alternative technique is proposed by Dance et al.[15]

Measurements are made with the paddle well above the dosemeter for consistency with other current UK protocols. This introduces a small inaccuracy because the method of dosimetry described by Dance et al assumes that the paddle is in contact with the dosemeter. Eventually, all UK protocols may change to match the geometry used by Dance et al.

2.3 Image uniformity and artefacts

The usual 2D tests should identify any non-uniformity or artefacts arising from the system hardware (for example, detector and filters). The additional test in tomosynthesis mode is intended to identify any significant non-uniformity or artefacts arising from the use of a different filter or from the reconstruction process.

2.4 Detector response

The detector response is the relationship of pixel value and noise to incident air kerma. In tomosynthesis mode it is not necessarily the same as in 2D mode. For example, the gain on the detector may be increased to deal with the lower doses of the projections. On some systems it may not be possible to characterise the detector response in tomosynthesis mode, so this is an optional test. Where possible, this test should be

carried out at least at commissioning, until the usefulness, or otherwise, of this test has been proven.

2.5 Geometric distortion and artefact spread

The distortion phantom consists of a 5mm thick sheet of polymethylmethacrylate (PMMA) in which 1mm diameter aluminium balls are embedded in a rectangular array, positioned with an accuracy of ± 0.1mm. Tomosynthesis imaging of this sheet within a stack of PMMA enables assessment of the spatial accuracy of the reconstructed image, and the reconstruction artefacts associated with the balls. Because the reconstructed tomosynthesis image is not a true 3D image, there are reconstruction artefacts associated with each ball. These appear in focal planes adjacent to the plane of the true height of the ball. The spread between focal planes of the reconstruction artefacts associated with a ball is a measure of inter-plane resolution and is often referred to as the z-resolution. The measurement of this spread is dependent upon the size of the ball. The appearance of reconstruction artefacts changes between focal planes; typically the ball stretches into a faint line in the direction of tube motion. The position of the artefact often shifts within the focal plane, relative to the position of the ball in focus, due to magnification effects.

The following are assessed:

- appearance in adjacent focal planes
- height of best focus - assessment of the apparent height of each ball shows whether the reconstructed focal planes are flat and horizontal
- positional accuracy within the focal plane - assessment of distortion or scaling errors within the focal plane
- spread of the reconstruction artefact associated with each ball - this is assessed in directions parallel to the surface of the detector and in the vertical direction perpendicular to the detector surface

2.6 Automatic exposure control

Automatic exposure control (AEC) testing is necessary to ensure that images in tomosynthesis mode consistently use the appropriate exposure parameters for a given breast thickness, and that the noise in the reconstructed image remains at the level accepted at commissioning. Optimal exposures for digital breast tomosynthesis are not yet known, but recording exposure parameters and measuring contrast to noise ratio (CNR) are useful in determining stability and for inter-system comparison.

The approach to AEC testing is essentially the same as for 2D, and uses similar test equipment. One important difference is that for tomosynthesis the clinical reconstruction protocol and image processing are used, as opposed to the raw unprocessed images used for 2D testing. This is because not all systems make available a reconstructed tomosynthesis image with minimal pre and post reconstruction processing for QC purposes. Also, testing a QC image might not test the reconstruction which is used clinically.

The proposed method of measurement of CNR in reconstructed focal planes may be inappropriate for systems that use iterative reconstruction. Further information on this is included in the manufacturer-specific guidance at Appendix 1.

CNR values in reconstructed tomosynthesis images appear to be very dependent on the size of the aluminium square used to produce contrast in the test object.

2.7 Image quality

The CDMAM is a useful performance test tool designed for use in 2D mammography. It is inadequate for assessment in tomosynthesis, because it takes no account of the ability of a tomosynthesis system to remove or reduce the appearance of overlying structures. Imaging a CDMAM with plain PMMA cannot be used to compare tomosynthesis image quality between systems of different design. This is because the ability to reduce the appearance of overlying tissue varies with tomosynthesis angular range. The CDMAM is therefore only useful as a partial measure of potential image quality, until a more suitable image quality test object is developed for tomosynthesis. Within these limitations, the CDMAM is proposed as an interim measure of tomosynthesis image quality. If the tomosynthesis images are in the standard BTO DICOM format, reconstructed focal planes need to be extracted as 2D images to enable automatic reading of the CDMAM images using CDCOM. TORMAX or TORMAM test objects are suggested as possible alternatives to CDMAM for routine image quality testing.

2.8 Dose

The method of estimating mean glandular dose (MGD) for a breast tomosynthesis examination is similar to that used in 2D mammography and is described by Dance et al[15]. The method employs an additional tomosynthesis factor, T, which varies with breast thickness. Further details of the derivation of the tomosynthesis factor are given in Appendix 2, together with calculated values of T for currently available tomosynthesis systems.

2.9 Equipment safety

Most safety features will be covered by the usual 2D tests, but depending on the design of the system further checks may be needed in tomosynthesis mode. Higher radiation energies may be used in tomosynthesis, in which case the adequacy of room shielding should be reviewed. Movement of the tube relative to the breast support table may cause additional mechanical hazards as well as beam alignment considerations. Where applicable, it should be checked that the safety features are functional in tomosynthesis mode as well as in 2D mode.

3. Test protocols

These tests specifically address the performance of a digital mammography system in tomosynthesis mode. The recommended tests, their frequency and limiting values are summarised in Appendix 3.

In addition to these generic protocols, some supplementary guidance has been developed to assist with applying the protocols on specific makes and models of equipment. This guidance is described at Appendix 1. It may be updated periodically to reflect developments in equipment.

When performing X-ray tube and generator tests, the detector should be protected from direct X-ray exposure according to manufacturer recommendations (for example, use a lead sheet to cover the whole of the detector area).

3.1 Alignment

3.1.1 Alignment of the X-ray beam to the image and detector

3.1.1.1 Test protocol

Acquire a tomosynthesis image and measure the alignment of the X-ray beam to the four edges of the reconstructed image and to the light beam at the level of the breast support table, or at the height of the centre of rotation, if this is above the breast support table and beam collimation is fixed.

Use the same method as for 2D images, for example, using X-ray rulers and self-developing film aligned to the edges of the light beam.

Take precautions to avoid burning an image into the detector if giving a high dose to achieve sufficient blackening of self-developing film. One way to achieve this is to cover the detector with an aluminium sheet of approximately 3mm thickness, and place the self-developing film on top of the aluminium.

Within the same image (or an additional image) measure the missed tissue at the chest wall edge by using a marker aligned with the chest wall edge of the breast support table.

If the lateral edges of the X-ray beam are not found with film, make further measurements, using a dosemeter if necessary, to check that the primary beam is stopped either by the detector or the surrounding structure. Repeat for any additional field sizes.

3.1.1.2 Evaluation

Use the self-developing film to assess the position of each edge of the X-ray beam relative to the edge of the light beam. Assess the position of each edge of the light beam relative to the edge of the projection or the edge of the reconstructed focal plane in which the marker is best in focus. From these measurements deduce the position of the X-ray beam relative to the detector / projection / focal plane.

Assess the missed tissue at the chest wall edge from the reconstructed image using the focal plane in which the edge marker on the breast support table is best in focus.

3.1.1.3 Remedial level

At chest wall edge	> 5mm or < 0mm overlap of the reconstructed image by the X-ray field
At lateral and nipple edges of X-ray beam	The primary X-ray beam must be blocked by the detector and its surrounding structure

3.1.1.4 Frequency

Commissioning and every six months.

3.1.2 Alignment of the imaged volume to the target volume

3.1.2.1 Test protocol

Measure the alignment of the upper and lower surfaces of the imaged volume to the target volume, using suitable markers.

Some small steel staples may be used, positioned on the breast support table and oriented perpendicular or parallel to the chest wall edge. Using masking tape, attach

markers to the underside of the compression paddle. These should be orthogonal to the lower ones (to avoid confusion when assessing the image).

Make measurements at various positions, including at least the central area and close to the chest wall edge.

To measure the worst case scenario, apply compression at the chest wall edge onto a vertical semi-circular PMMA sheet at the chest wall edge, using a flexible paddle.

Attenuation may be needed in the beam to enable reconstruction of a useful tomosynthesis image. This can be done by attaching a 2mm thick sheet of aluminium to the tube port, or by inserting a large sheet of PMMA or aluminium on top of the lower set of staples.

3.1.2.2 Evaluation

Assess the alignment of the imaged volume to the target volume at the top and bottom of the reconstructed tomosynthesis image from the images of the staples. Check whether all staples are brought into focus in either the top or bottom few focal planes as appropriate. If they are not brought into focus, estimate how far above or below the reconstructed volume they are, by looking at the degree of blurring in the direction of the tube motion.

3.1.2.3 Remedial level

The missed tissue at the chest wall edge must not exceed 5mm. All markers at the top and bottom of the target volume must be brought into focus within the range of the reconstructed tomosynthesis volume.

3.1.2.4 Frequency

Commissioning and every six months.

3.2 Tube output and HVL

If possible, make the measurements in a mode where the tube remains stationary at the zero degree position above the platform. In this mode it should deliver a manually set mAs in a series of pulses in the same way as projection exposures are made during a tomosynthesis scan. The mAs selected should be a value typical of clinical use. If such a mode is not available, use measurements made in 2D mode instead. If this is not possible, consider whether it is possible to measure tube output whilst the tube is in motion.

3.2.1 Test protocol

Use the same measurement geometry as in the 2D protocol, with the compression paddle in the beam and raised at least 50mm above the dosemeter. The paddle should be the one that is used for clinical tomosynthesis images.

Make manual exposures using a fixed mAs typical of clinical use. Repeat measurements at suitable kV intervals to cover the available range for each target filter combination. At each step measure the tube output and HVL.

3.2.2 Evaluation

Calculate tube output in terms of µGy per mAs at 500mm.

Calculate HVLs.

Plot the output and HVL against kV for each beam quality, and interpolate to generate values of output and HVL for all kV settings. These are for use in MGD calculations.

3.2.3 Remedial level

None, but unusual changes in output should be investigated.

3.2.4 Frequency

HVL	Commissioning and if output changes significantly
Output	Commissioning and every six months. (Check at a single kV for each target/filter combination, and only cover the full kV range if the output has changed)

3.3 Uniformity and artefacts

3.3.1 Test protocol

Place a uniform PMMA phantom, large enough to cover the detector, on the breast support table and acquire a clinical tomosynthesis image using typical exposure factors. An image acquired during AEC testing may be suitable.

On systems that use a different filter for tomosynthesis, 2D images using this filter should be should also be checked for uniformity, either by acquiring standard 2D images (if possible) or by inspecting the tomosynthesis projection images.

3.3.2 Evaluation

Using a narrow window width and appropriate zoom (at least 1:1), inspect the 2D image or processed, reconstructed planes for non-uniformity or artefacts such as unusual noise, edge artefacts or ghosting.

3.3.3 Remedial level

Any clinically significant artefacts.

3.3.4 Frequency

Commissioning and every six months.

3.4 Detector response

3.4.1 Test protocol

Follow the 2D protocol for detector response as described in NHSBSP Equipment Report 0604[2], using raw image data from the central projection image.

3.4.2 Evaluation

Refer to the 2D protocol in NHSBSP Equipment Report 0604.[2]

3.4.3 Remedial level

Refer to the 2D protocol in NHSBSP Equipment Report 0604.[2]

3.4.4 Frequency

Commissioning (optional).

3.5 Geometric distortion and artefact spread

3.5.1 Test protocol

Place the distortion phantom (see Section 2.5) within a stack of approximately 60mm plain PMMA, such that the aluminium balls are either close to the bottom, middle or top of the stack of PMMA. The balls should be no closer than 7mm to the bottom or the top of the reconstructed volume, to avoid difficulties in analysing the inter-plane spread of reconstruction artefacts.

Place the stack on the breast support table and acquire a total of three tomosynthesis images under AEC, one at each height.

Download the reconstructed tomosynthesis images for analysis.

3.5.2 Evaluation

Make a visual assessment of the apparent position of the balls within the reconstructed image, and the appearance of the associated artefacts in adjacent focal planes. Use software to carry out a more detailed quantitative assessment: either the tools provided by standard DICOM viewer software or more automated software developed for the purpose, such as that included in the “NCCPM Tools” ImageJ plug-in (Appendix 4).

3.5.2.1 Height of plane of best focus

The difference in height between the plane in which each ball appears most sharp and the average plane of best focus indicates the degree of any tilt or warping of the focal plane containing the balls.

3.5.2.2 Positional accuracy within focal plane

Compare the separation between balls in the directions parallel and perpendicular to the direction of tube motion, to the mean separation. From this, assess whether there is any significant distortion of the image within the focal plane at the true height of the balls. From the nominal pixel spacing (available from the DICOM header) calculate the distance between balls in the reconstructed image. Compare this to the known separation of the balls, to determine any scaling error in the nominal pixel spacing. Note that pixel spacings may differ between focal planes, in which case this should be evident from the DICOM header.

3.5.2.3 Appearance of ball in adjacent focal planes

Make a visual inspection of the appearance of artefacts and how they change and shift between focal planes.

Make quantitative measurements of the artefact spread in three dimensions in terms of full width at half maximum (FWHM) measurements in two orthogonal directions parallel to the detector surface and in the direction perpendicular to the detector surface. The half maximum value is the midpoint between the highest pixel value within the reconstructed image of the ball and the average background pixel value. (Take the background value from an artefact-free region surrounding the ball in the plane in which the ball is in focus.)

The FWHM is not necessarily measured in a straight line through the reconstructed image. Use the maximum pixel value within the artefact for each plane perpendicular to the direction of the FWHM. This makes allowance for the angulation and inhomogeneous spread of the artefact. Use automated software or DICOM viewer tools

to produce composite images of pixel maxima and reduce them to single lines of maxima. From these calculate the FWHM in each direction.

Compare the dimensions of the balls as they appear in the plane in which they are in focus to the FWHM spread of the associated artefacts in all focal planes. This gives a measure of the apparent shift or spread of each ball, as observed in focal planes adjacent to that of the height of the ball. The FWHM for all balls in the vertical (perpendicular to detector plane) direction gives a measure of inter-plane spread for a 1mm diameter aluminium ball. The maximum difference is found between the dimension of the ball in the plane in which it is in focus, and the FWHM in the same direction taking all planes into consideration. This then gives the maximum apparent spread or shift of the image of the ball between focal planes.

3.5.3 Remedial level

There is currently not sufficient evidence to recommend remedial levels. The following values are proposed as investigation levels. This indicates the need for repeat and/or additional tests.

Height of plane of best focus	> 2mm change from baseline
Distortion within focal plane (ratio of mean separations)	> 5% change from baseline
Scaling accuracy	> 5% change from baseline
FWHM perpendicular to detector	> 20% change from baseline
Spread parallel to detector (difference between composite and single plane FWHM)	> 2 pixels or 50% change from baseline

3.5.4 Frequency

Every six months.

3.6 Automatic exposure control

The recommended AEC settings for these tests on different models of equipment are given in the guidance at Appendix 1.

3.6.1 AEC repeatability

3.6.1.1 Test protocol

Make at least five tomosynthesis exposures of a 45mm thickness of PMMA at the recommended clinical setting, using AEC. Record the delivered mAs for each exposure. Measure SNR (for example using a 5mm x 5mm ROI, 40mm from the centre of the chest wall edge in the focal plane representing a height of 20mm above the breast support table) to check for repeatability of noise within the reconstructed image. SNR should be checked for at least ten images acquired at approximately the same dose. Alternatively, use a suitably uniform section of CDMAM images from test 3.7.1 to measure the repeatability of SNR, if only a few images are acquired of plain PMMA for repeatability of exposure measurements.

3.6.1.2 Evaluation

Calculate the maximum deviation from the mean for the mAs and the SNR.

3.6.1.3 Remedial level

Maximum deviation in mAs or SNR from mean	> 5%.

3.6.1.4 Suspension level

Maximum deviation in mAs or SNR from mean	> 10%.

3.6.1.5 Frequency

Commissioning and if problems are suspected.

3.6.2 AEC performance - CNR

3.6.2.1 Test protocol

Place 10mm of PMMA in the beam. Place a 0.20mm thickness of aluminium sheet (≥99.9% purity) of specified dimensions on top of the PMMA, on the midline, 60mm from the chest wall edge. CNR values in reconstructed tomosynthesis images may depend on the size of the aluminium, so a size of either 10mm x 10mm or 20mm x 20mm must be specified in local protocols and used consistently.

Place a further 10mm of PMMA on top. If the detector's dominant region is adjustable then select a region that excludes the aluminium. On some systems this may not be possible, in which case explore the influence of the presence of the aluminium on the AEC and make appropriate corrections.

Position the compression paddle at the height of the equivalent breast so that automatic selection of kV, target or filter corresponds to the settings chosen when using real breasts. On systems that require compression force to be applied, introduce an appropriate air gap by adding a spacer at the nipple edge between the PMMA and the paddle. Select the recommended clinical tomosynthesis exposure mode and image processing. Expose and record the selected exposure parameters (filter, target, kV and delivered mAs). If the system provides an estimate of mean glandular dose, record the value.

Repeat with other thicknesses of PMMA (30-70mm) by adding further slabs of PMMA on top of the phantom. These exposures can be used to measure the MGD, as described in Section 3.8.

Repeat this test on at least one PMMA thickness using all available AEC modes, including combination (2D + tomosynthesis) exposures.

3.6.2.2 Evaluation

Measure the CNR in the focal plane which is at the height of the aluminium square. Use a 5mm x 5mm ROI positioned in the centre of the aluminium square and at two background positions on the chest wall and nipple sides of the square. The CNR in the reconstructed tomosynthesis image may have a significant dependence on the size of aluminium foil used and the size and position of the ROIs. Therefore a standard ROI size of 5mm x 5mm is suggested with a distance of 10-15mm between the edges of the ROIs. If the reconstructed focal planes are non-uniform, then subdivide each ROI into smaller elements. For each ROI calculate the mean and standard deviation as the average of its constituent elements.

Measure the average pixel value and standard deviation in the background ROI (m_{bgd} and σ_{bgd} respectively) and in the ROI in the aluminium square (m_{Al} and σ_{Al} respectively). Calculate CNR as:

$$CNR = \frac{\left| m_{bgd} - m_{Al} \right|}{\sqrt{\frac{\sigma_{bgd}^2 + \sigma_{Al}^2}{2}}}$$

Since processed data is used it is not appropriate to linearise the pixel values. Note that, because of the effects of pixel size and image processing, CNR values are not comparable between different models.

Use measurements obtained at commissioning as baselines for subsequent routine tests.

3.6.2.3 Remedial level

Change from baseline CNR for any thickness	> 20% (In future “normal ranges” may be developed for each make and model)

3.6.2.4 Frequency

Commissioning and every six months.

Repeat for other AEC modes at commissioning.

3.7 Image quality

3.7.1 Detail detection

3.7.1.1 Test protocol

First carry out the geometric distortion test (Section 3.5) to check whether there is any tilt of the reconstructed focal planes relative to the surface of the breast support table. If there is, tilt the stack of PMMA containing the CDMAM so that the whole test object is brought into focus within a single focal plane.

Position the CDMAM in the middle of a 40mm stack of PMMA on the breast support table, aligned to the chest wall edge. Bring the compression paddle down to rest on top of the PMMA and expose using the factors that would be selected clinically for a 60mm thick breast. Acquire at least 8 exposures in tomosynthesis mode, moving the phantom fractionally between exposures. Download the images for analysis.

3.7.1.2 Evaluation

Tomosynthesis CDMAM images may be readable using CDCOM. To do this, extract the focal plane containing the CDMAM in focus from each reconstructed image. (For images in BTO format, first, extract from the BTO files a folder of individual images corresponding to the required focal plane from each file. A software tool is available from NCCPM for this – see Appendix 4.) If there is significant non-uniformity within the focal planes, CDCOM may fail to run or give a poor result. In this case, flatfield the images before they are read by CDCOM, using another software tool. In addition, extract two more focal planes, the one immediately above the plane of best focus and the one below. Run CDCOM on these, after flatfielding, if necessary, and use the best of the results from all three planes.

3.7.1.3 Remedial level

Compare with other units of the same make and model.

3.7.1.4 Frequency

At present, this is an optional test to be done at commissioning. It could be repeated every six months, or as part of fault investigation.

3.7.2 Regular image quality tests

3.7.2.1 Test protocol

If the CDMAM test object (sub-section 3.7.1) is not used for a regular image quality test, use TORMAX and TORMAM as follows.

Place the TORMAX test object (or other test object incorporating resolution gratings) on top of 20mm of PMMA with a further 20mm PMMA above. Acquire a tomosynthesis image (under AEC, if available) using the exposure factors typical of those used clinically. Use a mode that applies little or no image processing if available, because of the “non-clinical” appearance of the test object.

Place the TORMAM test object on top of 20mm of PMMA with a further 10mm PMMA above, and acquire a tomosynthesis image (under AEC, if available) using the exposure factors typical of those used clinically. Since this test object has features similar to a breast, it is appropriate to apply the image processing normally applied to clinical images. Note that fibres parallel to the direction of tube motion may be barely visible in tomosynthesis mode.

Optionally, repeat the test with the test object at different heights within the PMMA block.

3.7.2.2 Evaluation

Display the image on the normal reporting display media, score the details on the image that appears to be best in focus and record the score. If image quality appears to have changed significantly since the baseline measurements, repeat the detail detection procedure using the CDMAM test object.

3.7.2.3 Remedial level

CDMAM	significant change from baseline
TORMAX	limiting high contrast spatial resolution is significantly lower than baseline
	number of details detected is significantly less than baseline
TORMAM	visibility of details is significantly inferior to baseline

3.7.2.4 Frequency

Commissioning and every six months.

3.8 Dose

The standard breast model is simulated using PMMA and air gaps, taking care that the spacers do not attenuate the X-ray beam falling on the AEC area of the detector. The exposure factors selected under AEC are recorded to enable MGD to be calculated using the Dance method. The method used for dose measurement in tomosynthesis is almost the same as that used for 2D, but with an additional tomosynthesis factor (T) included in the MGD calculation.

Use the air kerma measurements described in Section 3.2, for the tube voltage and target/filter combinations used in tomosynthesis.

Higher energy spectra are used for digital mammography, so Dance et al[16] calculated g and c factors for HVLs greater than 0.6mm Al and for breast thicknesses greater than 80mm, to supplement existing g and c factor tabulations.

The dose measurements may use the values recorded in the CNR measurements if the presence of the aluminium square is found not to affect the operation of the AEC. If in doubt measure the dose and CNR separately.

3.8.1 Dose to typical breasts

3.8.1.1 Test protocol

Place PMMA on the breast support table aligned with or slightly overhanging the chest wall edge. Position the compression paddle such that the compressed breast thickness indicator reads the required equivalent breast thickness for that thickness of PMMA. Expose using the usual clinically selected exposure factors for each breast thickness. If the system requires compression to enable an exposure, use spacers positioned so as to avoid covering the AEC area of the detector. For tomosynthesis this is best done by placing a spacer at the nipple edge between PMMA and paddle. The spacer thickness required is not necessarily equal to the difference between the PMMA thickness and the equivalent breast thickness, especially if the compression paddle flexes or the compressed breast thickness indicator is poorly calibrated or large PMMA blocks are used.

Record the exposure factors (target, filter, kV, mAs) for each tomosynthesis exposure under AEC, using PMMA blocks with thicknesses of 20-70mm on commissioning. For routine testing, measure doses to 21, 53 and 90mm breast thicknesses, using 20, 45 and 70mm of PMMA respectively. If the system displays an estimate of mean glandular dose, record the value.

3.8.1.2 Evaluation

As described in Appendix 2, the MGD for a complete tomosynthesis examination D_T can be estimated from this equation:

$D_T = K_T gcsT$

where K_T is the incident air kerma at the top surface of the breast measured in the 0° or "straight through" projection but for the total mAs of the complete tomosynthesis examination, *g, c* and *s* are the standard conversion factors used in 2D mammography, and *T* is the

tomosynthesis factor for a complete examination. Tables A2.1 to A2.11 in Appendix 2 give values for the g, c and s factors and for the tomosynthesis factor, T.

If the system displays estimates of MGD, compare the values with those calculated.

The reference values for doses at different breast thicknesses are given in Table 2. These are the remedial levels for 2D mammography[2]. Tomosynthesis units should only exceed these values if they produce a significant improvement in clinical performance.

Table 2. Dose reference values

Thickness of PMMA (mm)	Thickness of equivalent breast (mm)	Reference mean glandular dose to equivalent breasts (mGy)
20	21	1.0
30	32	1.5
40	45	2.0
45	53	2.5
50	60	3.0
60	75	4.5
70	90	6.5

3.8.1.3 Remedial level

change in MGD from commissioning value	> 25%.
displayed values of MGD	> 30% different from calculated values

3.8.1.4 Frequency

MGD to 20mm, 45mm and 70mm PMMA	commissioning and every 6 months
MGD at other PMMA thicknesses	commissioning and when the AEC software is changed

3.8.2 Clinical breast dose

3.8.2.1 Test protocol

Dose surveys should be carried out to estimate the MGD for a sample of patients having tomosynthesis examinations. The breast thickness under compression and exposure factors for each exposure, and possibly patient age, should be recorded or extracted from DICOM headers.

Estimate the MGD (as described in Appendix 2) from the tube load (mAs) for each exposure and the air kerma measurements for varying tube voltages and target/filter combinations. Incident air kerma measurements should be inverse square corrected to the upper surface of the breast. Use appropriate g, c, s and T factors to determine MGDs for whole examinations.

The T factors listed in Appendix 2 were calculated for a standard breast model in the CC view. Provided the weights for each projection angle are the same, the same factors can also be used for MLO projections[15]. Where necessary, use piecewise linear interpolation of T factors for breast thicknesses between the values listed in Appendix 2.

3.8.2.2 Evaluation

Analyse the results in a similar way to 2D dose surveys. Use the average dose to 50-60mm breasts as a dose audit measure to establish, and subsequently check compliance with, a local Diagnostic Reference Level (DRL).

3.8.2.3 Remedial level

Dose audit measure significantly exceeds the local DRL.

3.8.2.4 Frequency

Commissioning, and at least every three years.

3.9 Equipment safety

3.9.1 Test protocol

Check features relevant to the tomosynthesis mode at commissioning of new equipment or any upgrade of existing equipment to add tomosynthesis capability. These may include:

- measurement of scatter dose rates to inform a review of room shielding, risk assessments and local rules
- response to premature release of the exposure button
- back-up timer
- operation and configuration of warning lights at the room entrance

3.9.2 Frequency

Commissioning.

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Appendix 1: Guidance on testing tomosynthesis systems currently available

A1.1 Introduction

This appendix provides supplementary guidance to assist with the QC testing recommended for breast tomosynthesis systems within the NHSBSP. This guidance will be revised as appropriate on a regular basis.

The guidance is provided in good faith to assist with the practical aspects of testing tomosynthesis systems in the NHSBSP. No judgements about the relative merits of the different systems should be inferred from this document. Tomosynthesis systems are subject to upgrades and development that may render some of the guidance inappropriate in due course. Therefore, users should always consult the equipment manufacturer for definitive advice on equipment operation, testing and specifications.

Several of the tests detailed in this guidance require images to be exported in DICOM format for further analysis. This is typically done using a non-encrypted memory stick or portable hard drive. Images should be transferred in accordance with local information security policies.

A1.2 Hologic Selenia Dimensions

A1.2.1 Tomosynthesis equipment and AEC operation

Tomosynthesis and 2D images are both acquired using the same compression paddles, 18cm x 24cm and 24cm x 29cm. No anti-scatter grid is used for the tomosynthesis views. A face shield larger than that for 2D, which remains stationary as the tube rotates, is used for tomosynthesis.

In AEC mode the system uses a 5mAs pre-pulse to determine the tube voltage and tube load for the tomosynthesis exposure. A manual mode is also available.

The Dimensions' *Combo* view consists of a tomosynthesis view without a grid followed by a 2D view (with grid) in the same compression. Doses for 2D and tomosynthesis should be measured in the *Combo mode,* as well as in individual 2D and tomosynthesis modes, to verify that they are the same.

A1.2.2 Dose measurements

As the Dimensions uses an aluminium target for tomosynthesis only, tube output and HVL measurements are needed for dose calculation purposes. Hologic provides a *Zero-degree Tomo* mode for this purpose under the QC tab. In this mode, the X-ray tube output is pulsed in the same way as for acquiring the 15 tomosynthesis projections, with the tube stationary at the zero degree angle and the grid out. Dose measurements should be made with the dosemeter in dose accumulation mode. Some dosemeters with solid-state detectors (e.g. Unfors RaySafe Xi) may require an upgrade to provide suitable calibration factors for the target/filter combination (tungsten target with 0.7mm aluminium filter) used in tomosynthesis mode.

A1.2.3 Image protocols

Hologic provides *Flatfield Tomo* views, available under the QC tab, which have less pre- and post-reconstruction processing applied than is the case for clinical views. These are reconstructed using raw projections to which no scatter corrections have been applied. The reconstructed tomosynthesis planes have, therefore, a noticeable low frequency variation, which is not evident in the clinical tomosynthesis views. These *Flatfield Tomo* views tend to amplify any very faint artefacts visible in the raw 2D *Flatfield Conventional* views, which may not be evident in the clinical reconstructed tomosynthesis views. It may therefore be appropriate to carry out some QC tests using clinical views instead of, or in addition to those carried out using *Flatfield Tomo* views.

A1.2.4 Image download

Generally, tomosynthesis QC images are not sent to PACS, but should be downloaded directly from the AWS, using either the DVD writer or an external drive connected to a USB port. When transferring to DVD, the number of tomosynthesis images per study should be limited to eight, to avoid space problems when writing to the disk.

A1.2.5 Tomosynthesis image format

In software version 1.4.2 tomosynthesis images are downloaded in the DICOM SC format. To view these images using DICOM viewer software the focal planes must be extracted from the SC file using a proprietary Hologic tool (available from NCCPM). In later software versions tomosynthesis images are available for download in either the DICOM BTO or CT format as well as the SC format. The advantage of the SC format is that it considerably reduces the size of the files by an order of magnitude. The image formats available for export are set up by the engineer at installation. For each *Flatfield Tomo* image, there are two image files: the projections and the reconstructed image. For each clinical tomosynthesis view there are three image files: the raw projections, the processed projections and the reconstructed image.

A1.2.6 ROI analysis on AWS

ROI analysis can be carried out on the AWS on the projections only, not on the reconstructed focal planes. Tomosynthesis images have to be downloaded so that quantitative analysis can be carried out.

A1.3 Siemens Mammomat Inspiration

A1.3.1 Tomosynthesis equipment and AEC operation

Tomosynthesis images are acquired using a dedicated compression paddle and without an anti-scatter grid. The face shield used for tomosynthesis is wider than that for 2D, and is angled to cover the extent of tube movement.

The breast support table is inclined very slightly down towards the chest wall edge and towards the left and right sides.

There are three exposure modes: *OpDose*, *AEC* and *Manual.* In *OpDose* mode automatic selection of beam quality is based on the compressed breast thickness. A preliminary 2D exposure (5mAs) at zero degrees is used to calculate the tube load for the tomosynthesis projections. This mode should be used for tests requiring clinical exposures. Alternatively, the factors chosen by *OpDose* for an equivalent thickness of PMMA can be selected in *Manual* mode.

Segmentation should be turned off to remove the dominance of the AEC area under the aluminium square during CNR tests. (Use *OpDose* to select appropriate beam quality, then deselect *Segmentation*. Remember to reselect *Opdose* when the next phantom thickness is used). It may be appropriate to leave *Segmentation* turned on for breast-like phantoms such as TORMAM. However, the position of the phantom has been found to have a significant effect on the choice of exposure factors, so for consistency testing, *Segmentation* should be turned off.

A 2D and a tomosynthesis image can be acquired in the same compression. This “combo” image is selected by choosing “Options > 2D + Tomo Scan” from the main menu. The 2D image is acquired first and then the grid is removed for the tomosynthesis exposure. The 2D image replaces the preliminary 5mAs 2D exposure and is stored as one of the projections. The 2D image (displayed as the 0 degree projection in the combo study) displays the post exposure mAs for the 2D acquisition only. The tomosynthesis projections display the total combo mAs (2D + Tomo). To obtain the Tomo only mAs, subtract the 2D mAs from the total combo mAs. If a manual exposure is made, the mAs selected is used for the 2D exposure, and twice this value is used for the tomosynthesis exposure.

A1.3.2 Dose measurements

Tomosynthesis is performed using the same tube voltage, target and filter combinations as used for 2D imaging so the 2D output and HVL measurements can be used for dose calculations. No stationary zero degree pulsed exposure is available.

A1.3.3 Image protocols

Siemens provides a raw image format for tomosynthesis QC tests. This is called “Physics QC Raw”, “Tomo QC Raw” or something similar.

A1.3.4 Image reconstruction

Siemens offers a choice of reconstruction kernels (Standard, Calcification, Phantom, Standard_Segmentation, Calcification_Segmentation and Phantom_Segmentation). Images can be reprocessed using any of these alternative kernels.

A1.3.5 Image download

QC images are downloaded from the AWS via a USB port. Entire studies, individual views or focal planes may be selected for download. These can be downloaded in DICOM format, which is appropriate for physics QC. JPEG and bitmap formats are also available.

A1.3.6 Tomosynthesis image format

Tomosynthesis images are in the DICOM CT format. For each tomosynthesis image there are three folders which contain the raw projections, processed projections and reconstructed focal planes.

A1.3.7 ROI analysis on AWS

The AWS has a tool for ROI analysis on tomosynthesis focal planes. It provides the minimum and maximum pixel values, area, mean, standard deviation and number of pixels.

A1.3.8 CNR measurements

The CNR measurements on this unit are strongly influenced by the size of the aluminium square, and a 20mm x 20mm square is recommended.

A1.4 IMS Giotto Tomo

A1.4.1 Tomosynthesis equipment and AEC operation

Tomosynthesis and 2D images are both acquired using the same compression paddle and a large face shield which remains stationary during the tube rotation in tomosynthesis. 2D images are acquired with an anti-scatter grid, which is automatically removed for tomosynthesis exposures.

For both 2D (*Mammo* mode) and tomosynthesis (*Tomo* mode) exposures, under AEC, the kV and filter are determined by the compressed breast thickness. In *Mammo* mode, there is a pre-pulse exposure which is used to determine the mAs for the exposure. This pre-pulse exposure is not included in the 2D image. In *Tomo* mode, the first of the 13 projections is used to determine the total mAs. The first and last projections have the same mAs. The remaining mAs for the exposure is divided equally between the other projections.

In *Combo* mode both a tomosynthesis and a 2D image are acquired in the same compression. The first projection is used to determine the total exposure for both the tomosynthesis and 2D exposures. After acquiring the 13 projections without a grid, the tube returns to the zero position, the grid is replaced and the 2D exposure is made.

To acquire 2D images without the anti-scatter grid, the user needs to be logged into service mode (M1 or M2).

Following a tomosynthesis exposure, a preview of the reconstructed image is displayed on the AWS, and there is a delay before the full quality reconstruction is available. If many tomosynthesis images are acquired in short succession, a reconstruction queue is formed. It may therefore be advisable to acquire tomosynthesis QC images at the start of the QC session. The operator also has the option removing tomosynthesis exposures from the reconstruction queue, or of changing priority in the queue.

A1.4.2 Dose measurements

Tomosynthesis is performed using the same tube voltage, target and filter combinations as used for 2D imaging so the 2D output and HVL measurements can be used for dose calculation. No stationary zero degree pulsed exposure is available. Dose measurements should be made in *Combo* mode, as well as for separate tomosynthesis and 2D views, to verify that they are the same.

A1.4.3 Image protocols

IMS provide a *Quality Control* mode for acquiring QC images, which gives raw unprocessed 2D images and tomosynthesis images with no post reconstruction processing applied.

A1.4.4 Image download

QC images can be downloaded from the AWS via a USB port.

A1.4.5 Tomosynthesis image format

Tomosynthesis images are in the DICOM BTO format.

A1.5 GE Healthcare SenoClaire

A1.5.1 Tomosynthesis equipment and AEC operation

The standard Bucky cover and grid must be replaced with the Motorised Tomosynthesis Device (MTD). This device uses specific compression paddles (including a sliding 18cm x24cm paddle). The MTD device contains a grid, and it can be used for both 2D and tomosynthesis acquisitions. However, differences in the grid design relative to the standard grid suggest that at least a subset of 2D image checks should be repeated with the MTD. The doses and image quality in 2D should be compared with results for conventional 2D images.

The AEC determines which target should be used, based on compressed breast thickness. A pre-pulse exposure is used to determine the filter, kV and mAs required.

There is no combined 2D and tomosynthesis mode; all views must be acquired separately.

A1.5.2 Dose measurements

The same filters are used for both 2D and tomosynthesis, so it should not be necessary to measure beam output and HVL in both modes. If the output and HVL are measured in tomosynthesis mode, the gantry can be fixed at 0°, as explained in the GE QC manual.[16]

A1.5.3 Image protocols

There are no specific QC imaging protocols available on the system. *FineView* and *PremiumView* can be turned off in the “Medical Applications Preferences” menu, however,

this does not appear to have any effect on the projections or the reconstructed slices and slabs.

A1.5.4 Image download

Raw projection images are available at the acquisition workstation and can be archived to a CD. Tomosynthesis reconstructions cannot be viewed or archived to CD at the acquisition workstation, but must be sent to a remote workstation (for example, an IDI workstation). They can then be viewed and downloaded using either the DVD writer or an external drive connected to a USB port. The system reconstructs both planes and slabs. The planes are spaced 0.5mm apart (with 1mm spacing as an option) and the slabs are 10mm thick, overlapping by 5mm.

A1.5.5 Tomosynthesis image format

Two image files are created for each reconstruction. One contains the reconstructed planes and the other contains the reconstructed volume formed of overlapping slabs. The DICOM format of the tomosynthesis data is Enhanced MG DICOM. ImageJ can be used to open the reconstructed image files and also to extract individual planes or slabs. The large size of the files results in the use of significant computer resources, particularly if large thicknesses are imaged with the 24cm x 30cm paddle. A 64-bit computer with the 64-bit version of ImageJ has been found to be effective in processing the images.

Appendix 2: Calculation of breast dose

The total mean glandular dose is the sum of doses received from individual projections. The mean glandular dose D(θ) for each projection angle θ can be estimated using the following equation.

$$D(\theta) = Kgcst(\theta) \qquad \text{A2.1}$$

where $D(\theta)$ is the breast dose for a single projection at angle θ, K is the incident air kerma measured in the 0° or "straight through" projection but for the mAs at projection angle θ, g, c and s are the standard conversion factors currently used in 2D mammography, and $t(\theta)$ is the tomosynthesis "t factor" for a single projection at angle θ.

For a complete tomosynthesis examination the mean glandular dose D_T can be estimated from

$$D_T = K_T gcsT \qquad \text{A2.2}$$

where K_T is the incident air kerma at the top surface of the breast measured in the 0° or "straight through" projection but for the total mAs of the complete tomosynthesis examination, g, c and s are the standard conversion factors currently used in 2D mammography, and T is the tomosynthesis "T factor" for a complete examination

$$\text{with } T = \sum_i \alpha_i t(\theta_i) \qquad \text{A2.3}$$

where T is the summation over all projection angles for the complete examination and α_i gives the proportion of the total tube loading for each projection. If there is no variation in tube loading between projections, the expression for T in equation A2.3 becomes

$$T = \frac{1}{N}\sum_i t(\theta_i) \qquad \text{A2.4}$$

where N is the number of projections. Values of T for commercially available equipment have been tabulated in the EUREF protocol[9] based on the work of Dance et al[15]. These are reproduced in Tables A2.10 and A2.11. The tables apply to the following breast tomosynthesis systems:

- Fujifilm Amulet Innovality
- GE Healthcare SenoClaire (2013 model)
- Hologic Selenia Dimensions (2011 model)
- IMS Giotto Tomo (2013 model)

- Siemens Mammomat Inspiration (2011 model)

Tables A2.1 and A2.3 reproduce the g and c factors for breasts simulated with PMMA from the EUREF protocol[9].

Tables A2.2, A2.4 and A2.5 show values of the g and c factors for different breast thicknesses based on the work of Dance et al[17.18,19] as tabulated in the EUREF protocol[9]. They include an extension to cover the higher HVLs used in some tomosynthesis units as found in the paper by Dance et al[15].

s factors for clinically used spectra, as published by Dance et al,[15,18,19] are given in table A2.6. An extension of the s factors for a tungsten target filtered by 0.7mm aluminium is given in tables A2.7 and A2.8 based on work by EUREF[9].

Table A2.9 gives typical HVL measurements for different tube voltage and target filter combinations. These include the attenuation effect of a compression paddle on measured HVL based on EUREF measurements[9].

Table A2.1. g-factors for breasts simulated with PMMA

PMMA thickness (mm)	Equiv. breast thickness (mm)	Gland-ularity of equiv. breast (%)	HVL (mm Al)										
			0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80
20	21	97	0.378	0.421	0.460	0.496	0.529	0.559	0.585	0.609	0.631	0.650	0.669
30	32	67	0.261	0.294	0.326	0.357	0.388	0.419	0.448	0.473	0.495	0.516	0.536
40	45	41	0.183	0.208	0.232	0.258	0.285	0.311	0.339	0.366	0.387	0.406	0.425
45	53	29	0.155	0.177	0.198	0.220	0.245	0.272	0.295	0.317	0.336	0.354	0.372
50	60	20	0.135	0.154	0.172	0.192	0.214	0.236	0.261	0.282	0.300	0.317	0.333
60	75	9	0.106	0.121	0.136	0.152	0.166	0.189	0.210	0.228	0.243	0.257	0.272
70	90	4	0.086	0.098	0.111	0.123	0.136	0.154	0.172	0.188	0.202	0.214	0.227
80	103	3	0.074	0.085	0.096	0.106	0.117	0.133	0.149	0.163	0.176	0.187	0.199

Table A2.2. g-factors (mGy/mGy) for average breasts

Breast thickness (mm)	HVL (mm Al)										
	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80
20	0.390	0.433	0.473	0.509	0.543	0.573	0.597	0.622	0.644	0.663	0.682
30	0.274	0.309	0.342	0.374	0.406	0.437	0.466	0.491	0.514	0.535	0.555
40	0.207	0.235	0.261	0.289	0.318	0.346	0.374	0.399	0.421	0.441	0.460
50	0.164	0.187	0.209	0.232	0.258	0.287	0.310	0.332	0.352	0.371	0.389
60	0.135	0.154	0.172	0.192	0.214	0.236	0.261	0.282	0.300	0.317	0.333
70	0.114	0.130	0.145	0.163	0.177	0.202	0.224	0.244	0.259	0.274	0.289
80	0.098	0.112	0.126	0.140	0.154	0.175	0.195	0.212	0.227	0.241	0.254
90	0.086	0.098	0.111	0.123	0.136	0.154	0.172	0.188	0.202	0.214	0.227
100	0.076	0.087	0.099	0.110	0.121	0.138	0.154	0.168	0.181	0.193	0.204
110	0.069	0.079	0.089	0.099	0.109	0.124	0.138	0.152	0.164	0.175	0.186

Table A2.3. c-factors for breasts simulated with PMMA

PMMA thickness (mm)	Equiv. breast thickness (mm)	Gland-ularity of equiv. breast (%)	HVL (mm Al)										
			0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80
20	21	97	0.889	0.895	0.903	0.908	0.912	0.917	0.921	0.924	0.928	0.933	0.937
30	32	67	0.940	0.943	0.945	0.946	0.949	0.952	0.953	0.956	0.959	0.961	0.964
40	45	41	1.043	1.041	1.040	1.039	1.037	1.035	1.034	1.032	1.030	1.028	1.026
45	53	29	1.109	1.105	1.102	1.099	1.096	1.091	1.088	1.082	1.078	1.073	1.068
50	60	20	1.164	1.160	1.151	1.150	1.144	1.139	1.134	1.124	1.117	1.111	1.103
60	75	9	1.254	1.245	1.235	1.231	1.225	1.217	1.207	1.196	1.186	1.175	1.164
70	90	4	1.299	1.292	1.282	1.275	1.270	1.260	1.249	1.236	1.225	1.213	1.200
80	103	3	1.307	1.299	1.292	1.287	1.283	1.273	1.262	1.249	1.238	1.226	1.213

Table A2.4. c-factors for average breasts for women in age group 50 to 64

Breast thickness (mm)	Gland-ularity	HVL (mm Al)										
	%	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80
20	100	0.885	0.891	0.900	0.905	0.910	0.914	0.919	0.923	0.928	0.932	0.936
30	72	0.925	0.929	0.931	0.933	0.937	0.940	0.941	0.947	0.950	0.953	0.956
40	50	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000
50	33	1.086	1.082	1.081	1.078	1.075	1.071	1.069	1.064	1.060	1.057	1.053
60	21	1.164	1.160	1.151	1.150	1.144	1.139	1.134	1.124	1.117	1.111	1.103
70	12	1.232	1.225	1.214	1.208	1.204	1.196	1.188	1.176	1.167	1.157	1.147
80	7	1.275	1.265	1.257	1.254	1.247	1.237	1.227	1.213	1.202	1.191	1.179
90	4	1.299	1.292	1.282	1.275	1.270	1.260	1.249	1.236	1.225	1.213	1.200
100	3	1.307	1.298	1.290	1.286	1.283	1.272	1.261	1.248	1.236	1.224	1.211
110	3	1.306	1.301	1.294	1.291	1.283	1.274	1.266	1.251	1.240	1.228	1.215

Table A2.5. c-factors for average breasts for women in age group 40 to 49

Breast thickness (mm)	Gland-ularity	HVL (mm Al)										
	%	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80
20	100	0.885	0.891	0.900	0.905	0.910	0.914	0.919	0.923	0.928	0.932	0.936
30	82	0.894	0.898	0.903	0.906	0.911	0.915	0.918	0.924	0.928	0.933	0.937
40	65	0.940	0.943	0.945	0.947	0.948	0.952	0.955	0.956	0.959	0.961	0.964
50	49	1.005	1.005	1.005	1.004	1.004	1.004	1.004	1.004	1.003	1.003	1.003
60	35	1.080	1.078	1.074	1.074	1.071	1.068	1.066	1.061	1.058	1.055	1.051
70	24	1.152	1.147	1.141	1.138	1.135	1.130	1.127	1.117	1.111	1.105	1.098
80	14	1.220	1.213	1.206	1.205	1.199	1.190	1.183	1.172	1.163	1.154	1.145
90	8	1.270	1.264	1.254	1.248	1.244	1.235	1.225	1.214	1.204	1.193	1.181
100	5	1.295	1.287	1.279	1.275	1.272	1.262	1.251	1.238	1.227	1.215	1.203
110	5	1.294	1.290	1.283	1.281	1.273	1.264	1.256	1.242	1.232	1.220	1.208

Table A2.6. s-factors for clinically used spectra

Target material	Filter material	Filter thickness (µm)	s-factors
Mo	Mo	30	1.000
Mo	Rh	25	1.017
Rh	Rh	25	1.061
W	Rh	50-60	1.042
W	Ag	50-75	1.042

Table A2.7. s-factors for a tungsten target filtered by 0.7mm aluminium, for breasts simulated with PMMA

PMMA thickness (mm)	Equiv. breast thickness (mm)	s-factor
20	21	1.052
30	32	1.064
40	45	1.082
45	53	1.094
50	60	1.105
60	75	1.123
70	90	1.136
80	103	1.142

Table A2.8. s-factors for a tungsten target filtered by 0.7mm aluminium, for average breasts

Breast thickness (mm)	Glandularity range (%)	Typical glandularity age 50-64	Typical glandularity age 40-49	kV range (kV)	*s*-factor
20	80-100	100	100	25-50	1.052
30	62-82	72	82	25-50	1.060
40	40-65	50	65	25-50	1.076
50	23-49	33	49	25-50	1.087
60	11-35	21	35	25-50	1.105
70	2-24	12	24	28-50	1.121
80	0.1-17	7	14	28-50	1.129
90	0.1-14	4	8	28-50	1.136
100	0.1-13	3	5	28-50	1.140
110	0.1-13	3	5	28-50	1.144

Table A2.9. Typical HVL measurements for different tube voltage and target filter combinations. (Data includes the effect on measured HVL of attenuation by a compression paddle)

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

Table A2.10. T factors for breasts simulated with PMMA

PMMA thickness (mm)	Equiv. breast thickness (mm)	$T_{Fujifilm}$ ± 7.5°	$T_{Fujifilm}$ ± 20°	T_{GE} ± 12.5°	$T_{Hologic}$ ± 7.5°	T_{IMS} ± 19°	$T_{Siemens}$ ± 24°
20	21	0.997	0.985	0.993	0.997	0.985	0.979
30	32	0.996	0.980	0.991	0.996	0.980	0.973
40	45	0.996	0.978	0.990	0.996	0.977	0.969
45	53	0.995	0.976	0.989	0.995	0.976	0.968
50	60	0.995	0.975	0.988	0.994	0.974	0.966
60	75	0.994	0.973	0.987	0.994	0.973	0.964
70	90	0.993	0.971	0.985	0.992	0.970	0.962
80	103	0.994	0.969	0.984	0.993	0.969	0.961

Table A2.11. T factors for average breasts

Breast thickness (mm)	$T_{Fujifilm}$ ± 7.5°	$T_{Fujifilm}$ ± 20°	T_{GE} ± 12.5°	$T_{Hologic}$ ± 7.5°	T_{IMS} ± 19°	$T_{Siemens}$ ± 24°
20	0.997	0.985	0.993	0.997	0.985	0.980
30	0.996	0.981	0.991	0.996	0.981	0.974
40	0.997	0.979	0.990	0.996	0.978	0.971
50	0.996	0.977	0.989	0.995	0.976	0.968
60	0.995	0.975	0.988	0.994	0.974	0.966
70	0.995	0.974	0.987	0.994	0.973	0.965
80	0.994	0.972	0.986	0.993	0.972	0.964
90	0.993	0.971	0.985	0.992	0.970	0.962
100	0.994	0.970	0.984	0.993	0.970	0.961
110	0.993	0.969	0.984	0.992	0.968	0.960

Appendix 3: Summary of tests

Where given, the limiting values are remedial levels unless otherwise indicated. All tests are performed at commissioning.

Section	Subsection	Frequency	Limiting value
3.1 Alignment	3.1.1 Alignment of the X-ray beam to the image and detector	Six monthly	> 5mm or < 0mm overlap of reconstructed image by X-ray field at the chest wall edge The primary X-ray beam must be blocked by the detector and its surrounding structure at lateral and nipple edges of X-ray beam
	3.1.2 Alignment of the imaged volume to the target volume	Six monthly	Missed tissue at the chest wall edge must not exceed 5mm All markers at the top and bottom of the target volume must be brought into focus within the range of the reconstructed tomosynthesis volume
3.2 Tube output and HVL		HVL: if output changes significantly Output: six monthly	Unusual changes in output should be investigated
3.3 Uniformity and artefacts		Six monthly	Any clinically significant artefacts
3.4 Detector response		Commissioning (optional)	Refer to 2D protocol NHSBSP Equipment Report 0604[2]

3.5 Geometric distortion and artefact spread		Six monthly	Investigation levels: Height of plane of best focus: > 2mm change from baseline Distortion within focal plane (ratio of mean separations): > 5% change from baseline Scaling accuracy: > 5% change from baseline FWHM perpendicular to detector: > 20% change from baseline Spread parallel to detector (difference between composite and single plane FWHM): > 2 pixels or 50% change from baseline
3.6 Automatic exposure control	3.6.1 AEC repeatability	Commissioning and if problems are suspected	Remedial level: maximum deviation in mAs or SNR from mean > 5% Suspension level: maximum deviation in mAs or SNR from mean > 10%
	3.6.2 AEC performance - CNR	Six monthly	Change from baseline CNR for any thickness > 20%
3.7 Image quality	3.7.1 Detail detection	Commissioning (optional)	Compare with other units of the same make and model

	3.7.2 Regular image quality tests	Six monthly	CDMAM: Significant change from baseline TORMAX: limiting high contrast spatial resolution is significantly lower than baseline number of details detected is significantly less than baseline TORMAM: visibility of details is significantly inferior to baseline
3.8 Dose	3.8.1 Dose to typical breasts	Six monthly for 20mm, 45mm and 70mm PMMA Other PMMA thicknesses at commissioning and when AEC software is changed	Change in MGD from commissioning value > 25% Displayed values of MGD > 30% different from calculated values
	3.8.2 Clinical breast dose	At least every three years	Dose audit measure significantly > local DRL
3.9 Equipment safety		Commissioning	

Appendix 4: Details of software available from NCCPM

The NCCPM has developed some software that may be used for the analysis of tomosynthesis images. Most of this can be downloaded from the NCCPM website at www.nccpm.org.

A4.1 Hologic SC images

Hologic Dimensions systems running the earlier versions of AWS software only make tomosynthesis images available for download in an SC DICOM format. While this considerably reduces the size of the reconstructed tomosynthesis image, a Hologic proprietary software tool is needed to extract the focal planes in a format compatible with DICOM viewing software. Hologic does not support the use of this tool, but allows NCCPM to give copies of it to individuals upon request. NCCPM can also supply a copy of their software to automatically run the Hologic expansion tool for all images within a folder. These tools for Hologic SC images are available on request from NCCPM.

A4.2 “NCCPM Tools” plugin for ImageJ

NCCPM has developed some tools for the analysis of tomosynthesis QC images. These tools have been packaged together in an ImageJ plugin. The plugin is available on the NCCPM website, with an explanation of what the tools do and instructions on their use. The tools currently available are described in this section.

A4.2.1 Geometric distortion

The location of each ball is found by moving a small ROI around within the search area to determine the ROI where the standard deviation of the pixels is greatest. The position of this ROI is recorded in terms of focal plane number and x, y coordinates within the plane.

To find the FWHM of a ball within the plane of best focus, the maximum pixel value from each column is taken, giving a single row of pixels. These are background corrected and a polynomial spline fitted to obtain a FWHM. The process is repeated in the orthogonal direction, taking the maximum pixel value from each row.

To measure a composite FWHM in the x and y directions taking all planes into consideration, a composite plane is created using the maximum pixel value from all planes. This is then reduced to a single row or column as above to obtain the composite FWHM in the x and y directions.

To measure a FWHM in the vertical direction, the stack of focal planes is re-sliced in the vertical direction. The processes described above are repeated to give the FWHM in the z direction.

A4.2.2 Flatfield

This tool may be used where necessary to reduce low frequency non-uniformities in CDMAM images prior to reading using CDCOM.

A rectangle is drawn around the CDMAM grid, allowing a small margin for phantom shift between images. The Flatfield tool is then selected from the tomo plugin menu. All images in the same folder will be flatfielded. The method of flatfielding is as follows:

1. Each image is cropped close to the useful area of the CDMAM and padded out to achieve an image size with dimensions in pixels equal to a power of two.

2. A Butterworth filter is applied in the frequency domain to remove the higher frequencies, including the grid and contrast details of the CDMAM.

3. The original image is then divided by the filtered image and the pixel values are rescaled.

A.4.2.3 Slice Hack

The standard DICOM format for tomosynthesis images is the BTO format. This consists of a single file which can be loaded into DICOM viewer software, making the individual slices available for analysis. However, to use other software, such as CDCOM, which was designed for use with 2D DICOM images, the required focal planes need to be extracted from the BTO file. This can be done with Slice Hack.

A.4.2.4 Virtual and Partial Dicom Opener

Tomosynthesis files are very large so it may not be possible to load the full images onto low power computers. To address this issue two plugins have been developed to load large DICOM files while using a low amount of computer RAM.

Virtual Dicom Opener loads each slice of the image into memory as it is requested. The speed of analysis with ImageJ is reduced; by how much depends on whether the images are located on the same computer, on a portable drive or on a network. Some features of ImageJ may not work when the Virtual Dicom Opener is used.

Partial Dicom Opener opens a reduced number of slices directly into RAM. This enables faster processing than with the Virtual Dicom Opener, but does not allow access to all the slices.

A4.3 Dose calculation software

The clinical dose calculation database developed by NCCPM for 2D has been updated to allow calculation of tomosynthesis doses. This software is now available on the NCCPM website.