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PROTOCOL FOR THE QUALITY CONTROL OF DIGITAL BREAST TOMOSYNTHESIS (DBT) SYSTEMS

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1. INTRODUCTION

This protocol is the result of the work of the AIFM (Associazione Italiana di Fisica Medica) Working Group on Digital Radiography. Within this document, we only consider Digital Breast Tomosynthesis (DBT) systems with a fullfield geometry (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) that, as far as we know, are present on the Italian market. For the same reason, DBT Scanning geometry systems are not taken into account.

1.1 Definitions and abbreviations

Below are some definitions and abbreviations used within this protocol.

ACCEPTANCE	Test carried out after installation of a system, or after major modifications, to ensure compliance with specifications, functional performance and to set reference values (baseline) of constancy QC parameters.
ACCEPTABLE LEVEL	Acceptable level is the minimum and/or maximum value of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum acceptable level indicate that corrective action must be taken.
ACCURACY	Term that indicates how close the measured value of a quantity is to the true value. It is used to check the correspondence between nominal and measured values of a parameter. The nominal value is taken as the true value.
AIR KERMA	Quotient of dE_{tr} by dm where dEtr is the sum of initial kinetic energies of all the charged ionising particles liberated by uncharged ionising particles in a mass of air dm. The measurement unit for air kerma in the SI system is the Gray (Gy). Air kerma measures, employing an ionisation chamber or another dose detector calibrated in mammography energy range, can be used to evaluate the Incident air kerma (K_i) or Entrance Surface Air Kerma (ESAK).
ANGLE (PROJECTION)	The projection angle is the angle between a line extended from the detector through the object to the source and the normal to the detector.
ANGLE (TUBE ROTATION)	The tube rotation angle is the angle between the line connecting the centre of rotation and the source and the normal to the detector.
ANGULAR RANGE	The difference in the first and last projection angle of a tomosynthesis acquisition.
ARTEFACT SPREAD FUNCTION (ASF)	Is the function that quantifies the signal spread of a small object in a uniform background along the reconstructed focal planes.

AUTOMATIC EXPOSURE CONTROL (AEC)	Device designed to select parameters which control detector dose, i.e. anode/filter combination, kVp, and mAs, according to the beam attenuation by each individual breast.
AVERAGE GLANDULAR DOSE (AGD)	The average absorbed dose in the glandular tissue (excluding skin) in a uniformly compressed breast. AGD value depends on X Ray beam quality (HVL), breast thickness and composition. If breast thickness and composition are not known, AGD can be referred to as a standard breast.
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). DR systems apply a "bad pixel correction" to remove the effect of possible defective dels. The maps from 2D and DBT might be different.
BASELINE	Value of a parameter generally defined during acceptance on the basis of many repeated measurements (at least 10), that can be considered typical for a system. Generally, the baseline level is used when absolute limits for a parameter do not exist.
CENTRE OF ROTATION	Centre point of the rotational movement of the X-ray tube.
COMPRESSION PADDLE	Thin, rectangular or oval shaped device, made of plastic material (typical PMMA or polycarbonate) that can be positioned parallel to and above the breast support table of a mammography system. It is intended to compress the breast during X-ray examination.
CONTRAST THRESHOLD	The minimum contrast of an object at a given detectability. Detectability can be determined using human or machine scoring. It is usually evaluated by contrast detail phantoms, which include multiple details (typically discs) with variable contrast and size.
DBT	Digital Breast Tomosynthesis.
DBT 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.
DEL	Single discrete detector element in a DR system.
DEL PITCH	Also referred to as pixel pitch. It is the physical distance between the centres of adjacent dels. The corresponding DICOM tag is (0018,1164) named imager pixel spacing. This is generally equal to detector element spacing.
DETECTOR BINNING	Binning is the term used to describe the technique of combining the output of adjacent dels on a detector. This can be performed in a single axis or in both directions. The corresponding tag DICOM is (0018,701A). Detector Binning: 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 bad pixel map. Corrections are also made for variations in individual del sensitivity, electronic gain and large area variations in signal (e.g. heel effect, beam divergence).
ELECTRONIC NOISE	Noise component which originates from various electronic sources: dark noise, readout noise, amplifier noise. It is assumed to be independent of the exposure level.
ENTRANCE SURFACE AIR KERMA (ESAK)	The air kerma at a point in a plane corresponding to the entrance surface of a specified object, e.g. a patient's breast or a standard phantom. The radiation incident on the object and the backscattered radiation are included.
EXPOSURE TIME (PROJECTION)	The duration of the X-ray exposure for a projection image.
FIRST PROJECTION IMAGE	The first projection image made in a DBT sequence of images with exposure parameters which have been determined by the AEC. It is noted that for some systems the first image in the series of projections is the pre-exposure in zero degree position or in the largest angle position, for other systems the first image is the projection image in the largest angle position. It should be ensured that the correct image is used when measurements are performed, i.e. the first projection image for which the exposure is determined by the AEC.
FFDM	Full Field Digital Mammography, 2D mammography.
FOCAL SPOT	Area on the surface of an X-ray tube anode (target) that is bombarded by the high-energy electrons from the cathode and where the x-radiation is produced.
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 FFDM and an X-ray tube that rotates 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.
FULL WIDTH AT HALF MAXIMUM (FWHM)	Is the width of a profile at half of its maximum height.
GEOMETRIC DISTORTION	An aberration that causes the displayed image to be geometrically dissimilar from the original image. The practical consequences of such distortions affect the relative sizes and shapes of image features, particularly for larger displays or large deflection angles.

GHOST IMAGE	Residual signal carried over from previous projection images into successive projection images.
HALF VALUE LAYER (HVL)	Thickness of absorber which attenuates the air kerma of X-ray beams by half. The absorber normally used to evaluate HVL of low energy X-ray beams, such as mammography beams, is high purity aluminium.
HEEL EFFECT	The non-uniform distribution of air-kerma rate in an X-ray beam in a direction parallel to the cathode-anode axis. It causes decreasing signal intensity measurable on an image detector in the cathode-anode direction, i.e. in the nipple side.
IMAGE QUALITY	There is no uniformly accepted definition of image quality. Any general definition must address the effectiveness with which the image can be used for its intended task. It is possible to define quality indices representing the information content of the image. Usually, image quality is assessed using test objects including details, whose images can be either rated according to given criteria, or analysed to measure objective parameters.
INCIDENT AIR KERMA	The air kerma at a point in a plane corresponding to the entrance surface of a specific object, e.g. a patient's breast or a standard phantom. Only the radiation incident on the object and not the backscattered radiation is included.
LINEAR SHIFT-INVARIANT SYSTEM	A system which is both linear and shift-invariant. A system is linear if it obeys the principle of superposition: the response to a weighted sum of any two inputs is the (same) weighted sum of the responses to each individual input. A system is shift-invariant (also called translation-invariant for spatial signals, or time-invariant for temporal signals) if the response to any input shifted by any amount is equal to the response to the original input shifted by amount. Such theory provides a description of how the system (image detector) acts on the input signal to produce the output (image) using the concept of "transfer function".
LINEARISED PIXEL VALUE	In FFDM or DBT 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.
MPE	Medical Physics Expert.
MODULATION TRANSFER FUNCTION (MTF)	A function which describes how the contrast of image components is transmitted as a function of their spatial frequency content.

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 a measure of noise.
NOISE POWER SPECTRUM (NPS)	A function which describes image noise as a function of spatial frequency.
PACS	Picture Archiving and Communication System.
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 typically from 1024 (10-bits) to 16384 (14 bits), depending on the system.
PIXEL VALUE OFFSET	Constant value that has been added to the values of each pixel during the generation of the projection image. Not all systems have a pixel value offset in the projection images.
PMMA	Polymethyl methacrylate.
PROJECTION IMAGE	A two dimensional image within a series of images, acquired at a specific tube rotation angle.
PROCESSED IMAGE	The image after image processing, ready for presentation on the monitor. In the DICOM file the value of the element Presentation Intent Type (0008,0068) is "FOR PRESENTATION".
PROCESSED PROJECTION IMAGE	A two dimensional projection image in which the DICOM tag (0008, 0068) is set to "FOR PRESENTATION". A manufacturer might process the projection images before image volume reconstruction.
QC	Quality Control.
QUANTUM NOISE	Noise component related to the statistical process of interaction between incident X-ray photons and image detector.
RECONSTRUCTED FOCAL PLANE	A two dimensional image representing a particular height within a reconstructed volume, with only objects at that height brought into sharp focus in that focal plane.
RECONSTRUCTED VOLUME	The volume represented by a reconstructed DBT image.
REFERENCE POSITION	A point on the breast support table at 60 mm perpendicular to the chest wall edge of the table and centred laterally.
REFERENCE REGION-OF-INTEREST (ROI) IN THE PROJECTION IMAGE	A region-of-interest (size: 5 mm x 5 mm) in the projection image. The centre of the ROI is positioned 60 mm perpendicular to the chest wall edge of the table and centred laterally.

REPRODUCIBILITY	The variation (usually relative standard deviation) in observed values for a set of measurements made over a period of time (long-term) or for a set of measurements made at about the same time (short-term).
SDNR	Signal-Difference-to-Noise-Ratio. It is obtained from the difference between the mean pixel values of background (PV_{bkg}) and aluminium detail (PV_{Al}), respectively calculated in a background ROI and in the reference ROI, divided by the standard deviation of the background (SD_{bkg}), according to the following formula: $$SDNR = \frac{PV_{bkg} - PV_{Al}}{SD_{bkg}}$$ If calculated from projection images, these images must first be linearized to air kerma using the response function.
SNR	Signal-to-Noise-Ratio. It is obtained from the mean pixel values PV, calculated in a reference ROI, divided by the standard deviation SD, according to the following formula: $$SNR = \frac{PV}{SD}$$ If calculated from projection images, these images must first be linearized to air kerma using the response function.
SPATIAL FREQUENCY	A spatial pattern such as an image can be represented as the summation of a set of spatial sinusoidal functions of appropriate amplitudes, each sinusoid covering a specific distance (e.g. millimetres) per cycle. The spatial frequency is the reciprocal of that distance and is specified in cycles/mm (or mm^{-1}) or line pairs per mm (lp/mm) since there are two pixels per cycle.
SBD	Source-Breast-Distance.
SCD	Source-Chamber-Distance.
SDD	Source-Detector-Distanc.e
SPD	Source-PMMA-Distanc.e
STANDARD TEST BLOCK	PMMA test object to represent a typical load for the system. The block may consist of several thinner slabs.
STRUCTURAL NOISE	Noise component related to the structure of a detector.
TUBE OUTPUT	Ratio between air kerma (mGy) measured without any test object and the tube loading (mAs), for a known distance between the X-ray source and the dosimeter and for pre-set exposure parameters (anode/filter combination and kVp value).

TYPICAL VALUE	Value of a parameter found in most facilities in comparable measurements. The statement of typical value is an indication about values that could be expected, without imposing any limits to obtainable results.
UNPROCESSED IMAGE/ PROJECTION IMAGE	A digital image or projection 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 to as "raw data".
PERCENT VARIATION	$\frac{\min - \max}{mean} \; x \; 100$
Z-DIRECTION	On DBT systems, the z-direction is perpendicular to the reconstructed planes.
ZERO DEGREE ANGLE STATIONARY MODE	A stationary mode at zero-degree angle which produces projection images in which the exposures of all projection images are 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.
ZERO DEGREE PROJECTION	A projection in which a line through the focal spot and centre of rotation is perpendicular to the bucky surface.
ZERO DEGREE LINE	A line from the focal spot towards the centre of rotation so that the focal spot line is perpendicular to the bucky surface.
Z- RESOLUTION	Is the spatial resolution along the z-direction, defined as the FWHM of the ASF.

1.2 Physical and geometrical characteristics of DBT systems

Listed in Table 1.1 are the physical and geometrical characteristics of the main DBT systems available on the market.

DBT System	GE Healthcare Pristina	Hologic Selenia Dimensions	Hologic 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration	Siemens Mammomat Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
Detector material	CsI-Si	a-Se	a-Se	a-Se / CsI-Si	a-Se	a-Se	a-Se	a-Se/ CsI-Si
Detector element pixel size (µm)	100	70	70	85 /83	85	85	68[1]	85/85
Projection pixel size (µm)	100	140	70/ 140[2]	85 / 83	85	-	100/150[2] ST 50/100[2] HR	85
Focal plane pixel size (µm)	100	95-117[3]	70 / 95-117[3]	90	85	85	100/150[2] ST 50/100[2] HR	85
X-ray tube motion	Step-and shoot	Continuous	Continuous	Step-and-shoot	Continuous	Continuous	Continuous	Continuous
Target	Mo/Rh	W	W	W	W	W	W	W
Filter	Mo: 30µm Ag: 30µm	Al: 700 µm	Al: 700 µm	Ag: 50 µm	Rh: 50 µm	Rh: 50 µm	Al: 700 µm	Al: 500 µm
Angular range (°)	25	15	15	30	50	50	15 ST 40 HR	15 Narrow 24 Intermediate 50 Wide
Number of projection images	9	15	15	11	25	25	15	11 Narrow 13 Intermediate 24 Wide
Nominal SDD Source to Detector Distance (mm)	660	700	700	690	655	655	650	660
Nominal Source to Bucky Distance (mm)	635	670	670	660	635[4]	635[4]	630	636
Distance between detector and centre of rotation (mm)	40	0	0	40	47	47	46	22
Total scan irradiation time (s)	8	3.7	3.7	10	21.8	21.8	3.5 ST 9.4 HR	Narrow Intermediate Wide
Grid used during DBT acquisition	Yes	No	No	No	No	No	No	Yes
Removable grid	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Table 1.1 Physical and geometrical characteristics of DBT systems available on the market.

1 Hexagonal shape • **2** Configurable by Field Engineer • **3** Variable with compression paddle height • **4** Bucky tilted respect to detector plane

1.3 AEC characteristics of DBT systems

Listed in Table 1.2 are the characteristics of the AEC of the different DBT systems available on the market.

DBT System	GE Healthcare Pristina	Hologic Selenia Dimensions	Hologic 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration	Siemens Mammomat Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
Fully automatic AEC modality	AOP	Autofilter	Autofilter	Auto	OPDOSE segmentation on	OPDOSE segmentation on	AEC, iAEC[5]	Full AUTO PRE Full AUTO FAST
Semi-automatic AEC modality	-	Autotime	Autotime	Available on request	AEC	AEC	-	Auto mAs
Dose Level	STD STD+[6]	Standard Enhanced	Standard/Low[7] Enhanced	Standard (Low dose and Contrast available on request)	Low Medium Low Normal Medium High High	Low Medium Low Normal Medium High High	L N H	Low dose High Contrast
Compression mandatory with AEC	Yes	No	No	Yes	Yes	Yes	No	Yes
Minimum compression force (N)	30	-	-	50	30	30	-	30
Pre-exposure (mAs)	2	5	5	Depends on breast thickness	5	5	Depends on breast thickness (from 1.3 to 2.2)	Depends on breast thickness (from 5 to 10)
Quality x-ray beam (anode/filter and kV) determined by compression paddle height	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Combo mode	Yes[7]	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Table 1.2 AEC characteristics of DBT systems available on the market.

5 The AEC mode uses pixel values from a fixed region to determine the correct exposure parameters (not used during clinical exposure). In iAEC mode the pixel values from the whole pre-exposure image are used to determine the breast area, composition (dense, fatty or implant), and the position of the dense area.

6 Depends on software version.

7 Configurable by Field Engineer.

1.4 Images types available in DBT systems

Image types available in DBT systems can be summarised as:

- **Projection images**: a series of FFDM images acquired at different tube rotation angles. These images are used by the system to reconstruct the final volume.
- **Zero-degree projection**: the projection acquired a tube rotation of zero degree, in which the beam axis is perpendicular to the detector plane.
- **First projection image (useful for AEC evaluation)**: the first projection image, not influenced by lag and ghosting artefacts from previous images, whose exposure parameters have been determined by the AEC.
  For some systems the first image in the series of projections is the pre-exposure at zero-degree position or at the largest angle position and thus the second projection should be used, while for other systems the first image is the projection image in the largest angle position determined by AEC. It should be ensured that the correct image is used when AEC tests are performed (see Table 1.3).
- **Reconstructed DBT images**: a stack of reconstructed focal planes at different heights from the bucky surface. The image stack is oriented parallel to the detector plane[8] with each image separated by 1 mm depth.
  The number of reconstructed images depends on the displayed height in mm, and thus on the compressed breast thickness. Typically, the whole reconstructed volume is determined by the displayed breast thickness increased by a variable number of additional reconstructed planes in order not to lose breast volume in the case of flexible compression paddle (see Table 1.4).
  For Siemens systems the maximum compressed breast thickness that can be reconstructed is 100mm.
  For thicknesses above this value, the systems allow the exposure but display a warning. GE systems could reconstruct further stacks, configurable from Field Engineer, typically one with larger slices (5 mm or 10 mm thick) and one with 0.5 mm slice thickness.
  The reconstruction algorithms used by different vendors are listed in Table 1.5. Given the possible subsequent update of the algorithms, this list reflects only the algorithms used at the time of publication of this report.
- **Synthetic image**: a FFDM image obtained from the stack reconstructed focal planes, similar to the acquired FFDM but with different spatial resolution, blurring and contrast.

GE Heathcare Pristina	Hologic Selenia Dimensions	Hologic 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration	Siemens Mammomat Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
First	First	First	Second	Second	Second	First	First

Table 1.3 First projection image (useful for AEC evaluation) where exposure parameters are determined by AEC.

GE Heathcare Pristina	Hologic Selenia Dimensions	Hologic 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration	Siemens Mammomat Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
Configurable by Field engineer	+6	+6	+4	+1	+1	Configurable by Field engineer	Configurable by Field engineer

Table 1.4 Increased number of reconstructed 1 mm DBT images with respect to compression paddle displayed height in mm.

8 In Siemens systems the DBT focal planes are parallel to the detector plane but not to the tilted bucky.

GE Heathcare Pristina	Hologic Selenia Dimensions	Hologic 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration	Siemens Mammomat Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
Iterative	FBP+Iterative	FBP+Iterative	Iterative	FBP or Iterative[9]	Iterative	FBP or Iterative[9]	Iterative

Table 1.5 Different reconstruction algorithm used to reconstruct DBT focal planes using acquired projection images.

9 Depends on software version.

Indicative image file sizes of different vendors for a 24cmx30cm field of a compressed breast 60 mm thick are shown in Table 1.6.

Total image file size (MB)	GE Heathcare Pristina	Hologic Selenia Dimensions	Hologic 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
Projection image	13 MB	6.5 MB	26 MB	19.2 MB	5.9MB/ 13MB 150um/100um	5.9MB/ 13MB 150um/100um	19.2 MB
Reconstructed DBT images stack	620 MB	620 MB	1.7 GB	640 MB	380MB/ 850MB 150um/100um	380MB/ 850MB 150um/100um	620 MB
Synthetic image	13 MB	9.4 MB	26 MB	6.7 MB	5.9MB/ 13MB 150um/100um	5.9MB/ 13MB 150um/100um	9.4 MB

Table 1.6 Indicative image file sizes (MB) for 24x30 field of a compressed breast 60 mm thick.

1.5 Breast Tomosynthesis DICOM standard

The DICOM standard objects defined in "Supplement 125: Breast Tomosynthesis Image Storage SOP Class" [4] for the different image types available in DBT systems are listed in Table 1.7.

Image Type	DICOM Format	DICOM Standard Object
Projection images	BPO FOR PROCESSING BPO FOR PRESENTATION	Breast Projection Object
Reconstructed DBT images	BTO FOR PRESENTATION	Breast Tomosynthesis Object
Synthetic images	MG FOR PRESENTATION	Mammography Object

Table 1.7 DICOM Standard Object defined in "Supplement 125: Breast Tomosynthesis Image Storage SOP Class" for different mage types available in DBT systems.

Besides standardised formats, some systems can also export reconstructed images as CTO (Computed Tomography Object) to allow storage in obsolete PACS that do not support the standard BTO.
Moreover, some systems can also export reconstructed and projection images in a proprietary format SCO (Secondary Capture Object) format.
A DICOM data element, or attribute, is composed of the following most important parts:

- a tag that identifies the attribute, usually in the format (XXXX,XXXX) with hexadecimal numbers, and may be divided further into DICOM Group Number and DICOM Element Number;
- a DICOM Value Representation (VR) that describes the data type and format of the attribute value.

Table 1.8 below contains an example of the Data Dictionary for BPO and BTO (or CTO) images.

Tag	Attribute Name	Attribute Description
(0008, 0060)	Modality	-
(0008, 0068)	Presentation Intent Type	-
(0008, 0070)	Manufacturer	Manufacturer of the equipment that produced the sources.
(0018, 0060)	kVp	Average of the peak kilo voltage outputs of the X-Ray generator used for all frames.
(0018,1020)	Software Versions(s)	Manufacturer's designation of software version of the equipment that produced the sources.
(0018,1030)	Protocol Name	User-defined description of the conditions under which the Series was performed.
(0008,1090)	Manufacturer's Model Name	Manufacturer's model name of the equipment that produced the sources.
(0018,1110)	Distance Source to Detector	Distance in mm from source to detector center on the chest wall line.
(0018,1111)	Distance Source to Patient	Distance in mm from source to the breast support side that is closest to the Imaging Subject, as measured along the X-Ray beam vector.
(0018,1114)	Estimated Radiographic Magnification Factor	Ratio of Source Image Receptor Distance (SID) over Source Object Distance (SOD).
(0018,1150)	Exposure Time	Duration of X-Ray exposure in msec.
(0018,1151)	X-ray Tube Current	X-Ray Tube Current in mA.
(0018,1152)	Exposure	The exposure expressed in mAs.
(0018,1153)	Exposure in uAs	The exposure expressed in µAs.
(0018,1160)	Filter Type	Type of filter(s) inserted into the X-Ray beam (e.g., wedges). Defined Terms: STRIP, WEDGE, BUTTERFLY, MULTIPLE, FLAT, NONE.
(0018,1164)	Imager Pixel Spacing	-
(0018,1166)	Grid	Identifies the grid. May be multi-valued. Defined Terms: FIXED, FOCUSED, RECIPROCATING, PARALLEL, CROSSED, NONE.
(0018,1190)	Focal Spot(s)	Nominal focal spot size in mm used to acquire the projection images.
(0018,1191)	Anode Target Material	The primary material in the anode of the X-Ray source. Defined Terms: TUNGSTEN, MOLYBDENUM, RHODIUM.
(0018,11A0)	Body Part Thickness	The average thickness in mm of the body part examined when compressed, if compression has been applied during exposure.
(0018,11A2)	Compression Force	The compression force applied to the body part during exposure, measured in Newtons.
(0018,11A4)	Paddle Description	Description of the compression paddle, if compression was applied to the body part during exposure.

Tag	Attribute Name	Attribute Description
(0018,1405)	Relative X-ray Exposure	Indication of the applied dose, in manufacturer specific units.
(0018,1510)	Positioner Primary Angle	Description of the compression paddle, if compression was applied to the body part during exposure.
(0018,1530)	Detector Primary Angle	
(0018,7001)	Detector Temperature	Detector temperature during exposure in degrees Celsius.
(0018,700C)	Date of Last Detector Calibration	
(0018,701A)	Detector Binning	Number of active detectors used to generate a single pixel. Specified as number of row detectors per pixel then column. Required if detector binning was applied to the projection images.
(0018,7050)	Filter Material	The X-Ray absorbing material used in the filter. Defined Terms: MOLYBDENUM, ALUMINIUM, COPPER, RHODIUM, NIOBIUM, EUROPIUM, LEAD
(0018,7052)	Filter Thickness Minimum	The minimum thickness in mm of the X-Ray absorbing material used in the filters.
(0018,7054)	Filter Thickness Maximum	The maximum thickness in mm of the X-Ray absorbing material used in the filters.
(0018,7060)	Exposure Control Mode	Type of exposure control. Defined Terms: MANUAL, AUTOMATIC.
(0018,7062)	Exposure Control Mode Description	Text description of the mechanism of exposure control. May describe the number and type of exposure sensors or position of the sensitive area of the imaging detector
(0018,9332)	Exposure	The exposure expressed in mAs
(0020,0062)	Laterality	The exposure expressed in mAs
(0028,0004)	Photometric Interpretation	
(0028,0030)	Pixel Spacing	
(0028,0100)	Bits Allocated	
(0028,0101)	Bits Stored	
(0028,0102)	High Bit	
(0028,1040)	Pixel Intensity Relationship	
(0028,1041)	Pixel Intensity Relationship Sign	
(0028,2110)	Lossy Image Compression	
(0040,0302)	Entrance Dose	

Tag	Attribute Name	Attribute Description
(0040,0314)	Half Value Layer	The thickness of Aluminium in mm required to reduce the X-Ray Output (0040,0312) by a factor of two
(0040,0316)	Organ Dose	Organ dose value measured in dGy
(0040,8302)	Entrance Dose in mGy	Entrance dose value measured in mGy at the surface of the patient.
(0040,8303)	Entrance Dose Derivation	Describes what type of dose is represented by the values of Entrance Dose in mGy (0040,8302). Enumerated Values: IAK Represents air kerma at the entrance surface, no backscatter included, no air kerma to tissue dose conversion applied. ESAK Represents air kerma at the entrance surface, with backscatter included, no air kerma to tissue dose conversion applied. ESDBS Represents absorbed dose in tissue at the entrance surface, with backscatter included. ESDNOBS Represents absorbed dose in tissue at the entrance surface, without backscatter included. Only meaningful if Entrance Dose in mGy (0040,8302) is present.
	Slice Location	-
	Slice Thickness	-
	Image Number	
	Image Acquisition	

Table 1.8 Example of Data dictionary for BTO, CTO and BPO images.

Another DICOM Object available in DBT systems is the Radiation Dose Structured Reporting (RDSR), a structured file containing the dosimetric information [5]. The RDSR consists of:

- DICOM header;
- Container with dose accumulation data;
- Radiation data container for each event during the procedure.

RDSR represents the hierarchical structure, or in other words "the tree structure" of content data obtained from the x-ray procedure, encoded in DICOM. Such an SR dose object allows the data flow and data management of radiation dose reports to be disengaged from the data flow and data management of images.

1.6 Dosimetry

The AAPM-EFOMP Task Group 282 published in 2024 a new dosimetry model [18] which uses a more realistic location of fibroglandular tissue in the breast and a new methodology to estimate the breast Average Glandular Dose (AGD) from x-ray based image acquisitions including standard mammography, contrast-enhanced mammography, and breast tomosynthesis.
The EFOMP Working Group (WG) entitled “Breast Tomosynthesis QC Protocol” published in 2023 the Protocol "Quality Control in Digital Breast Tomosynthesis (DBT)" [10], implementing the new dosimetry.

Therefore, the universal dosimetry model will probably be adopted by all the mammography equipment vendors in the next few years and, as soon as it will be published and implemented, an addendum or a new version of this protocol will be released.

1.7 QC test overview

In Table 1.9 and Table 1.10 the routine test (acceptance and constancy and relative frequencies) and test to be performed after main maintenance are listed. The suggested frequencies are proposed by the working group on the basis of existing protocols, guidelines and standards [7, 8, 9, 10] but could be changed by each MPE taking into account available resources or clinical use of the DBT systems (screening second level assessment, etc.).

	Routine QC Test	Acceptance	Constancy	Frequency
2. X-ray tube and dosimetry	2.1 Tube output	X	X	Every year[10]
	2.2 kV	X	-	-
	2.3 HVL	X	-	-
	2.4 AGD	X	X	Every year[10]
3. AEC	3.1 AEC performance	X	X	Every year[10]
	3.2 AEC Short term reproducibility	X	X	Every year[10]
	3.3 AEC Response to local variations in breast density	X	-	-
	3.4 AEC Long term reproducibility	X	X	Weekly/monthly
4. Image receptor	4.1 Response function	X	-	-
	4.2 Noise analysis	X	-	-
	4.3 MTF	X	X	Every year[11]
	4.4 Detector element failure[12]	X	-	-
	4.5 Uncorrected defective detector elements	X	X	Every year[10]
5. Image quality of reconstructed and synthetic images	5.1 Stability of image quality in the x-y plane	X	X	Every year[10]/ monthly
	5.2 Z-resolution	X	X	Every year[10]
	5.3 Homogeneity and artefact evaluation	X	X	Every year[10]/ weekly

Table 1.9 Routine QC test

10 A higher frequency is recommended if the DBT system is used daily or in the screening program.
11 Just with MTF edge at 40 mm height • **12** Just in case of detector binning.

	Test after main maintenance	X-ray tube/filter change	Detector change/ calibration	Software upgrade[13]
2. X-ray tube and dosimetry	2.1 Tube output	X	-	-
	2.2 kV	X	-	-
	2.3 HVL	X	-	-
	2.4 AGD	X	X	X
3. AEC	3.1 AEC performance	X	X	X
	3.2 AEC Short term reproducibility	-	X	-
	3.3 AEC Response to local variations in breast density	-	X	X
	3.4 AEC Long term reproducibility	X	X	X
4. Image receptor	4.1 Response function	-	X	X
	4.2 Noise analysis	-	X	-
	4.3 MTF	X	X	-
	4.4 Detector element failure[14]	-	X	-
	4.5 Uncorrected defective detector elements	-	X	-
5. Image quality of reconstructed and synthetic images	5.1 Stability of image quality in the x-y plane	X	X	X
	5.2 Z-resolution	-	X	X
	5.3 Homogeneity and artefact evaluation	X	X	X

Table 1.10 Test after main maintenance

13 Software upgrade influencing the image quality, dosimetry, AEC performance, processing.
14 Just in case of detector binning.

1.8 Software and images analysis

Evaluating the performance of digital mammography systems requires quantitative measurements; these may be carried out using the software tools on a review workstation or by exporting images in a DICOM format for offline analysis.
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, or exporting images to a PACS system. Images should be transferred in accordance with local information security policies.
To carry out image analysis it is possible to use either the tools provided by standard DICOM viewer software or more automated software developed for the purpose, such as ImageJ plugins like the *MAMMO_QC* set [14].
Note that in some cases, images saved by the mammography systems or PACS may be compressed, and need to be decompressed using appropriate tools (e.g. DCMTK) before being used.
MAMMO_QC is a free and platform independent software for QC performance tests in digital mammography (FFDM) and tomosynthesis (DBT).
The software has been developed for the test described in this protocol, but it could, also, be used for the tests of European guidelines and supplements [12, 13] and EUREF protocol version for DBT Systems [7].
MAMMO_QC consists of a series of ImageJ plugins for FFDM and DBT.
Software and any other information, including Reference manual, can be downloaded from AIFM website and from the Mendeley dataset (**https://data.mendeley.com/datasets/8jj7865wfn**).

Minimum requirements are:

- Java 8 installed
- Operating System: Windows, Linux or Mac OS X
- ImageJ v. 1.52 or above (**https://imagej.nih.gov/ij/download.html**)
- At least 4 GB RAM

MAMMO_QC contains four main categories of ImageJ plugins: a) Utilities, b) General Tests, c) FFDM and d) DBT. Listed in Table 1.11 the tests of this protocol associated with the plugins. In Table 1.12 other MAMMO_QC utilities are listed.

All plugins request the user to follow precise instructions. For plugins that perform the analysis on a "reference ROI", the user is asked to select the ROI size (in mm) and the ROI distance from the chest wall edge of the image (possible values: 4 cm, 5 cm and 6 cm). If the user does not enter any value, MAMMO_QC uses a default ROI of 5mm x 5mm, placed at 6 cm from the chest wall edge and laterally centred.
The plugin prompts to select the images to be opened and to insert (and eventually save through *Setup linearization coefficients* tool under *Utilities*) the coefficients and the type of the conversion function (linear or logarithmic) to convert the pixel values into dose values. The user can also choose to proceed without images linearization, by clicking the button "No linearization".
Some plugins report the output in a RESULTS window from which the data can be copied or exported using the context menu that appears upon right clicking the mouse. Some of the output plots can be printed, saved as images (e.g., png, jpg, tiff, etc.) and/or exported, saving the underlying data as a comma separated value csv file.
Please refer to each test in this protocol for a detailed description of the plugin procedure.

CQ test items	Test supported	Main categories	Plugin name
3.1 AEC performance (SDNR)	√	DBT – AEC	SDNR Tomo
3.2 AEC Short term reproducibility	√	DBT – AEC	Short-term DBT
3.3 AEC Response to local variations in breast density	√	DBT – AEC	Local Dense Area DBT
3.4 AEC Long term reproducibility	√	General Tests	AEC Long-term
4.1 Response Function	√	General Tests	Response Function
4.2 Noise analysis	√	General Tests	Noise Evaluation
4.3 MTF	√	General Tests	Edge pMTF
4.4 Detector element failure	√ (Siemens, Hologic)	General Tests	-
4.5 Uncorrected defective elements	√	DBT	Uncorrected defective elements (TOMO)
4.6 Homogeneity and artefact evaluation	√	FFDM	Homogeneity Artefact Evaluation
5.1 Stability of image quality in the x-y plane	√	DBT – Image Quality	TOMOPHAN TORMAM CIRS015
5.2 Z-resolution	√	DBT - ASF	Specks Phantom Spheres Phantom
5.3 Homogeneity and artefact evaluation	√	DBT- Homogeneity	UNIF Artefact

Table 1.11 Tests of the Protocol for which MAMMO_QC can be used.

CQ test items	Test supported	Main categories
AGD from Header	√	General Tests
DQE	√	General Tests
MTF in the x-y plane	√	DBT
NPS in the x-y plane	√	DBT
CDMAM	√	General Tests

Table 1.12 Other Tests or Utilities for which MAMMO_QC can be useful.

1.9 Acquisition modalities for QC

Each QC test must be performed in a specific modality or on a specific type of images. The different DBT acquisition modalities to be used for x-ray tube measurements with fixed tube are listed in Table 1.13

GE Heathcare Pristina	Hologic Selenia Dimensions	Hologic 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
3D static Modality	Zero Degree Mode	Zero Degree Mode	M2	Stationary mode	Stationary/ Fixed mode	Service

Table 1.13 DBT acquisition modalities with fixed tube for x-ray tube measurements.

The acquisition modalities to be used to obtain "DICOM for processing" images for each DBT system are listed in Table 1.14.

GE Heathcare Pristina	Hologic Selenia Dimensions	Hologic 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
-	Flat Field Tomo	Flat Field Tomo	Quality Control	QC Raw Tomo[15] Clinica Tomo HD[16]	TomoMax4.0	-

Table 1.14 Acquisition modalities to obtain for processing projection images.

Acquisition protocols and AEC modes to perform AEC tests are listed in Table 1.15.

	GE Heathcare Pristina	Hologic Selenia Dimensions 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
Acquisition protocol	3D	Flat Field Tomo/ PMMA Mode	Quality Control	QC Raw Tomo	TomoMax4.0	Tomo
Fully automatic AEC modality	AOP	Autofilter, AEC Sensor Auto	Autofilter	OPDOSE	iAEC	Full AUTO Pre
Dose Level1	**STD** STD+	**Standard**, Enhanced	**Standard** (Low dose and contrast available on request)	Low Medium Low **Medium** Medium High High	L **N** H	**Low Dose** High Contrast
Compression paddle	24x30	24x30 Fixed (not "fast")	24x30	24x30	24x30	24x30

Table 1.15 DBT acquisition modalities to be used for AEC tests. Standard dose levels are typed in bold.

15 No tomographic reconstruction, only projection acquisition "for processing" and "for presentation".
16 Projection acquisition "for processing" and reconstructed images.

The acquisition modalities to be used to obtain "DICOM for presentation" images for each DBT system are listed in Table 1.16.

	GE Heathcare Pristina	**Hologic Selenia Dimensions 3Dimensions**	**IMS Giotto Class**	**Siemens Mammomat Inspiration/ Revelation**	**Fujifilm Amulet Innovality**	**Metaltronica Helianthus**
Acquisition protocol	3D	Tomo HD RCC	Tomo	Tomo	Tomo	Tomo
Fully automatic AEC modality	AOP	Autofilter, AEC Sensor Auto	Autofilter	OPDOSE	iAEC	Full AUTO Pre
Dose Level[17]	**STD** STD+	**Standard**, Enhanced	**Standard** (Low dose and contrast available on request)	Low Medium Low **Medium** Medium High High	L **N** H	**Low Dose** High Contrast
Compression paddle	24x30	24x30 Fixed (not "fast")	24x30	24x30	24x30	24x30
Processing[18]	eContrast3 eContrast6	-	-	RPG Empire RPG Calc	-	-

Table 1.16 Acquisition modalities for image quality tests on reconstructed and synthetic images. Standard dose levels are typed in bold.

17 For acceptance test check all dose levels and AEC mode, for routine test choose the dose level used to perform clinical exams.
18 Examples of processing available for user selection on the mammography system.

1.10 Typical values

The provided typical values for different tests are listed in Table 1.17.

The typical values are calculated as median values and range of the minimum and maximum values obtained from measurements performed on different systems by the working group [19]. For GE Senoclaire are not provided any typical values.

Please note that the values for the *Stability of image quality in the x-y plane and 2D-Synthetic* test provided should not be considered as typical values, as they are closely related to the type of processing used and are provided only as examples.

Test	Measured values	Appendix
2.1 Tube output	Incident air kerma at 100 cm measured with compression paddle Ki (uGy/mAs)	Appendix A
2.3 HVL	HVL (mm Al) for different anode/filter and kV	Appendix B
2.4 AGD	AGD (mGy) for different breast thicknesses from 2 to 9 cm	Appendix C
3.1 AEC performance	- SDNR for different breast thicknesses from 2 to 9 cm	Appendix D
3.3 AEC Response to local and global variations in breast density	From 0% to 100% glandularity: - max SDNR % variation - max AGD variation - max kV variation	Appendix E
4.1 Response Function	Fit coefficient a,b	Appendix F
5.1 Stability of image quality in the x-y plane and 2D-Synthetic	Score visibility (SDNR) of details in Phantom(s) in the focal plane and 2D-Synthetic image	Appendix G
5.2 Z-resolution	ASF FWHM (mm) of details in Phantom(s)	Appendix H

Table 1.17 Typical values provided for different tests.

2. X-RAY TUBE AND DOSIMETRY

2.1 Tube output

2.1.1 Purpose

Purpose of the test is to check compliance with manufacturer's specifications at acceptance in terms of x-ray tube output. During constancy QC, the purpose of the test is to measure the incident air kerma Ki for different X-ray beam quality, to be used for AGD calculation (See 2.4).
It's important to perform this test in DBT modality even if the anode/filter combination is the same of that used in FFDM modality, because the x-ray impulse used in DBT are shorter respect to that of FFDM modality (15-20 ms for DBT against 1-2 seconds for FFDM), leading to a possible difference in kV or output measurements.

2.1.2 Images type

No images needed. Disable image acquisition if possible and shield the detector with a highly attenuating protective device (e.g., a lead sheet or lead apron).

2.1.3 Acquisition modality

GE Heathcare Pristina	Hologic Selenia Dimensions	Hologic 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
3D static Modality	Zero Degree Mode	Zero Degree Mode	M2	Stationary mode	Stationary/ Fixed mode	Service

Table 1.13 DBT acquisition modalities with fixed tube to be used for x-ray tube measurements.

2.1.4 Test equipment

- Protective device to shield the image detector
- Calibrated dosimeter (Ionisation chambers or solid-state detectors calibrated for clinical beam used)

2.1.5 Test procedure

<u>During constancy QC</u>

Shield the image detector with a highly attenuating objects and fix it. Fix the dosimeter on the shield with tape, ensuring that the sensitive area is located at the reference position. Measure the SCD in order to rescale the dosimeter reading to the useful distance for AGD calculation. Place the compression paddle (24x30 cm^2) as near as possible to the dosimeter[19]. Select the proper acquisition modality (see Table 1.13) and set the manual exposure mode from the mammography unit console.
Since tube output depends on the X-ray beam quality (anode/filter combination and kVp value), in principle, it should be measured for each X-ray beam used in the clinical practice. Nevertheless, it is possible to reduce the number of measurements using the method by Robson et al. [15].
Measure incident air kerma for each anode/filter combination clinically used at four different kVp values in the range of those clinically selected and for two different tube loading, 25 and 50 mAs. In Table 2.1 suggested kV values for different anode/filter combinations are listed.

19 Not mandatory for solid state detectors, see Remark 1.

Tube voltage	Mo/Mo	Mo/Rh	Rh/Rh	Rh/Ag	W/Rh	W/Ag	W/Al (0.5mm)	W/Al (0.7mm)
kV_{p1}	25	25	25	28	25	25	25	28
kV_{p2}	28	28	28	31	28	28	28	31
kV_{p3}	31	31	31	34	31	31	31	34
kV_{p4}	34	34	34	37	34	34	34	37

Table 2.1 Suggested peak voltage settings for tube output measurements. Choose the column(s) corresponding to the anode/filter combination available in your mammography unit.

For each mAs value derive the fitting parameter of ln(*A*) and *n* and use them to calculate the tube output for any beam quality (ie. for other tube voltage not measured).

$$K_i = A(kV_p)^n \rightarrow \ln(K_i) = \ln(A) + n\ln(kV_p)$$

Finally, a linear regression of the two incident air kerma for the two mAs values, provides the tube output in units of µGy/mAs @SCD for all anode/filter combinations and tube voltage in the range of interest. Correct the measured values with inverse square law correction to obtain the incident air kerma at 1 m.
Tube output is expressed in µGy/mAs and allows to estimate the incident air kerma at the entrance surface for any PMMA thickness for AGD calculation (with scattering from compression paddle but without backscatter from PMMA surface), using an inverse square law correction.

Remark 1: if a solid-state detector is used the position of the compression paddle doesn't influence the measurement, because the scattering from the compression paddle is not usually included in the measurements (due to the small size of the detector). A correction factor might be used to take into account the scattering from compression paddle, if declared by the detector's manufacturer. According to Brateman et al. [20] we suggest to use the compression paddle scattering factors in Table 2.2.

Solid-state detector	Mo/Mo	Mo/Rh	Rh/Rh	W/Rhr	W/Ag	W/Al (0.7 mm Al)
Radcal[a]	1.00	1.00	1.00	1.03	1.03	1.01
RaySafe[a]	1.02	1.03	1.03	1.03	1.03	1.03
PTW[a]	1.03	1.03	1.03	1.03	1.04	1.03
Piranha[b]	1.06	1.06	1.06	1.06	1.06	1.06

Table 2.2 Suggested compression paddle scattering factors. aBrateman et al. [20], bManufacturer's manual

Remark 2: since solid state detectors have an energy dependent response, be sure to use the appropriate calibration curves for the X-ray beams of interest. The correction may already be handled internally by the instrument or you may need to contact the instrument manufacturer for the correction factor.

Remark 3: 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.

At acceptance

During acceptance, in addition to the previous measurements, measure tube output without compression paddle or in the manufacturer conditions and for specified beam quality, to check compliance with manufacturer's specifications.

2.1.6 Image analysis

No images acquired.

2.1.7 Acceptable Levels

Percentage difference of tube output measurement respect to manufacturer's specifications <5%.

2.1.8 Typical Values

The output typical values in terms of incident air kerma in μGy/mAs at 100 cm with compression paddle are listed for the different DBT systems in Appendix A.

2.1.9 Test frequency

Every year or after the replacement of the X-ray tube/filter or the maintenance of the generator.

2.2 Tube voltage

2.2.1 Purpose

Purpose of the test is to verify tube voltage accuracy and precision, i.e. evaluating the relative difference between the peak voltage value (kVp) set on the system and the measured one, and the reproducibility of the measured values. Tube voltage, anode material and filtration determine the radiation quality of the emitted X-ray beam.
It's important to perform this test in DBT modality even if the anode/filter combination is the same of that used in FFDM modality, because the impulse used in DBT are shorter (15-20 ms for DBT against 1-2 seconds for FFDM), leading to a possible difference in kV or output measurements.

2.2.2 Images type

No images needed. Disable image acquisition if possible and shield the detector with a highly attenuating protective device (e.g., a lead sheet or lead apron).

2.2.3 Acquisition modality

GE Heathcare Pristina	Hologic Selenia Dimensions	Hologic 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
3D static Modality	Zero Degree Mode	Zero Degree Mode	M2	Stationary mode	Stationary/ Fixed mode	Service

Table 1.13 DBT acquisition modalities with fixed tube to be used for x-ray tube measurements.

2.2.4 Test equipment

- Protective device to shield the image detector
- kV-meter (calibrated for clinical beam used)

2.2.5 Test procedure

Shield the image detector with a highly attenuating object and fix it. Fix the dosimeter on the shield with tape, ensuring that the sensitive area is located at the reference position[20].
Position the compression paddle (24x30 cm^2), select the zero-degree angle stationary DBT mode (see Table 1.13) and set the manual exposure mode from the mammography unit console.
Perform the measurements for all anode/filter combinations.

Accuracy: check a number of tube voltages to cover the range clinically used.
Reproducibility: perform 5 repeated exposures at one fixed tube voltage normally used clinically (i.e. 28 kVp).

Remark: since solid-state detectors have an energy dependent response, be sure to select the appropriate calibration curves for the X-ray beams of interest, including the presence of the compression paddle.
The correction may already be handled internally by the instrument or you may need to contact the instrument manufacturer for the correction factor.

2.2.6 Image analysis

No images acquired.

2.2.7 Acceptable Levels

Accuracy: achievable < ± 1kV, acceptable < ± 2kV
Reproducibility: < ± 0.5kV

2.2.8 Typical Values

No typical values provided.

2.2.9 Test frequency

Acceptance test or after x-ray tube/filter change.

20 Check the kV-meter manual for eventual specific position prescription.

2.3 HVL

2.3.1 Purpose

Purpose of the test is to measure the Half Value Layer (HVL) in units of mm Al with compression paddle for all anode/filter combinations clinically used. This parameter characterises penetration capability of a polychromatic X-ray beam and determines the radiation quality of the emitted X-ray beam along with the tube voltage.
AGD can be estimated by multiplying the incident air kerma (see 2.1) by conversion factors, which depend on HVL and breast thickness (see 2.4).

2.3.2 Images type

No images needed. Disable image acquisition if possible and shield the detector with a highly attenuating protective device (e.g., a lead sheet or lead apron).

2.3.3 Acquisition modality

GE Heathcare Pristina	Hologic Selenia Dimensions	Hologic 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
3D static Modality	Zero Degree Mode	Zero Degree Mode	M2	Stationary mode	Stationary/ Fixed mode	Service

Table 1.13 DBT acquisition modalities with fixed tube to be used for x-ray tube measurements.

2.3.4 Test equipment

- Protective device to shield the image detector
- Aluminium filters (99% purity) of different thicknesses (from 0.3 mm to 0.8 mm)
- Calibrated dosimeter (Ionisation chambers or solid-state detectors, only if correction factors and/or calibration is provided both for clinical beam and for additional Al filters used)

2.3.5 Test procedure

Since HVL is a function of anode/filter combination and kVp value in principle, it should be measured for each X-ray beam used in the clinical practice. Nevertheless, it is possible to reduce the number of measurements by using the method of Robson et al. [15].
Shield the image detector with a highly attenuating object and fix it. Fix the dosimeter on the shield with tape, ensuring that the sensitive area is located at the reference position.
Use the smallest field available and position the compression paddle as high as possible to assure good geometry conditions[21].
Use the compression paddle as support for the aluminium filters and select the zero-degree angle stationary tomo mode and set the manual exposure mode from the mammography unit console (see Table 1.13).
Acquire incident air-kerma (K_i) measurements for each anode/filter combination clinically used at three different kVp values. Keep the mAs value constant, to ensure the dose intensity is high enough even when the thicker aluminium filter is used. The mAs value should be in the range 25-50 mAs. Suggested values of tube voltage are reported in Table 2.3.

21 Not mandatory for solid state detectors, see Remark 1.

Tube voltage	Mo/Mo	Mo/Rh	Rh/Rh	Rh/Ag	W/Rh	W/Ag	W/Al (0.5mm)	W/Al (0.7mm)
kV_{p1}	25	25	28	31	25	25	25	28
kV_{p2}	28	28	31	34	31	31	31	34
kV_{p3}	31	31	34	37	34	34	34	37

Table 2.3 Suggested peak voltage settings for HVL measurements.

For each selected beam (anode/filter, kVp), measure three K_i values:

- without any additional filter (T_0)
- with the aluminium filter of thickness T_1
- with the aluminium filter of thickness T_2

The aluminium foils must be placed on the compression paddle to cover the dosimeter area.
Suggested values of aluminium thickness are listed in Table 2.4.

Al thickness (mm)	Mo/Mo	Mo/Rh	Rh/Rh	Rh/Ag	W/Rh	W/Ag	W/Al (0.5mm)	W/Al (0.7mm)
kV_{p1}	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
kV_{p2}	0.3	0.4	0.4	0.5	0.5	0.5	0.3	0.5
kV_{p3}	0.5	0.6	0.6	0.7	0.7	0.7	0.5	0.8

Table 2.4 Suggested thickness (in mm) of the aluminium filters used to experimentally determine the HVLs for the X-ray spectra listed in Table 2.3.

For each selected beam (anode/filter combination and *kVp* pair), perform a linear regression between K_i and aluminium thickness *T* and compute slope and intercept from the log-log linear relationship:

$$\ln(K_i) = \ln(K_i)_{t_0} - \mu T = A + B \cdot T$$

where K_i is the incident air kerma measured with Al thickness T and $(K_i)_{t_0}$ is the incident air kerma measured without filters.

The experimental *HVL* for the selected beam can be obtained from the exponential attenuation law as:

$$HVL = \frac{\ln\left(\frac{(K_i)_{t_0}}{2}\right) - A}{B}$$

where *A* and *B* are the intercept and the slope.

For each anode/filter combination, the three experimental *HVL* values obtained at three different *kVp* values are used to determine the polynomial fit coefficients *a, b* and *c*.

$$HVL = a(kV_p)^2 + b(kV_p) + c$$

Finally, the fitting coefficients *a, b* and *c* are replaced in to recalculate *HVLs* at any kV_p value.
This allows to estimate the *HVL* for any tube voltage value, for a fixed anode/filter combination.

Remark 1: if a solid-state detector is used, the position of the compression paddle and the collimation don't influence significantly the measurement, because the scattering is not usually included in the measurement (due to the small size of the detector) and thus the good condition geometry is obtained even with compression paddle close.

Remark 2: since solid-state detectors have an energy dependent response, be sure to select the appropriate calibration curves for the X-ray beams of interest, including the presence of the compression paddle.
The correction may already be handled internally by the instrument or you may need to contact the instrument manufacturer for the correction factor. It is therefore fundamental to consider the correction for the Al thicknesses used to experimentally determine the HVL if a solid-state detector is used.

Remark 3: some solid-state detectors (multimeters) are provided by software capable of deriving HVL (mmAl) values from the attenuation of the X-ray beam by multiple filters of different materials.
During acceptance measurements, without filter on the paddle, collect the calculated HVL values (HVL_{calc}) from the multimeter and compare them with those measured with Al filters (HVL_{mis}). Check on the instrument calibration certificate whether HVL_{calc} is certified or not.
If the difference between (HVL_{calc}) and (HVL_{mis}) < 10%, the multimeter is suitable to be used for a fast check during the annual constancy test.

2.2.6 Image analysis
No images acquired.

2.3.7 Acceptable Levels
No acceptable levels are provided.

2.3.8 Typical Values
The HVL typical values in mm Al measured with compression paddle are listed for the different DBT systems in Appendix B.

2.2.9 Test frequency
Acceptance test or after x-ray tube/filter change.

2.4 AGD

2.3.1 Purpose

Purpose of the test is to calculate AGD for a range of typical breast thicknesses. The used method is based on the equivalence in attenuation between different thicknesses of PMMA and typical breasts [7, 12, 13].

2.4.2 Images type

No acquisitions needed.

2.4.3 Acquisition modality

No acquisitions needed.

2.4.4 Test equipment

No acquisitions needed.

2.4.5 Test procedure

The estimation of AGD for different breast thicknesses are obtained by:

$$AGD = K_p \cdot g \cdot c \cdot s \cdot T$$

where K_p is the incident air kerma on PMMA surface (without backscatter from PMMA but with scattering from compression paddle) measured in the "zero degree" position for the total mAs of the tomosynthesis acquisition, and *g, c, s* and T are conversion factors [7].

The factor g gives the AGD for a breast of glandularity 50% and is tabulated against breast thickness and HVL (see Table 2.6).

The factor c allows for breasts of different glandularity and is tabulated against HVL and breast thickness for typical breast compositions (see Table 2.7).

The factor s allows for the use of different X-ray spectra (see Table 2.8 and Table 2.9).

The factor T, is the tomo factor typical for each DBT system (see Table 2.10). For AGD calculation for Helianthus systems, the T factors to be used for narrow, intermediate and wide angles are respectively the Hologic, IMS and GE ones.

PMMA thick-ness (mm)	Equiv. breast thick-ness (mm)	Gland. of equiv. breast (%)	g-factors(mGy/mGy)										
			HVL(mmAl)										
			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

Table 2.6 g-factors

PMMA thick-ness (mm)	Equiv. breast thick-ness (mm)	Gland. of equiv. breast (%)	g-factors										
			HVL(mmAl)										
			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	1.199	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

Table 2.7 c-factors

Target material	Filter material	Filter thickness (μm)	s-factors
Mo	Mo	30	1.000
Mo	Rh	25	1.017
Rh	Rh	25	1.061
Rh	Rh	30	1.087[1]
w	Rh	50-60	1.042
w	Ag	50-75	1.042

[1] Personal communication with David Dance

Table 2.8 s-factors for some anode/filter combination

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

Table 2.9 s-factors for W target filter with 0.7 mm Al

Breast thickness (mm)	$T_{Fujifilm}$ ± 7.5°	$T_{Fujifilm}$ ± 20°	T_{GE} ± 12.5°	$T_{Hologic}$ ± 7.5°	T_{IMS*} ± 19°	$T_{Planmed}$ ± 15°	$T_{Siemens}$ ± 24°	$T_{IMSClass*}$ ± 15°
20	0.997	0.985	0.993	0.997	0.985	0.991	0.980	0.991
30	0.996	0.981	0.991	0.996	0.981	0.989	0.974	0.988
40	0.997	0.979	0.990	0.996	0.978	0.988	0.971	0.987
50	0.996	0.977	0.989	0.995	0.976	0.986	0.968	0.986
60	0.995	0.975	0.988	0.994	0.974	0.985	0.966	0.984
70	0.995	0.974	0.987	0.994	0.973	0.984	0.965	0.983
80	0.994	0.972	0.986	0.993	0.972	0.983	0.964	0.982
90	0.993	0.971	0.985	0.992	0.970	0.981	0.962	0.981
100	0.994	0.970	0.984	0.993	0.970	0.981	0.961	0.980
110	0.993	0.969	0.984	0.992	0.968	0.980	0.960	0.979

**** Note: for the T-values given, it is assumed that dose is distributed evenly between all projections.***

Table 2.10 T-factors

Use the exposure parameters (anode/filter combination, kV and mAs) recorded in test 3.1 for different equivalent breast thickness from 20 to 90 mm obtained using different PMMA plates thicknesses.
For each PMMA thickness, calculate Kp in mGy on the surface of PMMA plate, using the incident air kerma K_i measured for different x-ray beam quality in section 2.1 (with a scaling factor of 10^3), using inverse square law and scaling to the appropriate value of current-time product (mAs):

$$K_p = 10^3 \cdot K_i \cdot mAs \cdot \left(\frac{SPD(cm)}{100} \right)^2$$

where K_i is the incident air kerma (μGy/mAs) at 100 cm (with scattering from the compression paddle but without backscatter from PMMA surface), mAs are the values obtained with automatic AEC during test 3.1, and SPD is the source to PMMA surface distance (expressed in cm). To note that the K_i must be converted in mGy multiplying the value by 10^3.
Use the appropriate g,c,s and T factor in the Eq. 2.5 to calculate AGD values for each equivalent breast thickness. *g-factors* and *c-factors* depend on HVL values measured in test 2.3.

Calculate the percentage difference $Diff_{AGD}(\%)$ for AGD displayed and recorded in DICOM Tag Organ Dose (0040,0316) respect to calculated AGD values as:

$$Diff_{AGD}(\%) = \frac{10^2 \cdot AGD_{DICOM}}{AGD} - 1$$

To note that the AGD_{DICOM} is expressed in dGy and must be converted in mGy multiplying the value by 10^2.

Correct the measured air kerma K_i using inverse square law to obtain the incident air kerma on the equivalent breast surface:

$$K_B = 10^3 \cdot K_i \cdot mAs \cdot \left(\frac{SBD(cm)}{100} \right)^2$$

where K_i is the incident air kerma uGy/mAs at 100 cm and SBD is the source to breast surface distance (expressed in cm).

Calculate the percentage difference $Diff_K(\%)$ for incident air kerma displayed and recorded in Dicom Tags (0040,8302) respect to measured air kerma as:

$$Diff_K(\%) = \frac{K_{DICOM}}{K_B} - 1$$

Remark 1: DICOM Tag Organ Dose (0040,0316) is expressed in dGy and needs to be converted in mGy using a multiplying factor of 100.

Remark 2: ask to manufacturer the AGD calculation methods for DICOM Tag Organ Dose (0040,0316) used and if recorded K values in Tag (0040,8302) are with or without backscatter.

2.4.6 Image analysis

No images acquired.

2.4.7 Acceptable Levels

For standard dose levels (see Table 2.11) the limiting values in terms of AGD in mGy for different breast thicknesses are reported in Table 2.12. For higher dose levels available, no limiting values are provided.

GE Heathcare Pristina	Hologic Selenia Dimensions / 3 Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
STD	Standard	Standard	Medium	N	Low Dose

Table 2.11 Standard dose levels for different DBT systems

Equivalent breast thickness (mm)	Average glandular dose to equivalent breasts. Limiting value (mGy)
21	1.2
32	1.5
45	2.0
53	2.5
60	3.0
75	4.5
90	6.5

Table 2.12 Acceptable Levels in terms of AGD for different equivalent breast thicknesses

Difference AGD %: Acceptable 25%
Achievable 15%

Difference K %: Acceptable 25%
Achievable 15%

2.4.8 Typical Values

The AGD typical values in mGy for standard dose levels and different breast thicknesses are listed for the different DBT systems in Appendix C.

2.4.9 Test frequency

Acceptance test, constancy test every year and after x-ray tube/filter change, detector change or software upgrade.

3. AEC

3.1 AEC performance

3.1.1 Purpose

The purpose is to check if the Automatic Exposure Control (AEC) works properly maintaining the desired target SDNR (Signal Difference to Noise Ratio) for different breast thicknesses.
This test also allows to check the exposure parameters in a clinical range of breast thicknesses to evaluate the AGD (see test 2.4) with a method based on the equivalence in attenuation between different thicknesses of PMMA and typical breasts [7, 12, 13].

3.1.2 Images type

First/second 'for processing' projection images where exposure parameters are determined by AEC (see table Table 1.3).

GE Heathcare Pristina	Hologic Selenia Dimensions	Hologic 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration	Siemens Mammomat Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
First	First	First	Second	Second	Second	First	First

Table 1.3 First projection image (useful for AEC evaluation) where exposure parameters are determined by AEC.

3.1.3 Acquisition modality

Clinically used AEC mode with moving tube (see Table 1.15), compression only if needed (see Table 1.2), compression paddle at equivalent breast thicknesses (see table 3.1).

	GE Heathcare Pristina	Hologic Selenia Dimensions / 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
Acquisition protocol	3D	Flat Field Tomo/ PMMA Mode	Quality Control	Tomo	QC Raw Tomo	Tomo
Fully automatic AEC modality	AOP	Autofilter, AEC Sensor Auto	Autofilter	OPDOSE	iAEC	Full AUTO Pre
Dose Level[22]	**STD** STD+	**Standard**, Enhanced	**Standard** (Low dose and contrast available on request)	Low Medium Low **Medium** Medium High High	L **N** H	**Low Dose** High Contrast
Compression paddle	24x30	24x30 Fixed (not "fast")	24x30	24x30	24x30	24x30

Table 1.15 DBT acquisition modalities to be used for AEC tests.
Standard dose levels are typed in bold.

22 For acceptance test check all dose levels and AEC mode, for routine test choose the dose level used to perform clinical exams.

3.1.4 Test equipment

- 7 PMMA plates (rectangular or breast shape, not covering the whole detector, 10 mm thick)
- 1 PMMA plate (rectangular or breast shape, not covering the whole detector, 5 mm thick)
- Spacers (only if compression is mandatory)
- Al sheet (10mm x 10mm, 0.2 mm thick)

3.1.5 Test procedure

Automatic exposure control performance in the clinically relevant AEC mode for different equivalent breast thicknesses should be measured using PMMA plates with thicknesses ranging from 20 to 70 mm (see Table 3.1).

PMMA thickness (mm)	Equivalent breast thickness (mm)
20	21
30	32
40	45
45	53
50	60
60	75
70	90

Table 3.1 Height of the compression paddle when using different PMMA thickness.

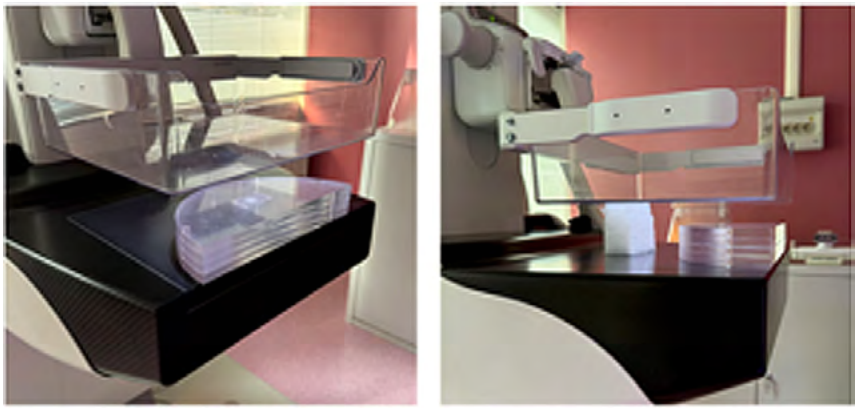

Figure. 3.1 Set up for the AEC performance test without (left) and with (right) spacer.

Figure. 3.2 Set up for the AEC performance test, front view and side view a) without and b) with spacer.

Position an aluminium sheet of dimensions 10 mm x10 mm and 0.2 mm thick on 20 mm PMMA plates or between two 10 mm PMMA plates. Position the aluminium at reference position (6 cm from the chest wall), as shown in Figure 3.1 and Figure 3.2 and the compression paddle at the equivalent breast thickness (see Table 3.1).
If compression is necessary to make an exposure with AEC, then spacers may be used, positioning them at least 17 cm from the chest wall region. Expose with DBT acquisition modality of Table 1.15. Record the exposure parameters (anode/filter combination, kV, mAs, ESAK and AGD).
Repeat this measurement for the PMMA thicknesses according to Table 3.1 by adding additional slabs of PMMA on top of the stack and positioning the compression paddle at the equivalent breast thickness.

Remark 1: if displayed compression height for the 2 smaller thicknesses are greater than 21 mm or 32 mm (due to compression paddle) with any compression force used, perform the exposure in the semiautomatic mode, using anode/filter combination and kV that would be selected with correct compression heightRemark 2: ask to manufacturer the AGD calculation methods for DICOM Tag Organ Dose (0040,0316) used and if recorded K values in Tag (0040,8302) are with or without backscatter.

Remark 2: at acceptance, verify that the Al sheet of dimensions 10 mm x10 mm and 0.2 mm thick doesn't modify significantly the exposure parameters, by acquiring images of the same phantoms without Al sheet.

3.1.6 Image analysis

Linearize the acquired projection images. Position a 5 mm x 5 mm ROI in the centre of the image of the aluminium sheet in the first projection image, and position two 5 mm x 5 mm ROIs in the background areas on the chest wall and nipple sides of the aluminium sheet, see Figure 3.3.
In the first projection image, locate the aluminium sheet and place a 5 mm x 5 mm ROI in its centre; in addition place two 5 mm x 5 mm ROIs in the background areas on either sides of the chest wall and nipple of the aluminium sheet (see Figure 3.3).

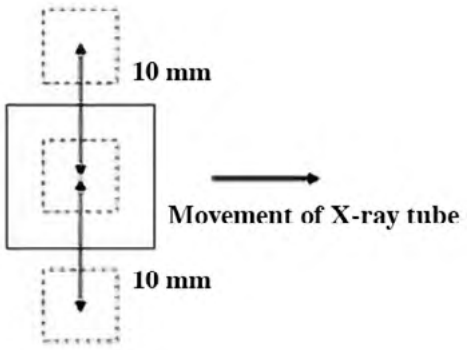

Fig.3.3 Position of the ROIs for calculating SDNR.

The centres of both background areas should be at a distance of 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 pixel values PV_{AI} in the ROI centred in the aluminium sheet and PV and SD in the background ROIs. Calculate PV_{BG} (background) and SD_{BG} (background) according to:

$$SD_{BG} = \frac{\sum_{1}^{2} SD\,(ROI_n)}{2}$$

$$PV_{BG} = \frac{\sum_{1}^{2} PV\,(ROI_n)}{2}$$

Calculate the SDNR of the aluminium object with the formula:

$$SDNR = \frac{PV_{BG} - PV_{AI}}{SD_{BG}}$$

For the analysis MAMMO_QC could be used *(Group DBT, subgroup AEC, plugin SDNR Tomo)*.

3.1.7 Acceptable Levels

Variation in SDNR with respect to the corresponding baseline value should be <15%.

3.1.8 Typical Values

The SDNR typical values for standard dose levels and different breast thicknesses are listed for the different DBT systems in Appendix D.

3.1.9 Test frequency

Acceptance test, constancy test every year and after x-ray tube/filter change, detector calibration or change, software upgrade.

3.2 Short term reproducibility

3.2.1 Purpose

Purpose of the test is to verify the stability of the AEC in 5 different repeated exposures in terms of exposure parameters, signal and dose.

3.2.2 Images type

First/second 'for processing' projection images (see table 1.3).

GE Heathcare Pristina	Hologic Selenia Dimensions	Hologic 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration	Siemens Mammomat Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
First	First	First	Second	Second	Second	First	First

Table 1.3 First projection image (useful for AEC evaluation) where exposure parameters are determined by AEC.

3.2.3 Acquisition modality

Clinically used AEC mode with moving tube (see table 1.15), compression about 100 N.

	GE Heathcare Pristina	Hologic Selenia Dimensions / 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
Acquisition protocol	3D	Flat Field Tomo/ PMMA Mode	Quality Control	Tomo	QC Raw Tomo	Tomo
Fully automatic AEC modality	AOP	Autofilter, AEC Sensor Auto	Autofilter	OPDOSE	iAEC	Full AUTO Pre
Dose Level[23]	**STD** STD+	**Standard**, Enhanced	**Standard** (Low dose and contrast available on request)	Low Medium Low **Medium** Medium High High	L **N** H	**Low Dose** High Contrast
Compression paddle	24x30	24x30 Fixed (not "fast")	24x30	24x30	24x30	24x30

Table 1.15 DBT acquisition modalities to be used for AEC tests.
Standard dose levels are typed in bold.

3.2.4 Test equipment

PMMA plates 40 mm thick (rectangular or breast shape, not covering the whole detector).

3.2.5 Test procedure

Position the PMMA stack on the bucky, compress and expose in the clinically used AEC mode. Record the exposure settings. Move the compression paddle, then compress again and repeat the procedure 4 more times .

3.2.6 Image analysis

Linearize the acquired projection images.
Measure the average PV and SD in the reference ROI in the first/second projection image and calculate SNR. Calculate the variation in terms of current-time product (mAs) and SNR.

For the analysis MAMMO_QC could be used *(Group DBT, subgroup AEC, plugin Short-term DBT).*

23 For acceptance test check all dose levels and AEC mode, for routine test choose the dose level used to perform clinical exams.

3.2.7 Acceptable Levels

Acceptable: Variation in total current-time product (mAs) < 5%, variation in SNR < 10%.

3.2.8 Typical Values

No typical values are provided.

3.2.9 Test frequency

Acceptance, constancy every year or after detector change.

3.3 AEC Response to local and global variations in breast density

3.3.1 Purpose

The purpose of the Local Dense Area test is to verify whether the AEC system correctly adjusts kV and mAs to achieve the desired target image quality level (SDNR) within the densest area of the breast.
Most systems measure the attenuation of the imaged object during a pre-exposure. The areas with highest attenuation in the clinically relevant part of the image should determine the exposure factors for imaging.
We require that the SDNR in the projection images is adjusted to the (relatively large) regions with highest density.

3.3.2 Images type

First/second "for processing" projection images (see table 1.3).

GE Heathcare Pristina	Hologic Selenia Dimensions	Hologic 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration	Siemens Mammomat Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
First	First	First	Second	Second	Second	First	First

Table 1.3 First projection image (useful for AEC evaluation) where exposure parameters are determined by AEC.

3.3.3 Acquisition modality

Clinically used AEC mode with moving tube (see table 1.15), compression only if needed (see table 1.2), compression paddle at 50 mm height.

	GE Heathcare Pristina	Hologic Selenia Dimensions / 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
Acquisition protocol	3D	Flat Field Tomo/ PMMA Mode	Quality Control	QC Raw Tomo	TomoMax4.0	Tomo
Fully automatic AEC modality	AOP	Autofilter, AEC Sensor Auto	Autofilter	OPDOSE	iAEC	Full AUTO Pre
Dose Level[24]	**STD** STD+	**Standard**, Enhanced	**Standard** (Low dose and contrast available on request)	Low Medium Low **Medium** Medium High High	L **N** H	**Low Dose** High Contrast
Compression paddle	24x30	24x30 Fixed (not "fast")	24x30	24x30	24x30	24x30

Table 1.15 DBT acquisition modalities to be used for AEC tests. Standard dose levels are typed in bold.

24 For acceptance test check all dose levels and AEC mode, for routine test choose the dose level used to perform clinical exams.

3.3.4 Test equipment

- PMMA plates 40 mm thick (rectangular or breast shape, not covering the whole detector)
- Two spacers (10 mm thick) (only if compression is mandatory)
- Small PMMA plates 4-10-14 mm thick (dimensions 20 mm x 40 mm)
- Small Al sheet (0.2 mm thick)

3.3.5 Test procedure

Position a stack of 40 mm PMMA on the bucky. Put spacers on top of the stack (if needed), such that the compression paddle is positioned at a height of 50 mm above the breast holder (compression force can be applied if needed). This simulates the attenuation of a 50 mm thick fatty breast.
On the compression paddle, put a small Al sheet (0.2 mm thick) at reference position, make an exposure in the clinically relevant AEC mode and record the exposure factors (anode/filter combination, kV, mAs) and AGD.
Then a first small PMMA plate representing an area with higher glandularity (dimensions: 20 mm x 40 mm, 4 mm thick) is positioned on the Al sheet, see figure 3.4.

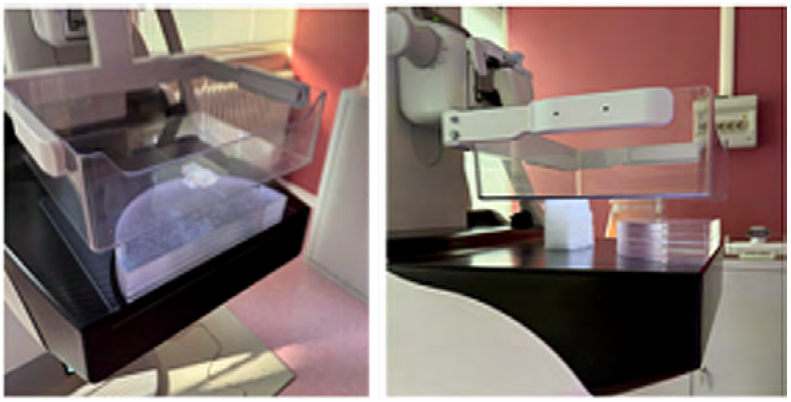

Figure 3.4 Set up for the AEC response for local and global variation without (left) and with (right) spacer.

Repeat an exposure in the same AEC mode and record the exposure factors and AGD_{Ref}.
Add other small PMMA plates to reach 10 mm and repeat the procedure until a total thickness of 14 mm small PMMA plates has been added.
This is approximately equivalent to a 50 mm thick standard model breast with 100% glandularity in the central region (see Table 3.4).

Small added PMMA thickness (mm)	Glandularity (%)
0	0%
4	**29% (Reference)**
10	71%
14	100%

Table 3.4 Equivalent breast glandularity for a 50 mm breast simulated adding small PMMA thickness to 40 mm PMMA block.

3.3.6 Image analysis

Linearize the acquired projection images.

On the first/second projection images (see table 1.3), measure PV and SD in the area of small PMMA plates (extra attenuation area) using ROIs of 5x5 mm^2 (see Figure 3.5) and calculate the average values PV_{PMMA} and SD_{PMMA} according to:

$$SD_{PMMA} = \frac{\sum_{1}^{2} SD\,(ROI_n)}{2} \qquad PV_{PMMA} = \frac{\sum_{1}^{2} PV\,(ROI_n)}{2}$$

Measure PV_{Al} on the corresponding ROI 5x5 mm^2 centred on the Al sheet (see Figure 3.5) and calculate SDNRi with the following formula:

$$SDNR_i = \frac{PV_{BG} - PV_{AI}}{SD_{BG}}$$

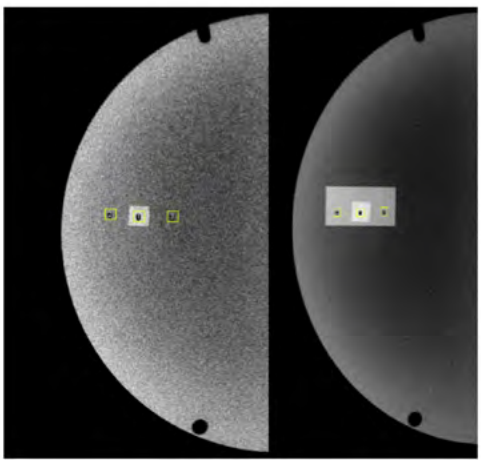

Figure 3.5 ROI for SDNR evaluation on the projection images

For each breast glandularity calculate the variation in terms of SDNR and AGD:

$$AGD_{dev}(\%) = 100 \cdot \frac{AGD_i - AGD_{Ref}}{AGD_{Ref}} \qquad SDNR_{dev}(\%) = 100 \cdot \frac{SDNR_i - SDNR_{Ref}}{SDNR_{Ref}}$$

Where AGD_{ref} and SDN_{Rref} are relative to 4 mm added small PMMA.
Calculate the max AGD_dev(%) value and min SDNR_dev(%) value.

For the analysis MAMMO_QC could be used *(Group DBT, subgroup AEC, plugin Local Dense Area DBT).*

3.3.7 Acceptable Levels

max AGD_dev(%) > 0
min SDNR_dev(%) > -30%

3.3.8 Typical Values

Typical values in terms of minimum percentage SDNR deviation SDNR_dev(%) and maximum percentage AGD deviation AGD_dev(%) respect values obtained for the reference glandularity are listed in Appendix E.
For some systems kV are increased with increasing small PMMA plates thickness.

3.3.9 Test frequency

Acceptance or after detector change or software upgrade.

3.4 Long term reproducibility

3.4.1 Purpose

Purpose of the test is to verify the stability of the AEC over time in terms of exposure parameters, signal and dose.

3.4.2 Images type

Reconstructed DBT images.

3.4.3 Acquisition modality

Clinically used AEC mode with moving tube (see table 1.16), compression about 100 N.

	GE Heathcare Pristina	Hologic Selenia Dimensions / 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
Acquisition protocol	3D	Tomo HD RCC	Tomo	Tomo	Tomo	Tomo
Fully automatic AEC modality	AOP	Autofilter, AEC Sensor Auto	Autofilter	OPDOSE	iAEC	Full AUTO Pre
Compression paddle	24x30	24x30 Fixed (not "fast")	24x30	24x30	24x30	24x30

Table 1.16 Acquisition modalities for image quality tests on reconstructed and Synthetic images.

3.4.4 Test equipment

Weekly: PMMA plates 45 mm thick (rectangular, covering the whole detector) or alternatively standard block supplied by vendors (see table 3.6).

Monthly: PMMA plates 20 and 70 mm thick.

GE Healthcare SenoClaire	GE Heathcare Pristina	Hologic Selenia Dimensions/ 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fujifilm Amulet Innovality
25	25	40	40	-	40

Table 3.6. Typical PMMA thickness of standard block supplied by vendors.

3.4.5 Test procedure

Weekly: Position the standard PMMA stack on the bucky and expose in the clinically used AEC mode.
Record the exposure settings (anode/filter combination, kV, mAs) and AGD.

Monthly: Repeat the test for PMMA 20 and 70 mm thick.
Calculate the percentage mAs variation *mAs_var (%)* with respect to baseline.

$$mAs\_\mathrm{var}\,(\%) = 100 \cdot \frac{mAs_i - mAs_{Ref}}{mAs_{Ref}}$$

3.4.6 Image analysis

Visual inspection of the images.

3.4.7 Acceptable Levels

Target/Filter combination and kV should remain unchanged. The *mAs_var(%)* should be <10%.
No artefacts should be present.

3.4.8 Typical Values

No typical values provided.

3.4.9 Test frequency

Acceptance test, constancy test every week/month and after x-ray tube/filter change, detector calibration or change, software upgrade.

4. IMAGE RECEPTOR

4.1 Response function

4.1.1 Purpose

The purpose of the test is to establish the relationship between the average PV and detector exposure and to calculate the monotonic function to be used to linearize the 'for processing' projection images.

4.1.2 Images type

First "for processing" projection image.

Remark: in manual mode (in the absence of a pre-exposure) the total mAs are evenly distributed across all projections, thus the first projection is always suitable for the analysis regardless of the system.

4.1.3 Acquisition modality

First "for processing" projection image.

GE Heathcare Pristina	Hologic Selenia Dimensions	Hologic 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
3D static Modality	Zero Degree Mode	Zero Degree Mode	M2	Stationary mode	Stationary/ Fixed mode	Service

Table 1.13 DBT acquisition modalities with fixed tube for x-ray tube measurements.

GE Heathcare Pristina	Hologic Selenia Dimensions	Hologic 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
-	Flat Field Tomo	Flat Field Tomo	Quality Control	QC Raw Tomo	TomoMax4.0	-

Table 1.14 Acquisition modalities to obtain for processing projection images.

4.1.4 Test equipment

- Protective device to shield the image detector
- Calibrated dosimeter (Ionisation chambers or solid-state detectors calibrated for clinical beam used)
- 2 mm thick Al sheet (purity ≥ 99%)
- Spreadsheet to calculate the response function

4.1.5 Test procedure

Air Kerma measurements

Remove all detachable parts from the X-ray beam, including the compression paddle. Attach the 2 mm thick aluminium sheet to the X-ray tube and cover the detector with the protective device. Select the correct acquisition mode (see Table 1.13) and set the manual exposure mode from the mammography unit console. Select the target/ filter combination and tube voltage chosen in fully automatic clinical AEC mode for a 45 mm thick PMMA block or

standard block. Place the sensitive area of the dosimeter in the reference point and measure the dose three consecutive times by manually setting increasing mAs, i.e. 10, 20, 30 mAs. Correct the measured air kerma values with the inverse square law to obtain the relationship between the current-time product and the air kerma/projection on the input plane of the detector (K_D).
This linear trend is used to choose five mAs values that produce a KD/projection on the detector between ~5 μGy/projection and ~50 μGy/projection.

Images acquisition
Remove the protective device, select the proper acquisition modality (see Table 1.14) and set the manual exposure mode from the mammography unit console. Acquire the DBT scans at the chosen mAs values (at least 5), or the closest that can be set. The antiscatter grid must be removed. For systems where the antiscatter grid must be in place during DBT scans, a transmission factor should be estimated in FFDM mode using the same X-ray spectrum and 2 mm thick Al filter used to acquire the response function scans.

Remark: for GE Pristina, which does not allow the antiscatter grid removal, consider a transmission factor of 0.6.

4.1.6 Image analysis
Measure the average PV in the reference ROI in the first projection image. Plot the average PV against incident air kerma at the detector input plane. Fit the appropriate model function and record the fit coefficients *a,b* and the correlation coefficient:

$$PV = a \cdot K_D + b$$

or

$$PV = a \cdot \ln(K_D) + b$$

For the analysis ImageJ plugins MAMMO_QC *(Group General Tests, plugin Response function)* or COQ *(Mammography-Response Curve)* could be used.

4.1.7 Acceptable Levels
Where $R^2 \leq 0.98$ detector response should be investigated. The response function should match the specification of the manufacturer.

4.1.8 Typical Values
A linear response curve is expected for all the main DBT systems available on the market, with the exception of the FujiFilm Amulet Innovality system, characterised by a logarithmic trend. The typical values in terms of coefficients a and b are reported in Appendix F.

4.1.9 Test frequency
Acceptance or after detector change or software upgrade.

4.2 Noise analysis

4.2.1 Purpose

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

4.2.2 Images type

First 'for processing' projection image.

4.2.3 Acquisition modality

The images acquired for measurement of detector response (test 4.1) are used for this test.

4.2.4 Test equipment

- Spreadsheet to perform the noise component analysis

4.2.5 Test procedure

Use the images made in test 4.1.

4.2.6 Image analysis

Linearize the acquired projection 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 σ against air kerma/projection K at the input plane of the x-ray detector. Fit the polynomial curve in equation:

$$\sigma^2 = e + q \cdot K + s \cdot K^2$$

where e is the electronic noise fit coefficient, q quantum noise coefficient and s is the structure noise coefficient. 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 K.
In order to establish the typical clinical detector air kerma/projection levels, use the measured pixel value from the AEC performance test (see section 3.1). 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 analysis MAMMO_QC could be used *(Group General Tests, plugin Noise Evaluation)*.

4.2.7 Acceptable Levels

Quantum noise must be the largest noise component at clinical detector air kerma levels. 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.

4.2.8 Typical Values

No typical values are provided.

4.2.9 Test frequency

Acceptance test and after detector calibration or change.

4.3 System projection MTF

4.3.1 Purpose

The purpose of the test is to quantify the blurring in projection images at various height above the bucky.

4.3.2 Images type

Projection image closest to the 0°.

4.3.3 Acquisition modality

GE Heathcare Pristina	Hologic Selenia Dimensions	Hologic 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
-	Flat Field Tomo	Flat Field Tomo	Quality Control	QC Raw Tomo	TomoMax4.0	-

Table 1.14 Acquisition modalities to obtain for processing projection images.

4.3.4 Test equipment

- A thin radiopaque edge with straight, sharp edges of minimum dimension 50 x 50 mm^2 suitable for the measurement of the MTF
- 2 mm thick Al sheet (purity ≥ 99%)
- 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
- Spreadsheet to calculate the MTF50

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.

4.3.5 Test procedure

Remove the compression paddle. If a compression paddle is required, then position it in contact with the edge.
Position a 2 mm thick aluminium sheet 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 (Figure 4.1).
Expose with a clinically used protocol with the same anode/filter combination, kV and mAs (or the closest values that can be set in manual mode) obtained in the test 3.1 for 20 mm PMMA thick.
Rotate the MTF edge through 90° and repeat to acquire the MTF edge image in the orthogonal direction i.e., chest wall-nipple direction (Figure 4.1). 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 PMMA respectively obtained in the test 3.1. 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.

Remark: at constancy tests measuring MTF only at 40 mm above the breast support.

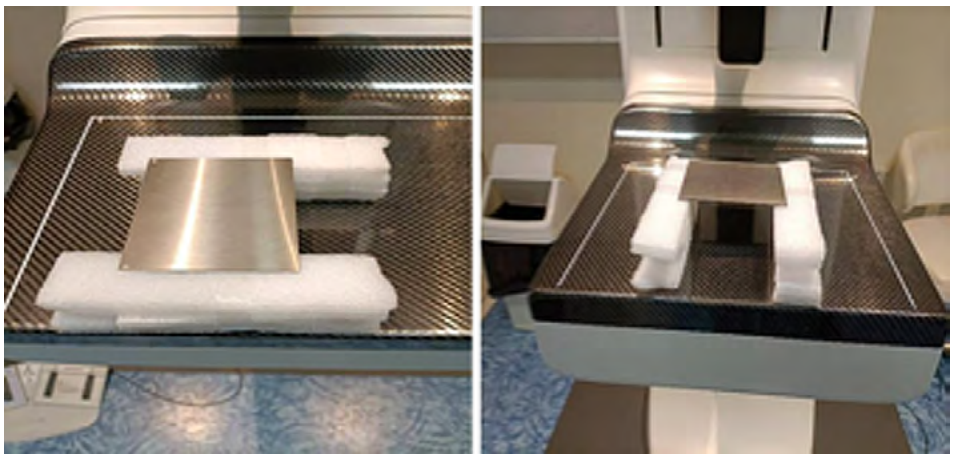

Figure. 4.1 Set up for the system projection MTF test at 40 mm height above the breast support table.

4.2.6 Image analysis

Linearize 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.

For the analysis ImageJ COQ Plugin *(Mammography-DQE-MTF)* or MAMMO_QC Plugin could be used *(General Tests, plugin Edge MTF).*

4.2.7 Acceptable 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 1: 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.

Remark 2: 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 3: if a change in MTF is suspected, then additional steps should be taken to determine the origin of the change.

4.2.8 Typical Values
No typical values are provided.

4.2.9 Test frequency
Acceptance test, constancy test every year (at 40 mm height) and after x-ray tube/filter change, detector calibration or change.

4.4 Detector element failure

4.4.1 Purpose
The purpose of the test is to check that the interpolation of pixels for non-functioning detector elements ("dels") is not introducing disturbing artefacts with the potential to influence diagnostics.

4.4.2 Images type
No images needed.

4.4.3 Acquisition modality
No acquisition needed.

4.4.4 Test equipment
- Manufacturer's "bad pixel map" on the DBT system

4.4.5 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".

4.4.6 Image analysis
The bad pixel map obtained during the routine QC tests should be compared to previous maps.

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.

4.4.7 Acceptable 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.

4.4.8 Typical Values
No typical values are provided.

4.4.9 Test frequency
Just in case of detector binning: acceptance test and after detector calibration or change.

4.5 Uncorrected defective detector elements

4.5.1 Purpose

The purpose of the test is 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'.

4.5.2 Images type

"For processing" projection images.

4.5.3 Acquisition modality

GE Heathcare Pristina	Hologic Selenia Dimensions	Hologic 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
-	Flat Field Tomo	Flat Field Tomo	Quality Control	QC Raw Tomo	TomoMax4.0	-

Table 1.14 Acquisition modalities to obtain for processing projection images.

Clinically used protocol with moving tube, no compression paddle, manual mode using the exposure setting from AEC performance test 3.1.

4.5.4 Test equipment

- Standard test block

4.5.5 Test procedure

Accurately clean all the equipment parts before performing this test. Make an exposure of the standard test block in manual mode without the compression paddle, using the exposure setting from AEC performance test 3.1.

4.5.6 Image 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.

For the analysis ImageJ plugin MAMMO_QC could be used *(Group DBT, plugin Uncorrected defective elements (TOMO)* or COQ *(Mammography-Bad Pixel).*

4.5.7 Acceptable 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.

4.5.8 Typical Values

No typical values are provided.

4.5.9 Test frequency

Acceptance test, constancy test every year and after detector calibration or change or software upgrade.

5. IMAGE QUALITY OF RECONSTRUCTED AND SYNTHETIC IMAGES

5.1 Stability of image quality in the x-y plane and synthetic image

The test is intended as a performance constancy test over time and in no case it should be interpreted as an absolute measure of image quality nor it could be used to compare equipment from different vendors.
According to EFOMP [10], we recommend the use of readily available digital mammography phantoms, due to the lack of alternative validated methods. Phantoms were chosen among the most widespread options and they are not necessarily designed for DBT acquisitions. Other phantoms, although not mentioned, containing details useful for mammography image quality evaluation, could be considered suitable for the purpose.
Values are given per manufacturer, model and reconstruction algorithm and are derived from measurements made by members of the working group, but should not be regarded as typical values, as they are closely related to the type of processing used. Values are provided just for the phantom structures reported (masses, circular details and spheres). However, to assess the stability of image quality, it is advisable to consider any structures contained in the phantom (e.g. fibres and specks), even if no typical values are given.
Since synthetic images are now widespread and sometimes used clinically, extending the tests to this type of images as well, is advisable.
It is to be noted that, in general, typical values and references adopted for 2D digital mammography aren't suitable for DBT evaluation. Furthermore, the use of linear system theory metrics for reconstructed images is still debated. It is uncertain whether these metrics remain meaningful and reproducible when applied to images reconstructed with iterative or filtered back projection algorithms.

5.1.1 Purpose

The purpose of the test, at acceptance, is to set reference values for technical image quality for synthetic and reconstructed DBT images. Subsequent routine QC test results are intended to be compared with established reference values, in order to detect any changes in performance over time.

5.1.2 Images type

"For presentation" 2D-Synthetic and reconstructed images containing details.

5.1.3 Acquisition modality

Clinically used AEC mode with moving tube (see table 1.16), compression only if needed (see Table 1.2), compression paddle at a height of the Total Thickness of the used phantom (see Table 5.1), dose level and processing algorithm used in the clinic.

	GE Heathcare Pristina	Hologic Selenia Dimensions 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
Acquisition protocol	3D	Tomo HD RCC	Tomo	Tomo	Tomo	Tomo
Fully automatic AEC modality	AOP	Autofilter, AEC Sensor Auto	Autofilter	OPDOSE	iAEC	Full AUTO Pre
Compression paddle	24x30	24x30 Fixed (not "fast")	24x30	24x30	24x30	24x30

Table 1.16 Acquisition modalities to be used to obtain "for presentation" images.

5.1.4 Test equipment

- Option 1: TOMOPHAN phantom (Fig. 5.1 a, Fig. 5.2 a, Table 5.1)
- Option 2: TORMAM phantom (Fig. 5.1 b, Fig. 5.2 b, Table 5.1)
- Option 3: CIRS 015 phantom (Fig. 5.1 c, Table 5.1)

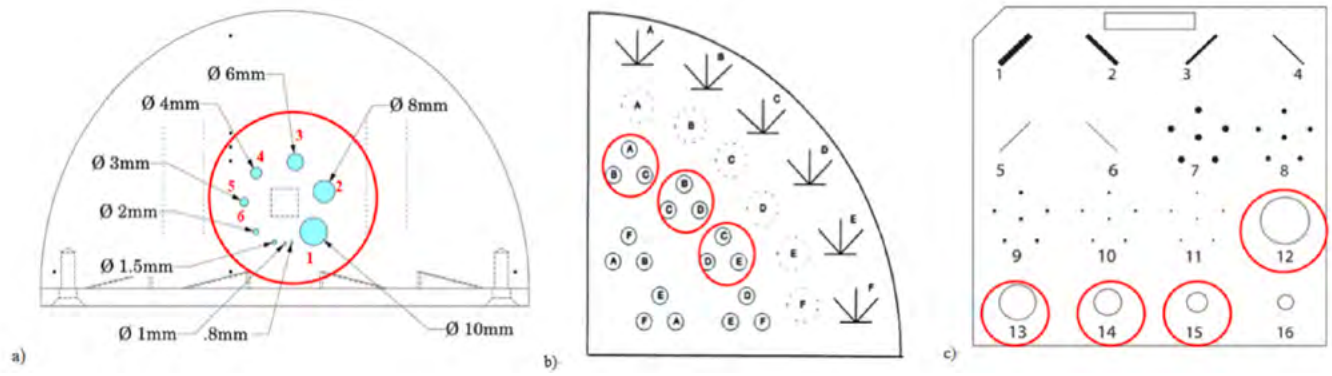

Figure 5.1 Schematic content of the different DBT phantoms and 2D mammography phantoms (a) Tomophan, (b) Tormam, (c) CIRS 015. Details chosen for the analysis are highlighted in red.

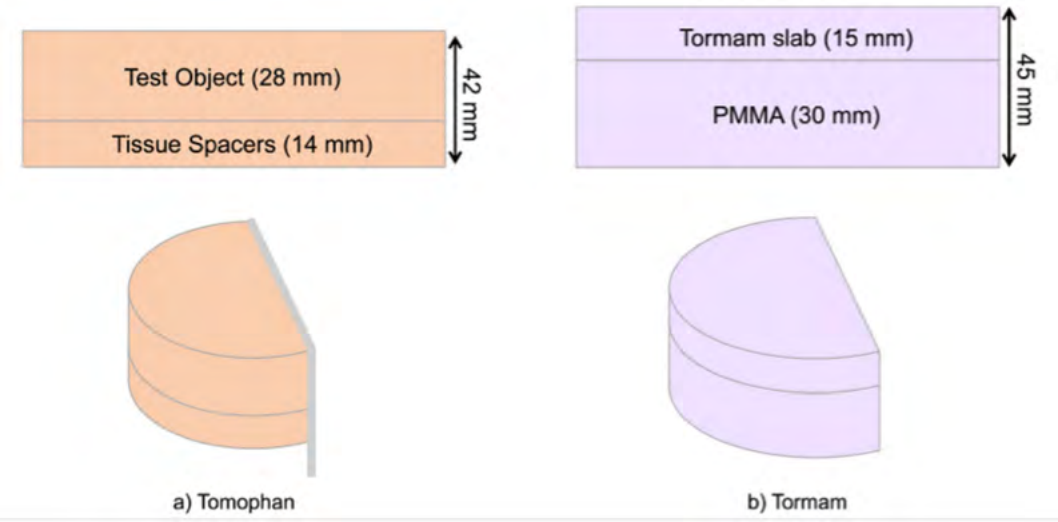

Figure 5.2 Configurations used. (a) For Tomophan the configuration comprises the 14 mm thick Tissue Spacers positioned under the Test Object, for a total thickness of 42 mm. (b) For Tormam the configuration consists of the 15 mm thick Tormam on 30 mm thick PMMA, for a total thickness of 45 mm

	TOMOPHAN	TORMAM	CIRS 015
Analysed details	Low contrast acrylic spheres	Circular details	Masses
Added PMMA thickness(mm)	14	30	-
Total phantom thickness (mm)	42	45	44

Table 5.1 Specifications of different phantoms for image quality test of reconstructed and synthetic images.

Remark 1: the phantoms of options 1 and 3 might be used both for test 5.1Stability of image quality in the x-y plane and synthetic image and for 5.2 Z-resolution.

Remark 2: any phantom, although not mentioned, containing details useful for mammography image quality evaluation, could be considered suitable for the purpose (see Manufacturer specifications for set-up and image quality evaluation). If any useful details for Contrast detail evaluation are present, the image analysis described in section 5.1.6 should be followed.

5.1.5 Test procedure

Position the phantom on the bucky, position the compression paddle at the corresponding total thickness (Table 5.1 and Figure 5.3) and expose with clinical AEC protocol and dose level (Table 1.16). Record the exposure parameters and the AGD value.

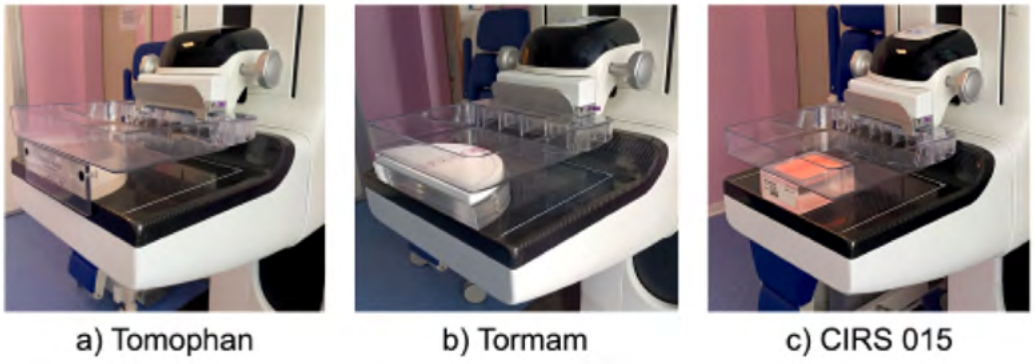

Figure 5.3 Set-up for (a) Tomophan, (b) Tormam, (c) CIRS 015 phantom

Remark: note that for some systems the bucky and the detector are slightly tilted. For all objects to be in focus on the same plane it is necessary to tilt the phantom so that it is parallel to the detector.

5.1.6 Image analysis

On the reconstructed focal plane and synthetic image calculate the detail contrast SDNR for each detail contained in the phantom as:

$$SDNR = \frac{PV_{detail} - PV_{Bg}}{SD_{Bg}}$$

where PV_{detail} is the average pixel values (PV) of the detail ROI, PV_{Bg} is the average PV of Background ROIs and SD_{Bg} is the Standard Deviation of the Background ROIs.
ROI sizes and positions and for the different phantoms are reported respectively in Table 5.2 and Figures 5.4, 5.5 and 5.6.

For the analysis MAMMO_QC could be used *(Group DBT, Subgroup Image Quality, plugin TOMOPHAN, TORMAM or CIRS015).*

TOMOPHAN		
Background ROI Area (mm²)	26,0	
Detail ROI Area (mm²)	**Sphere Ø 10 mm**	26,0
	Sphere Ø 8 mm	17,0
	Sphere Ø 6mm	9,0
	Sphere Ø 4 mm	4,0
	Sphere Ø 3 mm	2,0
	Sphere Ø 2 mm	1,0

TORMAN		
Background ROI Area (mm²)	20,0	
Detail ROI Area (mm²)	**A**	5,0
	B	
	C	
	D	
	E	

CIRS 015		
Background ROI Area (mm²)	35	
Detail ROI Area (mm²)	**Mass 12**	35
	Mass 13	17,5
	Mass 14	12,5
	Mass 5	5

Table 5.2 Areas of Background ROIs and detail ROIs used for the SDNR evaluation with the different phantoms.

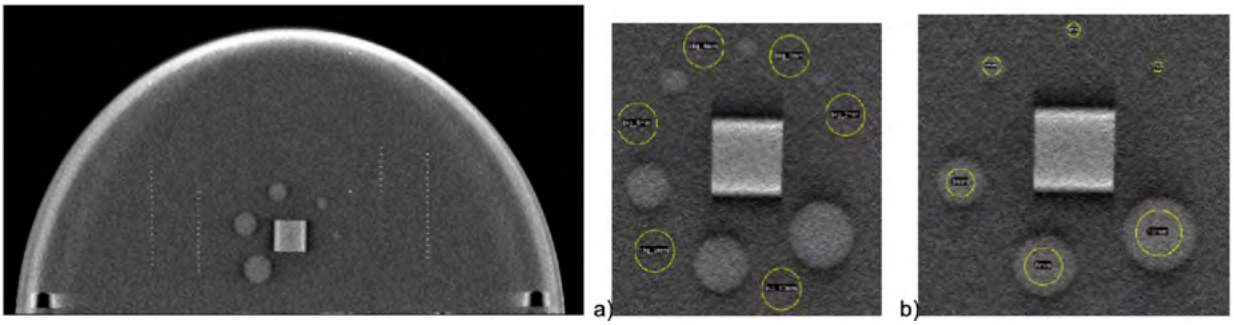

Figure 5.4 Position of (a) Background ROIs and (b) detail ROIs used for the SDNR evaluation with Tomophan phantom.

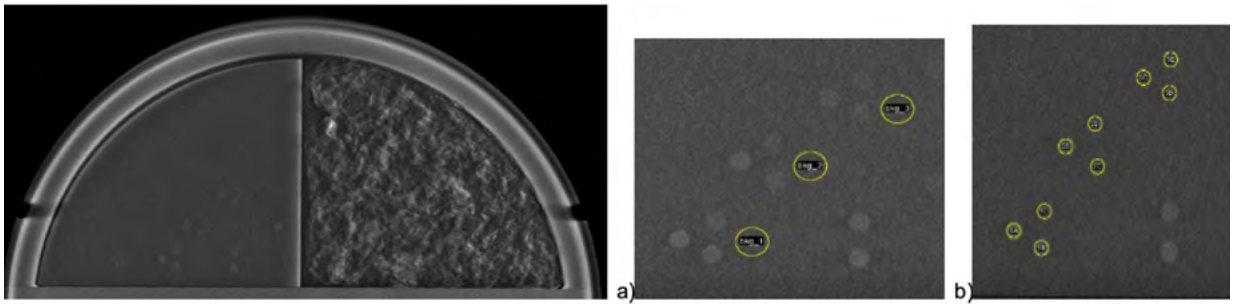

Figure 5.5 Position of (a) Background ROIs and (b) detail ROIs used for the SDNR evaluation with Tormam phantom.

Figure 5.6 Position of (a) Background ROIs and(b) detail ROIs used for the SDNR evaluation with CIRS 015 phantom.

5.1.7 Acceptable Levels

For each detail contained in the considered phantom the difference in SDNR respect to the corresponding baseline value should be <25%.

5.1.8 Typical Values

No typical values are given. As an example, the SDNR values for reconstructed and synthetic images for standard dose levels and different phantoms measured by the working group on different DBT systems are given in Appendix G, but it should be noted that the use of different processing could result in different values.

5.1.9 Test frequency

Acceptance test, constancy every year or after X-ray tube, detector/ clinical AEC mode change or software upgrade.

5.2 Z-resolution

5.2.1 Purpose

The purpose of the test is to quantify the resolution in the z-direction, i.e. the signal spread of an object between planes. This test can also be useful as a measure of the geometric stability of the system over time.

5.2.2 Images type

"For presentation" reconstructed DBT images.

5.2.3 Acquisition modality

Clinically used AEC mode with moving tube (see table 1.16), compression only if needed (see Table 1.2), compression paddle at a height of the Total Thickness of the used phantom (see Table 5.1).

	GE Heathcare Pristina	Hologic Selenia Dimensions 3Dimensions	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fujifilm Amulet Innovality	Metaltronica Helianthus
Acquisition protocol	3D	Tomo HD RCC	Tomo	Tomo	Tomo	Tomo
Fully automatic AEC modality	AOP	Autofilter, AEC Sensor Auto	Autofilter	OPDOSE	iAEC	Full AUTO Pre
Compression paddle	24x30	24x30 Fixed (not "fast")	24x30	24x30	24x30	24x30

Table 1.16 Acquisition modalities to obtain for presentation images.

5.2.4 Test equipment

- Option 1: CIRS 011 A phantom (Fig. 5.7 a, Table 5.3)
- Option 2: CIRS 015 phantom (Fig. 5.7 b, Table 5.3)
- Option 3: Modular DBT phantom (Fig. 5.7 c, Fig. 5.8 a, Table 5.3)
- Option 4: PIXMAM phantom (Fig. 5.7 d, Fig. 5.8 b, Table 5.3)
- Option 5: TOMOPHAN phantom (Fig. 5.7 e, Fig. 5.8 c, Table 5.3)

Remark: the phantoms of options 1, 2, 3 and 5 might be used both for test 5.1. Stability of image quality in the x-y plane and synthetic image and for 5.2 Z-resolution.

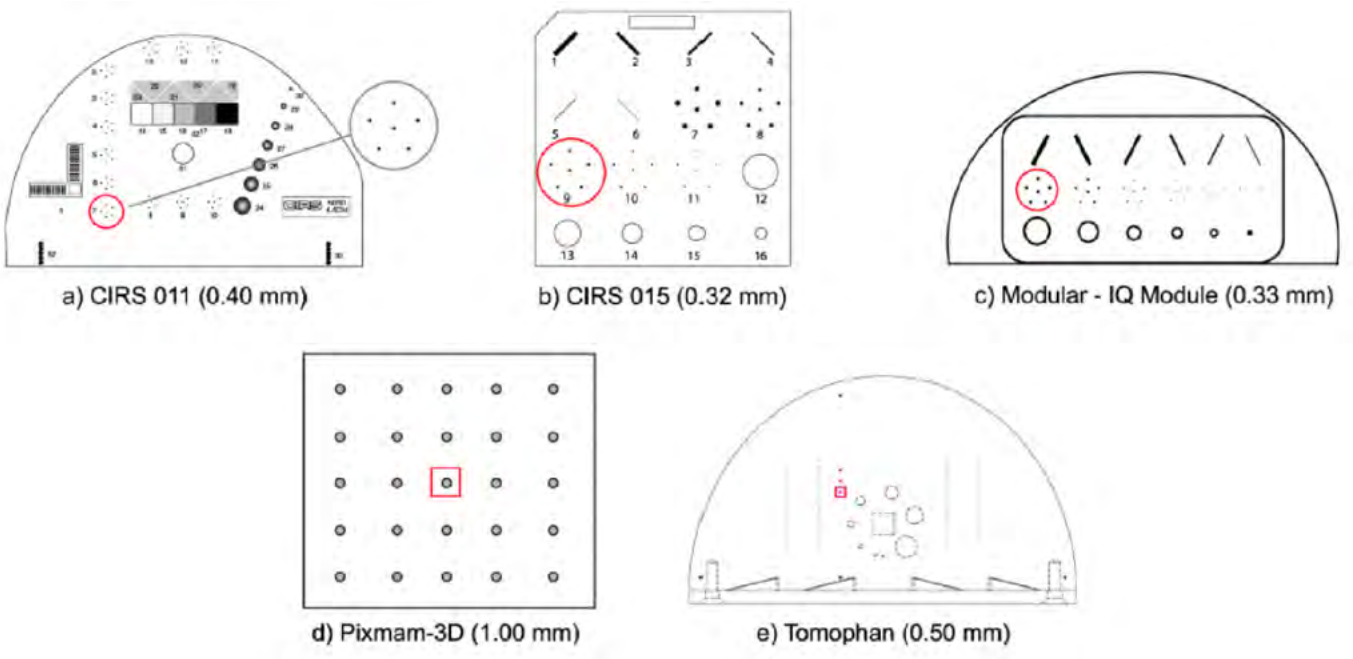

Figure 5.7 Schematic content of the different DBT phantoms and 2D mammography phantoms. (a) CIRS 011 (b) CIRS 015. (c) Modular DBT. (d) PIXMAM. (e) Tomophan. Details chosen for the analysis are highlighted in red.

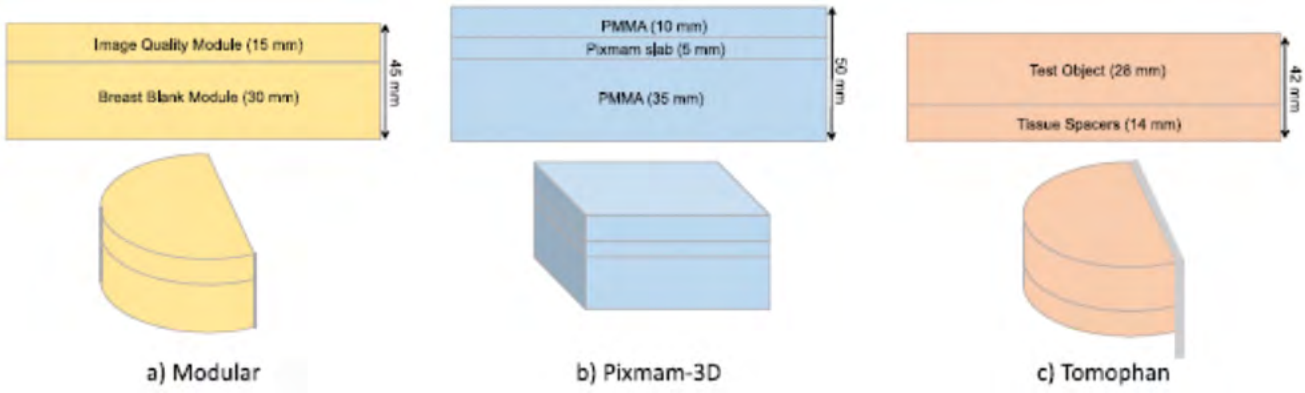

Figure 5.8 Setups used for phantoms with modular designs. (a) The configuration consists of a 15 mm thick Image Quality module on a 30 mm thick Breast Blank module, for a total thickness of 45 mm. (b) The Pixmam-3D phantom consists of a 5 mm thick PMMA sheet containing details. The configuration chosen for this study consists of 35 mm thick PMMA, Pixmam phantom, 10 mm thick PMMA, for a total thickness of 50 mm. (c) The configuration comprises also the 14 mm thick Tissue Spacers positioned under the Test Object, for a total thickness of 42 mm.

Phantom	CIRS 011	CIRS 015	Modular	Pixmam-3D	Tomophan
N_p	12	17	3	16	17
Phantom thickness (mm)	45	44	45	50	42
Detail type	specks	specks	specks	spheres	spheres
Detail material	$CaC0_3$	Al_20_3	Al_20_3	Al	Al
Detail diameter * (mm)	0.40	0.32	0.33	1.00	0.50
Detail height ** (mm)	23	37	37	37	38

* Diameter declared in the x-y plane (parallel to the detector).
** Height at which the detail is positioned relative co the detector plane.

Table 5.3 Characteristics of different phantoms for z-resolution test [19].

5.2.5 Test procedure

Position the phantom on the bucky, position the compression paddle at the corresponding total phantom thickness (Table 5.3 and Figure 5.9) and expose with clinical AEC protocol (Table 1.16).

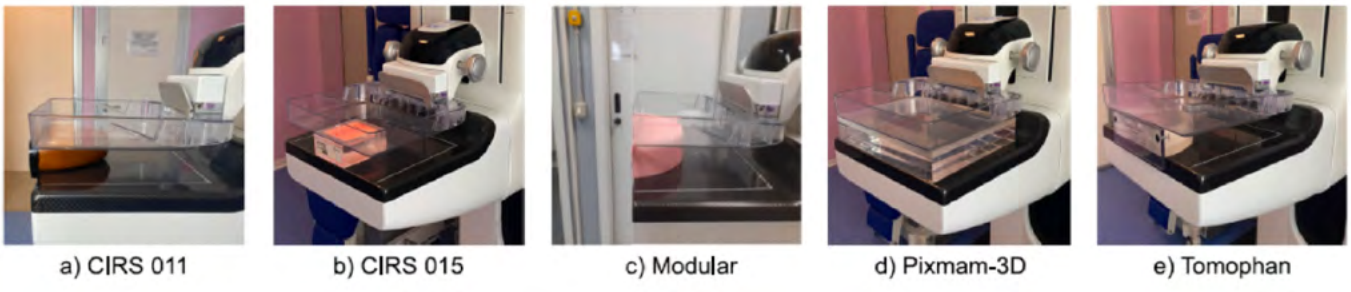

Figure 5.9 Set-up for different phantoms

5.3.5 Image analysis

For each reconstructed images i, measure the average PV in the Background ROI and the maximum PV in the Detail ROI (corresponding to sphere or speck in the focal plane) and calculate ASF as:

$$ASF\ (i) = PV^{max}_{detail}\ (i)\ -\ \overline{PV_{Bg}(i)}$$

Renormalize the ASF(i) values in the interval [0,1] according to the formula:

$$ASF_{norm} = \frac{ASF\ (i)\ -\ \min\ (ASF)}{\max\ (ASF)\ -\ \min\ (ASF)}$$

Calculate the z-resolution as the FWHM of the ASF_{norm} profile.

ROIs size and positions for different phantoms are given in Table 5.4 and Figure 5.9.

For the analysis MAMMO_QC could be used *(Group DBT, Subgroup ASF, plugin Specks Phantom or Spheres Phantom)*.

	CIRS 011	CIRS 015	Modular DBT (IQ Module)	Pixmam-3D	Tomophan
Detail type	specks	specks	specks	spheres	spheres
Background ROI (mm^2)	15	15	15	15	15
Detail ROI (mm^2)	3.5	3.5	3.5	15	15

Table 5.4 Background ROIs and details ROIs for different phantoms

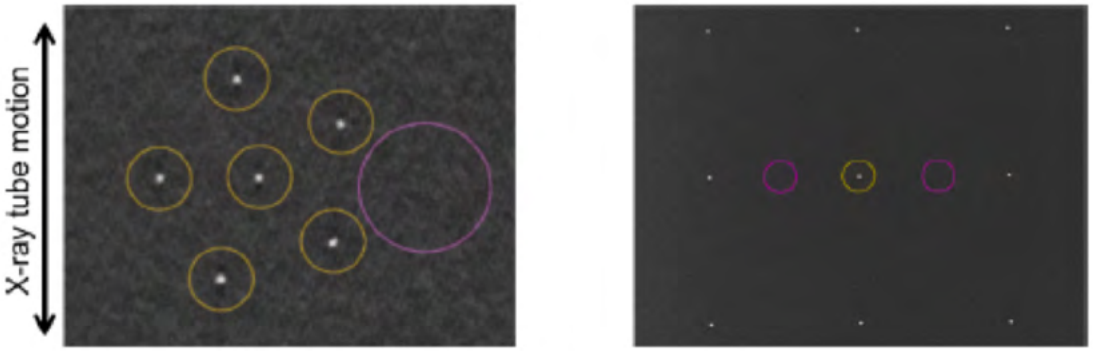

Figure 5.10 ROIs used for specks (a) and spheres (b) for ASF evaluation

5.2.7 Acceptable Levels

Difference in FWHM value should be ≤ 20% respect to baseline.

5.2.8 Typical Values

The FWHM typical values for different phantoms are given for the different DBT systems in Appendix H [19].

5.2.9 Test frequency

Acceptance test, constancy test every year and after x-ray detector change, software upgrade.

5.3 Homogeneity and Artefact evaluation

5.3.1 Purpose

Purpose of the test is to evaluate the homogeneity and the potential presence of artefacts on the DBT reconstructed and 2D-Synthetic images.

5.3.2 Images type

DBT reconstructed and 2D-Synthetic images.

5.3.3 Acquisition modality

Clinically used protocol with moving tube, no compression paddle, manual exposure.

5.3.4 Test equipment

PMMA plates 50 mm thick (rectangular, covering the whole detector).

5.3.5 Test procedure

Position the standard PMMA stack on the bucky and expose it with a clinically used protocol.
Expose the phantom with the same anode/filter combination, kV and mAs (or the closest values that can be set in manual mode) obtained in the test 3.4 for 50 mm PMMA thick.

5.3.6 Image analysis

Visually inspect all focal planes of the reconstructed tomosynthesis and synthetic images for artefacts and inhomogeneities.
For the analysis MAMMO_QC *(Group DBT, Homogeneity, plugin UNIF BTO for DBT images and Group FFDM, plugin Homogeneity (EUREF)* or COQ *(Mammography -Uniformity)* could be used.

5.3.7 Acceptable Levels

No artefacts or visible inhomogeneities should be present.

5.3.8 Typical Values

No typical values are provided.

5.3.9 Test frequency

Acceptance test, constancy test every year and after x-ray tube/filter change, detector calibration or change, software upgrade.

6. DOCUMENTS AND REFERENCES

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APPENDIX A • Typical X-ray Tube output values

GE Pristina		
Anode/Filter	**kV**	**Tube output (μGy/mAs) at 100 cm**
Mo/Mo	26	26.5 (24.2 - 28.0)
Rh/Ag	34	43.5 (37.5 - 46.9)

Table A.1 Typical incident air kerma (μGy/mAs) at 100 cm measured with compression paddle for GE Pristina systems.

Hologic Selenia Dimensions/3Dimensions		
Anode/Filter	**kV**	**Tube output (μGy/mAs) at 100 cm**
W/Al	28	30.0 (25.7 - 36.7)
W/Al	31	38.6 (33.7 - 46.3)
W/Al	34	48.8 (43.1 - 57.2)
W/Al	37	60.8 (54.0 - 70.0)

Table A.2 Typical incident air kerma (μGy/mAs) at 100 cm measured with compression paddle for Hologic Dimension/3Dimensions systems.

IMS Class		
Anode/Filter	**kV**	**Tube output (μGy/mAs) at 100 cm**
W/Ag	25	13.7 (9.2 - 15.8)
W/Ag	28	19.3 (13.3 - 21.9)
W/Ag	31	26.1 (18.5 - 29.3)
W/Ag	34	34.4 (24.9 - 38.3)

Table A.3 Typical incident air kerma (μGy/mAs) at 100 cm measured with compression paddle for IMS Class systems.

Siemens Inspiration/Revelation		
Anode/Filter	**kV**	**Tube output (μGy/mAs) at 100 cm**
W/Ag	25	8.3 (8.1 - 8.9)
W/Ag	28	11.1 (10.8 - 11.8)
W/Ag	31	14.5 (14.0 - 15.2)
W/Ag	34	18.4 (17.7 - 19.1)

Table A.4 Typical incident air kerma (μGy/mAs) at 100 cm measured with compression paddle for Siemens Inspiration/Revelation systems.

Fuji Amulet Innovality		
Anode/Filter	**kV**	**Tube output (µGy/mAs) at 100 cm**
W/Al	28	31.1 (28.9 - 32.8)
W/Al	31	40.8 (37.7 - 42.9)
W/Al	34	52.1 (47.9 - 54.8)
W/Al	37	65.3 (59.0 - 68.6)

Table A.5 Typical incident air kerma (µGy/mAs) at 100 cm measured with compression paddle for Fuji Amulet Innovality systems.

Metaltronica Helianthus		
Anode/Filter	**kV**	**Tube output (µGy/mAs) at 100 cm**
W/Al	25	45.4 (41.6 - 51.3)
W/Al	28	59.5 (54.4 - 65.4)
W/Al	31	76.0 (69.5 - 81.7)
W/Al	34	95.2 (86.9 - 100.1)

Table A.6 Typical incident air kerma (µGy/mAs) at 100 cm measured with compression paddle for Metaltronica Helianthus systems.

APPENDIX B • Typical HVL values

GE Pristina		
Anode/Filter	**kV**	**HVL (mm Al)**
Mo/Mo	26	0.37 (0.35-0.39)
Rh/Ag	34	0.58 (0.54-0.61)

Table B.1 HVL typical values (mm Al) measured with compression paddle for GE Pristina systems.

Hologic Selenia Dimensions/3Dimensions		
Anode/Filter	**kV**	**HVL (mm Al)**
W/Al	28	0.52 (0.48-0.59)
W/Al	34	0.63 (0.57-0.75)
W/Al	37	0.68 (0.62-0.83)

Table B.2 HVL typical values (mm Al) measured with compression paddle for Hologic Dimension/3Dimensions systems.

IMS Class		
Anode/Filter	**kV**	**HVL (mm Al)**
W/Ag	25	0.50 (0.47-0.55)
W/Ag	31	0.61 (0.56-0.64)
W/Ag	34	0.65 (0.57-0.67)

Table B.3 HVL typical values (mm Al) measured with compression paddle for IMS Class systems.

Siemens Inspiration/Revelation		
Anode/Filter	**kV**	**HVL (mm Al)**
W/Rh	25	0.53 (0.50-0.58)
W/Rh	31	0.60 (0.54-0.64)
W/Rh	34	0.61 (0.59-0.65)

Table B.4 HVL typical values (mm Al) measured with compression paddle for Siemens Inspiration/Revelation systems.

Fuji Amulet Innovality		
Anode/Filter	**kV**	**HVL (mm Al)**
W/Al	28	0.52 (0.49-0.56)
W/Al	34	0.63 (0.53-0.70)
W/Al	37	0.66 (0.57-0.75)

Table B.5 HVL typical values (mm Al) measured with compression paddle for Fuji Amulet Innovality systems.

Metaltronica Helianthus		
Anode/Filter	**kV**	**HVL (mm Al)**
W/Al	25	0.41 (0.40-0.42)
W/Al	31	0.47 (0.44-0.49)
W/Al	34	0.51 (0.50-0.53)

Table B.6 HVL typical values (mm Al) measured with compression paddle for Metaltronica Helianthus systems

APPENDIX C • Typical AGD values

Breast Thickness (mm)	Hologic Selenia Dimensions/ 3Dimension	Fuji Amulet Innovality ST	Fuji Amulet Innovality HR	GE Pristina	IMS Class	Siemens Ispiration/ Revelation	Metaltronica Helianthus Narrow	Metaltronica Helianthus Intermediate	Metaltronica Helianthus Wide
21	0.9 (0.7-1.1)	1.0 (0.6-1.2)	1.0 (0.8-1.2)	0.5 (0.5-0.6)	0.9 (0.7-1.0)	0.9 (0.8-1.2)	0.9 (0.9-1.1)	0.9 (0.9-1.1)	0.9 (0.9-1.1)
32	1.0 (0.9-1.2)	0.9 (0.6-1.1)	1.2 (0.8-1.5)	0.9 (0.6-1.0)	1.0 (0.9-1.2)	1.0 (1.0-1.6)	1.2 (1.1-1.3)	1.4 (1.2-1.4)	1.3 (1.3-1.4)
45	1.2 (1.0-1.7)	1.1 (0.6-1.2)	1.8 (1.2-2.2)	1.2 (1.2-2.2)	1.3 (1.2-1.6)	1.7 (1.3-2.1)	1.9 (1.5-2.0)	2.0 (1.8-2.1)	2.0 (1.8-2.1)
53	1.5 (1.4-2.3)	1.4 (0.8-1.5)	2.3 (1.5-2.9)	1.4 (1.3-2.2)	1.6 (1.4-1.9)	1.9 (1.5-2.4)	2.3 (1.9-2.3)	2.5 (2.1-2.4)	2.4 (2.1-2.5)
60	1.8 (1.6-2.7)	1.7 (0.9-1.8)	2.6 (1.7-3.3)	1.6 (1.4-2.7)	1.9 (1.7-2.1)	2.1 (1.7-2.7)	2.6 (2.5-2.6)	2.8 (2.7-2.9)	2.8 (2.8-2.9)
75	2.7 (2.4-4.0)	2.2 (1.2-2.4)	3.1 (2.0-3.9)	2.2 (1.8-3.0)	2.8 (2.6-3.2)	2.9 (2.2-3.7)	3.6 (3.6-3.6)	4.1 (3.9-4.2)	4.1 (4.1-4.3)
90	3.7 (3.2-5.1)	2.7 (1.5-3.0)	3.3 (2.0-3.8)	2.7 (2.5-3.1)	4.0 (3.6-4.8)	3.3 (2.8-5.5)	4.7 (4.4-5.1)	5.4 (5.1-5.7)	6.0 (5.7-6.0)

Table C.1 AGD typical median (min-max) values (mGy) for standard dose levels and different DBT systems.

APPENDIX D • Typical SDNR values

Breast Thickness (mm)	Hologic Selenia 3Dimension	Hologic Dimensions	Fuji Amulet Innovality ST Projection 150 um	Fuji Amulet Innovality ST Projection 100 um	Fuji Amulet Innovality HR	GE Pristina	IMS Class	Siemens Ispiration/ Revelation	Metaltronica Helianthus Narrow	Metaltronica Helianthus Intermediate	Metaltronica Helianthus Wide
21	2.6 (2.5-2.6)	4.9 (3.6-5.2)	7.2 (5.5-7.6)	7.0 (6.1-7.8)	5.2 (4.4-6.0)	7.2 (6.0-7.8)	5.0 (3.8-6.6)	2.5 (2.3-2.9)	3.0 (2.8-3.2)	2.8 (2.7-2.9)	1.8 (1.8-1.9)
32	2.1 (2.1-2.1)	3.8 (3.0-4.5)	5.1 (4.0-5.4)	4.6 (4.3-5.5)	4.3 (3.3-4.9)	7.1 (5.7-7.2)	4.0 (3.3-5.3)	2.1 (2.0-2.3)	2.7 (2.7-2.8)	2.6 (2.5-2.6)	1.6 (1.6-1.8)
45	1.8 (1.8-1.8)	3.2 (2.7-4.0)	4.0 (3.0-4.4)	3.4 (3.4-3.9)	3.5 (2.8-4.4)	6.3 (5.0-6.6)	3.2 (2.4-4.0)	1.9 (1.7-2.0)	2.4 (2.3-2.5)	2.3 (2.3-2.4)	1.5 (1.4-1.7)
53	1.8 (1.8-1.8)	3.2 (2.7-4.1)	4.0 (3.0-4.3)	3.2 (2.9-3.6)	3.2 (2.7-4.4)	5.4 (4.0-6.0)	3.1 (2.3-3.9)	1.8 (1.5-1.9)	2.5 (2.4-2.5)	2.3 (2.1-2.4)	1.5 (1.4-1.6)
60	1.7 (1.6-1.7)	3.0 (2.5-4.0)	3.7 (2.8-4.3)	3.0 (2.4-3.0)	2.8 (2.4-4.2)	5.0 (4.3-5.7)	2.9 (2.0-3.6)	1.6 (1.3-1.8)	2.3 (2.3-2.6)	2.3 (2.2-2.4)	1.5 (1.4-1.6)
75	1.8 (1.5-2.1)	2.8 (2.0-3.6)	3.0 (2.5-3.5)	2.0 (1.0-2.6)	2.2 (1.4-3.9)	4.3 (3.7-5.5)	2.7 (1.9-3.4)	1.3 (1.1-1.6)	2.2 (2.1-2.4)	2.2 (2.1-2.2)	1.4 (1.4-1.5)
90	1.5 (1.3-1.7)	2.2 (1.7-3.0)	2.4 (2.0-3.4)	1.6 (0.6-2.1)	1.6 (0.7-3.5)	3.9 (3.4-4.4)	2.2 (1.1-3.1)	1.1 (0.9-1.5)	2.1 (2.0-2.2)	2.1 (2.0-2.1)	1.4 (1.3-1.5)

Table D.1 SDNR typical median (min-max) values for different DBT systems

APPENDIX E • Typical AGD and SDNR values for local density variation

	Hologic Selenia 3Dimension	Fuji Amulet Innovality	GE Pristina	IMS Class	Siemens Ispiration/ Revelation	Metaltronica Helianthus
Max AGD_deviation(%)	20.4% (0.6%÷26.8%)	30.7% (15.8%÷36.9%)	13.1% (10.8%÷16.4%)	38.5% (37.5%÷ 46.2%)	53.9% (43.8%÷64.1%)	-
Min % SDNR_deviation(%)	-16.9% (-77.2%÷-0.0%)	-15.3% (-23.7%÷-7.9%)	-15.4% (NA)	8.0% (-8.8%÷ -1.1%)	-5.1% (-7.5% ÷ -2.7%)	-
kV variation	No	Yes	No	No	No	-

Table E.1 Typical median (min-max) values for AEC response to local density variation in terms of max AGD_dev(%) and min SDNR_dev(%)

APPENDIX F • Typical Response Function coefficients values

	GE Healthcare Pristina	Hologic Selenia 3Dimension	IMS Giotto Class	Siemens Mammomat Inspiration/ Revelation	Fuji Amulet Innovality	Metaltronica Helianthus
Response Curve	Linear	Linear	Linear	Linear	Logarithmic	Linear
Anode/Filter kV	Rh/Rh 34 kV	W/Al 31 kV	W/Ag 28 kV	W/Rh 29 kV	W/Al 32 kV	W/Al 29 kV
a	72.1	14.6	21.0	12.5	1806.0	22.1
b	-6.5	47.5	24.0	38.3	5734.7	11.1

Table F.1 Typical values for Response Function coefficients for linear $PV = a \cdot K_D + b$ *or logarithmic* $PV = a \cdot \ln(K_D) + b$ *response fucntion*

APPENDIX G • Examples of SDNR values for technical image quality evaluation in x-y plane

DBT Model	AGD (mGy)	Image type	Diameter				
			10 mm	8 mm	6 mm	4 mm	3 mm
GE Healthcare Pristina	1.1 (1.0 - 1.1)	DBT	2.4 (2.2-2.6)	2.1 (2.1-2.2)	2.1 (1.9-2.1)	1.5 (1.4-1.6)	1.3 (1.3-1.4)
		2D-S	3.5 (3.5-3.5)	3.1 (3.1-3.1)	2.9 (2.9-2.9)	1.8 (1.8-1.8)	1.7 (1.7-1.7)
Hologic Selenia Dimensions	1.2 (1.1 - 1.2)	DBT	2.4 (2.3-2.6)	2.4 (2.2-2.5)	2.6 (2.4-2.7)	2.1 (2-2.2)	1.7 (1.6-1.7)
		2D-S	2.2 (1.9-2.2)	2.1 (1.9-2.2)	2.3 (2.2-2.4)	1.8 (1.8-1.9)	1.3 (1.2-1.3)
Hologic Selenia 3Dimensions	1.1 (NA)	DBT	2.1 (NA)	2 (NA)	2.0 (NA)	1.7 (NA)	1.4 (NA)
		2D-S	1.2 (NA)	1.2 (NA)	1.3 (NA)	1.1 (NA)	0.8 (NA)
IMS Giotto Class	1.3 (1.2 - 1.4)	DBT	2.5 (2.4-2.6)	2.5 (2.3-2.6)	2.3 (2.1-2.6)	1.9 (1.8-2.2)	1.8 (1.7-1.9)
		2D-S	3.2 (2.7-3.8)	2.7 (2.4-3.1)	2.3 (2.0-2.8)	1.6 (1.5-1.8)	1.1 (1.0-1.1)
Siemens Mammomat Inspiration FBP	1.4 (1.4 - 1.4)	DBT	1.2 (1.2-1.2)	1.1 (1.1-1.1)	1.2 (1.2-1.2)	1.1 (1.1-1.2)	1.0 (1.0-1.0)
		2D-S	-	-	-	-	-
Siemens Mammomat Inspiration iterative	1.6 (1.6 - 1.6)	DBT	1.8 (NA)	1.7 (NA)	2.0 (NA)	1.3 (NA)	1.2 (NA)
		2D-S	3.7 (NA)	3.2 (NA)	3.2 (NA)	1.5 (NA)	1.0 (NA)
Siemens Mammomat Revelation iterative	1.5 (1.4 - 1.5)	DBT	2.1 (2.0-2.1)	1.8 (1.7-1.8)	1.9 (1.9-2.0)	1.6 (1.5-1.6)	1.2 (1.2-1.3)
		2D-S	2.6 (2.6-3.1)	2.5 (2.4-2.9)	2.2 (2.1-2.7)	1.5 (1.4-1.5)	1.0 (1.0-1.1)
Siemens Mammomat Brilliant	1.5 (NA)	DBT	2.8 (NA)	2.7 (NA)	2.8 (NA)	2.5 (NA)	1.9 (NA)
		2D-S	2.7 (NA)	2.2 (NA)	2.3 (NA)	1.9 (NA)	1.4 (NA)
Fujifilm Amulet InnovalityST (100 um)	1.0 (1.0 - 1.1)	DBT	2.4 (2.3-2.5)	2.2 (2.1-2.3)	2.3 (2.3-2.4)	1.8 (1.8-1.9)	1.6 (1.4-1.8)
		2D-S	3.5 (3.4-3.6)	3.0 (3.0-3.1)	2.7 (2.5-3.1)	2.0 (1.8-2.1)	1.5 (1.4-1.6)
Fujifilm Amulet InnovalityST (150 um)	1.1 (1.1 - 1.2)	DBT	3.1 (3.0-3.1)	2.8 (2.7-2.9)	2.6 (2.5-2.8)	2.4 (2.2-2.5)	2.1 (1.9-2.2)
		2D-S	2.6 (2.5-3.3)	2.2 (2.1-2.9)	1.9 (1.9-2.6)	1.6 (1.5-1.9)	1.4 (1.2-1.6)
Fujifilm Amulet InnovalityHR	1.8 (1.7 - 1.9)	DBT	2.2 (2.1-2.5)	2.0 (1.9-2.2)	2.0 (2.0-2.3)	2.0 (1.9-2.1)	1.6 (1.5-1.8)
		2D-S	2.3 (2.2-2.3)	2.0 (1.9-2.1)	1.8 (1.7-1.9)	1.6 (1.3-1.7)	1.0 (1.0-1.1)
Metaltronica Helianthus narrow	-	DBT	-	-	-	-	-
		2D-S	-	-	-	-	-

Table G.1 Median measured SDNR values (1st and 3rd quartile) obtained on reconstructed focal planes and 2D-synthetic images for different details of Tomophan phantom tested.
Ravaglia V. et Al., "A straightforward method for assessing the technical image quality of reconstructed and synthetic 2D images for Digital breast tomosynthesis systems", Physica Medica 130 (2025) 104907

DBT Model	AGD (mGy)	Image type	SDNR				
			A	B	C	D	E
GE Healthcare Pristina	1.2 (1.2 - 1.2)	DBT	2.2 (2.1-2.3)	1.8 (1.8-1.9)	1.0 (1-1.1)	0.9 (0.9-0.9)	0.7 (0.6-0.7)
		2D-S	2.6 (2.6-2.6)	1.8 (1.8-1.8)	0.8 (0.8-0.8)	0.8 (0.8-0.8)	0.5 (0.5-0.5)
Hologic Selenia Dimensions	1.3 (1.3 - 1.5)	DBT	2.8 (2.3-2.9)	1.9 (1.7-2.3)	1.2 (1.0-1.3)	0.9 (0.8-1.0)	0.5 (0.5-0.6)
		2D-S	2.4 (2.3-2.5)	1.7 (1.4-1.9)	0.9 (0.8-1)	0.7 (0.6-0.7)	0.4 (0.3-0.5)
Hologic Selenia 3Dimensions	1.2 (NA)	DBT	2.1 (NA)	1.5 (NA)	0.9 (NA)	0.8 (NA)	0.6 (NA)
		2D-S	1.6 (NA)	1.1 (NA)	0.6 (NA)	0.5 (NA)	0.4 (NA)
IMS Giotto Class	1.6 (1.5 - 1.8)	DBT	3.1 (2.9-3.1)	2.3 (2.2-2.3)	1.3 (1.2-1.3)	0.9 (0.9-1.0)	0.7 (0.6-0.8)
		2D-S	2.2 (2.1-2.4)	1.5 (1.5-1.6)	0.7 (0.7-0.8)	0.4 (0.4-0.4)	0.3 (0.2-0.5)
Siemens Mammomat Inspiration FBP	2.3 (2.1 - 2.5)	DBT	1.8 (1.8-1.8)	1.4 (1.4-1.4)	0.8 (0.8-0.8)	0.6 (0.6-0.6)	0.4 (0.4-0.5)
		2D-S	-	-	-	-	-
Siemens Mammomat Inspiration iterative	2.1 (NA)	DBT	2.9 (NA)	2.1 (NA)	1.3 (NA)	1.0 (NA)	0.6 (NA)
		2D-S	3.2 (NA)	2.1 (NA)	1.0 (NA)	0.5 (NA)	0.3 (NA)
Siemens Mammomat Revelation iterative	1.7 (NA)	DBT	2.9 (NA)	2.2 (NA)	1.0 (NA)	0.8 (NA)	0.6 (NA)
		2D-S	2.5 (NA)	1.7 (NA)	0.8 (NA)	0.2 (NA)	0.0 (NA)
Siemens Mammomat Brilliant	-	DBT	-	-	-	-	-
		2D-S	-	-	-	-	-
Fujifilm Amulet InnovalityST (100 um)	1.2 (1.2 - 1.3)	DBT	2.9 (2.8-3.0)	2.3 (2.2-2.4)	1.2 (1.2-1.2)	0.8 (0.8-0.9)	0.7 (0.7-0.7)
		2D-S	3.5 (3.3-3.7)	2.3 (2.2-2.5)	1.2 (1.1-1.3)	0.7 (0.7-0.8)	0.5 (0.3-0.6)
Fujifilm Amulet InnovalityST (150 um)	1.3 (NA)	DBT	2.6 (2.6-2.6)	2.0 (2.0-2.0)	0.9 (0.9-0.9)	0.8 (0.8-0.8)	0.6 (0.6-0.6)
		2D-S	2.4 (2.4-2.4)	1.6 (1.6-1.6)	0.5 (0.5-0.5)	0.5 (0.5-0.5)	0.1 (0.1-0.1)
Fujifilm Amulet InnovalityHR	2.0 (2.0 - 2.2)	DBT	2.8 (2.7-2.8)	2.1 (2.0-2.1)	1.1 (1.1-1.1)	0.9 (0.8-0.9)	0.6 (0.6-0.6)
		2D-S	2.2 (2.0-2.4)	1.6 (1.5-1.7)	0.7 (0.7-0.8)	0.5 (0.4-0.6)	0.3 (0.2-0.4)
Metaltronica Helianthus narrow	-	DBT	-	-	-	-	-
		2D-S	-	-	-	-	-

Table G.2 Median measured SDNR values (1st and 3rd quartile) obtained on reconstructed focal planes and 2D-synthetic images for different details of Tormam phantom tested.
Ravaglia V. et Al., "A straightforward method for assessing the technical image quality of reconstructed and synthetic 2D images for Digital breast tomosynthesis systems", Physica Medica 130 (2025) 104907

DBT Model	AGD (mGy)	Image type	SDNR			
			Mass 12	Mass 13	Mass 14	Mass 15
GE Healthcare Pristina	1.3 (1.2 - 1.3)	DBT	1.9 (1.9-1.9)	1.1 (1.0-1.3)	1.0 (0.9-1.0)	0.8 (0.8-0.8)
		2D-S	1.5 (1.5-1.6)	0.9 (0.9-1.0)	0.9 (0.7-0.9)	0.7 (0.6-0.7)
Hologic Selenia Dimensions	1.3 (1.2 - 1.3)	DBT	1.9 (1.7-2.2)	1.3 (1.2-1.6)	1.1 (1.0-1.3)	1.0 (0.9-1.1)
		2D-S	1.6 (1.4-2.1)	1.2 (1.1-1.5)	1.0 (1.0-1.2)	0.9 (0.9-1)
Hologic Selenia 3Dimensions	1.3 (1.3 – 1.3)	DBT	1.9 (1.9-2.0)	1.2 (1.2-1.2)	0.8 (0.8-0.9)	0.9 (0.9-0.9)
		2D-S	1.0 (0.9-1.0)	0.6 (0.6-0.7)	0.5 (0.5-0.5)	0.6 (0.6-0.6)
IMS Giotto Class	1.6 (1.5 - 1.7)	DBT	2.8 (2.5-2.9)	1.7 (1.6-1.8)	1.4 (1.3-1.5)	1.2 (1.2-1.3)
		2D-S	2.2 (1.9-2.4)	1.4 (1.4-1.4)	1.4 (1.4-1.4)	1.4 (1.4-1.5)
Siemens Mammomat Inspiration FBP	-	DBT	-	-	-	-
		2D-S	-	-	-	-
Siemens Mammomat Inspiration iterative	1.6 (NA)	DBT	1.3 (NA)	1.2 (NA)	1.1 (NA)	0.8 (NA)
		2D-S	2.1 (NA)	1.6 (NA)	1.5 (NA)	1.5 (NA)
Siemens Mammomat Revelation iterative	1.7 (1.7 – 1.8)	DBT	1.4 (1.3-1.5)	1.3 (1.2-1.3)	1.2 (1.2-1.3)	1.0 (1.0-1.0)
		2D-S	2.0 (NA)	1.4 (NA)	1.2 (NA)	1.1 (NA)
Siemens Mammomat Brilliant	-	DBT	-	-	-	-
		2D-S	-	-	-	-
Fujifilm Amulet InnovalityST (100 um)	1.3 (1.1 – 1.3)	DBT	1.6 (1.5-1.7)	1.1 (1.0-1.1)	1.0 (1.0-1.1)	0.9 (0.9-0.9)
		2D-S	2.5 (2.3-2.6)	1.2 (1.2-1.6)	1.4 (1.2-1.5)	0.9 (0.9-1.1)
Fujifilm Amulet InnovalityST (150 um)	1.2 (1.2 – 1.2)	DBT	1.9 (1.9-1.9)	1.8 (1.8-1.9)	1.6 (1.5-1.7)	1.3 (1.2-1.4)
		2D-S	1.6 (1.6-1.6)	1.3 (1.3-1.3)	1.1 (0.9-1.2)	0.9 (0.8-1.1)
Fujifilm Amulet InnovalityHR	2.3 (2.1 – 2.5)	DBT	1.8 (1.6-2.0)	1.4 (1.1-1.8)	1.2 (0.9-1.4)	1.0 (0.7-1.4)
		2D-S	1.8 (1.5-1.9)	1.1 (0.8-1.3)	0.9 (0.8-0.9)	0.7 (0.6-0.9)
Metaltronica Helianthus narrow	2.1 (2.1 – 2.1)	DBT	1.7 (1.7-2.8)	1.3 (1.2-1.9)	1.1 (1.1-1.4)	0.8 (0.7-1.0)
		2D-S	2.7 (2.1-3.6)	2.2 (1.7-2.8)	1.8 (1.4-2.4)	1.4 (1.1-2.0)

Table G.3 Median measured SDNR values (1st and 3rd quartile) obtained on reconstructed focal planes and 2D-synthetic images for different details of CIRS015 phantom tested.
Ravaglia V. et Al., "A straightforward method for assessing the technical image quality of reconstructed and synthetic 2D images for Digital breast tomosynthesis systems", Physica Medica 130 (2025) 104907

APPENDIX H • Typical FWHM values for z-resolution evaluation

DBT Model	CIRS 011	CIRS 015	Modular DBT	Pixmam-3D	Tomophan
GE Healthcare Pristina	2.9 (2.9 – 3.0)	2.1 (1.8 – 2.6)	2.5 (2.1 – 2.9)	6.0 (NA)	3.2 (3.0 – 3.2)
Hologic Selenia Dimensions/3Dimensions	4.8 (4.6 – 5.4)	3.1 (2.8 – 3.6)	3.1 (3.1 - 3.3)	9.7 (8.6 – 11.0)	5.0 (4.6 – 5.3)
IMS Giotto Class	3.1 (3.1 – 3.1)	1.9 (1.8 – 2.4)	2.1 (NA)	5.0 (4.6 – 5.4)	2.4 (2.4 – 3.0)
Siemens Mammomat Inspiration/Revelation	-	2.3 (2.3 – 2.6)	3.2 (NA)	6.9 (5.3 – 7.4)	4.6 (4.0 – 4.8)
Fujifilm Amulet InnovalityST	6.3 (6.0 - 7.0)	3.7 (3.5 - 4.4)	-	11.0 (9.6 – 12.0)	6.6 (6.5 - 7.0)
Fujifilm Amulet InnovalityHR	2.4 (2.0 – 2.9)	2.1 (1.5 – 2.4)	-	4.2 (3.6 – 4.5)	2.5 (2.4 – 3.1)
Metaltronica Helianthus narrow	-	4.4 (3.8 - 4.5)	-	12.0 (12.0 – 13.0)	-
Metaltronica Helianthus intermediate	-	3.2 (2.8 – 3.4)	-	9.5 (8.7 – 10.0)	-
Metaltronica Helianthus wide	-	1.9 (1.8 – 3.1)	-	4.5 (4.4 – 4.7)	-

Table H.1 Median measured FWHM (mm) values (min-max values) obtained for the 5 phantoms tested [19]