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Quality Control in Mammography; An Assessment of System's Performance of 3D Breast Tomosynthesis

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ABSTRACT

Breast tomosynthesis has become a well-established imaging technique for clinical assessment of breast cancer. This Tree-Dimensions (3D) imaging technique is one of a major recently used method for early breast cancer detection particularly for women with a dense breast. It can also aid in the clarifying of a breast cancer diagnosis, whether by initial screening or following up after a suspicious area in the breast has been found. The image of such technique must have an optimal contrast to display mass densities and speculated fibrous structures, in order to diagnose breast cancer accurately at the earliest feasible stage. Furthermore, the spatial resolution must be sufficient to reveal the size and form of micro calcifications. To improve the accuracy of imaging diagnosis system, an effective Quality Control (QC) program can be implemented to optimize the accurate diagnosis of mammographic imaging. The main aim of this study is to evaluate the QC of 3D Tomosynthesis system, including Kilo voltages peak (kVp) accuracy, mAs linearity, Half Value Layer (HVL), Automatic Exposure Control (AEC), radiation output and mean glandular dose (MGD). Image quality assessment also included to check of spatial resolution, Signal to Noise Ratio (SNR) and Contrast to Noise Ratio (CNR). Accreditation phantoms have been used during the study. This study reveals that international standard guidelines which contain basic requirements for QC are obtained.

Keywords: 3D, Tomosynthesis, X-ray Mammography, QC, MGD, HVL.

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INTRODUCTION

Mammography is the standard imaging modality for breast cancer screening and diagnosis. For breast cancer patients, early detection paired with focused therapy provides the greatest outcome [1]. Mammography is the most common radiologic evaluation that minimizes disease-related mortality [2]. The mammographic imaging used for breast cancer screening must produce high-quality images with the least amount of radiation dose [3]. This this due to its advantages in providing a reasonably high sensitivity; providing a high resolution, and low patient dose. However, the current clinical practice X-ray mammography still suffers from being a two-dimensional (2D) projection of a three-dimensional (3D) object. The resulting overlap of normal fibroglandular tissue cannot only obscure the detection and characterization of lesions but also present false alarms leading to unnecessary recall studies. Studies demonstrate that through the 3D breast tomosynthesis system, cancer detection has been increased by 27%, as well as detection of invasive cancer by 40%, and unnecessary callback has been decreased by 20 - 40% [4]. Unfortunately, with such a diagnosis comes an increased risk of radiation-induced carcinogenesis, making the assessment of breast dose critical [5]. X-rays are ionizing radiation that can cause harm to the human body; breast tissue is one of the most radiosensitive organs in the body [6]. As a result, the importance of optimal equipment performance and dose management for mammography cannot be underestimated [7]. Periodic testing of the mammography machines is required as part of routine QC procedures for mammography, including measuring kVp accuracy, mA linearity, exposure reproducibility, HVL, radiation output and incident air Kerma to calculate mean glandular dose [8]. The international standards such as, American College of Radiology has developed and published Mammography Quality Control Manuals in 1990 [9] and the Breast Imaging Reporting and Data System (BIRADS) in 1993 [10]. The European Commission has developed and published the European Protocol for the Quality Control of the Technical Aspects of Mammography Screening and the European Guidelines for Quality Assurance in Mammography Screening in 1993 [11,12]. Tomosynthesis systems measure X-ray transmission through the breast over a limited range of angles, followed by reconstruction of a series of images of the breast for different heights above the detector. These images represent breast tissue at the height of the corresponding focal planes as well as a remaining portion of overlying tissue. In this protocol such systems will be referred to as Digital Breast Tomosynthesis (DBT) systems. This imaging modality is distinct from computed tomography (CT), in which a three-dimensional image is reconstructed using x-ray transmission data from a rotation of at least 180˚ around the imaged volume [13, 14]. Routine QC tests Series of tests carried out at regular intervals (e.g., yearly, or half-yearly) during the lifetime of a system to ensure that the functional

performance of the equipment continues to meet established criteria. As well as to detect changes in component performance or in overall system performance

MATERIALS AND METHOD

Study Design and Criteria

A comprehensive QC assessment of 3D tomosynthesis mammography system was conducted to evaluate variables include kVp accuracy, mAs linearity, HVL, AEC, radiation output and Mean glandular dose (MGD). Image quality assessment was also included to check spatial resolution, SNR, and quality of image. Accreditation phantoms were used during the study. The study was performed on a digital breast tomosynthesis system of Hologic health company by using a RaySafe ionizing chamber detector (See Figure 1A), with source/image distance of 70 cm, a target/filter combination of Tungsten /Rhodium, kVp range of 25–30 kVp and mAs range of 5–180 at the radiology department in Riyadh, Kingdom of Saudi Arabia. The digital breast Tomosynthesis imaging device was built at the radiology department in January 2012. The device complies with FDA radiation performance standards and Federal Communications Commission (FCC) (part 15) rules. FCC set limitations on the amount of electromagnetic interference allowed from digital and electronic devices. The study was performed on a 24 cm ×29 cm single plate, TFT-based direct capture technology (Amorphous selenium) conventional mammography; tomosynthesis; combined conventional mammography and tomosynthesis imaging modes [15].

Standards and Protocols

The results from the assessment have been compared to International Standards to ensure that patients who have undergone mammography procedures have the greatest benefit. In this study the American Association of Physicists in Medicine (AAPM 74), ACR accreditation for Mammography and Recommendation of Quality Control Manual of Manufacture Have been followed.

Equipment and Phantoms

The study was conducted using the main equipment X-ray devices and radiation detector, observed variables include kV, mA, exposure time, HVL and radiation output dose. ACR DM Phantom was required for QC assessment in the study. It is a 4.2 cm (about 1.65 in) thick compressed breast consisting of 50% glandular and 50% adipose tissue [16]. Poly methyl methacrylate Slabs (PMMA), commonly called Perspex was used to mimic different thickness of the female breast. The MGD was estimated using the entrance air Kerma, without back scatter which was obtained using the same ACR phantom that was mentioned earlier. The RaySafe X-ray test equipment and tools include mammography sensor and base unit, have been used for some measurements (see Figure

1). RaySafe equipment are specifically designed to minimize the need for user interaction. A groundbreaking concept in sensor design and circuit provides unparalleled accuracy, reproducibility, and sensitivity. Intelligent algorithms indicate when a parameter is outside its specified range [17].

Figure 1: (A) shows the mammography detector, (B) shows detector with compression paddle, (C) shows RaySafe equipment, (D) shows suitcase of RaySafe and (E) shows Unit Base.

RESULTS AND DISCUSSION

Mammography is used both for investigating symptomatic patients (diagnostic mammography) as well as screening of asymptomatic women (selected age groups). A typical mammographic screening examination consists of one or more commonly two views of each breast Cranio-caudal (CC) and medial-lateral oblique (MLO). Breast tissues intrinsically lack subject contrast so low-energy X-ray spectrum is required. Thus emphasizes compositional differences of the breast. Nowadays there are a lot of medical exposures in radiographic imaging in Saudi and worldwide. Radiological requirements for X-ray mammography include sufficient spatial resolution i.e. details possibly as fine as 50 µm must be adequately visualized. Also adequate contrast in image for such low-energy X-ray spectra. In addition broad dynamic range required due to composition of the breast and age-dependent changes in the breast. Moreover lowest absorbed dose compatible with adequate diagnostic image quality. Quality administration in the X-ray Breast Tomosynthesis is the management of the QC procedures, this includes making sure that the equipment monitoring and

performance evaluation is properly done, assessed and recorded. It also involves following up with necessary corrective measures. QC can reduce patient dose by at least 30 % [18]. Quality control tests related in this work were based on "Nuclear and Radiological Regularity Commission (NRRC)" which is supported by International Atomic Energy Agency (IAEA). However, some tests were adjusted to our needed radiometric measurements, leakage radiation, accuracy and repeatability of the nominal kV, etc. On the other hand, Automatic Exposition Control (AEC) Tests and imaging quality were made taken the guidelines given by SEFM.

kVp Accuracy and Reproducibility

Kilovolt Peak (kVp) is the component that controls the quality of the x-ray beam produced. It is also what controls the contrast or gray scale in the produced X-ray film. The higher the kVp, the lower the contrast. The accuracy and reproducibility were evaluated by applying several tube voltages, covering the range of the clinically used settings (25–30 kVp) and repeating the measurements 3 times, using the Ionizing chamber detector. The measured kVp was within the range of (25.2 – 30.3 kVp), the results indicate that the clinically used measurements were within the recommendation of ± 0.5 kV [16] and with Coefficient of Variation (CV) ranges from 0.11-0.61. Results of assessment of kVp over a range of clinically available values are presented in Table 1. The utility of equations (1) and (2) [19]; help in calculating the CV and SD, to find out the reproducibility and accuracy. The standard formula for calculating the coefficient of variation is as follows: CV = (Standard Deviation/Mean) × 100.

Table 1: Results of kVp assessment over a range of clinically available values. Note that exposures made at the same kVp and mA stations of the same phantom thickness should produce the same optical density on the resulting image.

	kVp accuracy					Reproducibility	
Set kVp	Measured kVp			Average (Mean)	Accuracy%	SD	C V
25	25.2	25.2	25.2	25.20	0.80	0.14	0.55
26	26.3	26.3	26.1	26.23	0.88	0.16	0.61
27	27.2	27.3	27.2	27.23	0.85	0.16	0.59
28	28.3	28.2	28.3	28.26	0.95	0.03	0.11
30	30.3	30.3	30.2	30.26	0.87	0.18	0.59

$$\text{Coefficient of variation} = (SD/M) \times 100 \qquad \text{(Eq. 1)}$$

Where, SD = Standard deviation, M = mean of the values. The exposure reproducibility should be < 0.1 [20].

$$\text{KVp accuracy} = (\text{kVp measured} - \text{kVp set}) / \text{kVp set} \qquad \text{(Eq.2)}$$

mAs Linearity

To determine if the X-ray Tomosynthesis unit produces the same radiation output linearity for the same kVp and mAs regardless of the mA station used. linearity in radiography is the production of a constant amount of radiation for different combinations of milli amperage and exposure time". In the clinical setting, it is essential that X-ray unit produce a proportional change in exposure as milli amperage (mA) varies. Start with a 5 mAs with a fixed 28 kVp and 70 SID, the results were recorded after repeating the process 3 times each time mAs was duplicated, as a result the air Kerma values were increased and the result were illustrated as a continues raised slop as presented in (Figure 2). The mAs accuracy can be identified by using equation (3) [19];

$$\text{mAs accuracy} = (\text{mAs measured} - \text{mAs set})/\ \text{mAs set} \qquad \text{(Eq.3)}$$

The Linearity coefficient was determined using the relation (4) [19];

$$\text{Linearity coefficient} = X_{max} - X_{min} / X_{max} + X_{min} \qquad \text{(Eq.4)}$$

Results from the linearity test represented in Table 2, show that the repeatability of the air Kerma for a given mAs and the linearity with the mAs is consistent.

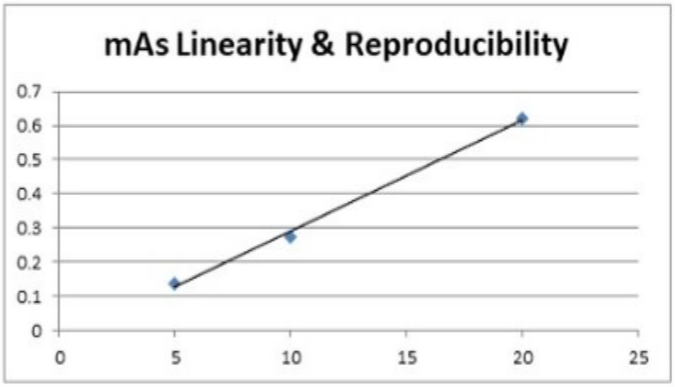

Figure 2: illustrates the mAs linearity and reproducibility.

Table 2: Results of detector linearity and reproducibility

Set mAs	Air Kerma (mGy)				Average	Reproducibility SD	Coefficient of Variation
5	0.136	0.136	0.136	0.136	0	0	
10	0.273	0.273	0.273	0.273	0	0	
20	0.62	0.62	0.62	0.62	0	0	

AEC (Automatic Exposure Control) Thickness Tracking

AEC is a radiographic density control device that terminates the exposure when a predetermined amount of radiation has been reached. Newer systems control kVp and mA as well as exposure time. To assess the performance of the AEC function and to verify consistency in detector signal-

to-noise level for a range of breast thickness, tissue-equivalent attenuators (e.g., acrylic, BR-12, BR-50) providing approximate thicknesses of 2, 4, 6, and 8 cm have been used [16]. Note that the BR abbreviation is basically breast tissue equivalent and BR-12 mean (47% glandular / 53% adipose) is most commonly used. Results from the AEC test show that the system can image a clinically expected breast thickness and ensures that there is adequate penetration of radiation (Figure 3). After dividing the average value of Standard Deviation (SD) by the average of Mean values, the Coefficient of variation was 1.6% which is below the limiting value of 5%; as recommended [21]. Assessment was undertaken using 20,30, 40 ,50 and 60 mm PMMA slabs at 28 kVp and 70 SID, with compression paddle. The results were presented in Table 3.

Table 3: Results of AEC (automatic exposure control) thickness tracking.

PMMA thickness (mm)	Mean	SNR	STD	CV
20	366.45	56.09	6.53	
30	259.63	51.99	5.69	0.016
40	310.45	53.54	5.80	
50	314.48	44.96	6.31	
60	399.4	55.56	7.18	
Average	377.282		6.302	

Signal-to-Noise Ratio (SNR)

SNR in mammography is a measure of true signal (i.e. reflecting actual anatomy) to noise (e.g. random quantum mottle). A lower SNR generally results in a grainy appearance to images. SNR is calculated from the ratio of the mean signal and the standard deviation of the noise within a region of interest. The higher a signal is above the noise, the higher the SNR value. A high SNR value makes the evaluation of a digital radiographic image easier. To assess the SNR value, on the radiologist workstation, using a circular or rectangular region of interest (ROI; approximately 3 cm from chest wall and centered left to right) to measure the mean signal value (or mean analog to digital units) in the middle of the phantom. (Figure 4) [16]. After recording the mean signal value as Mean background (BG) Signal on the form; recording the standard deviation as SD of background ,to calculate the SNR as Eq. 5 [16];

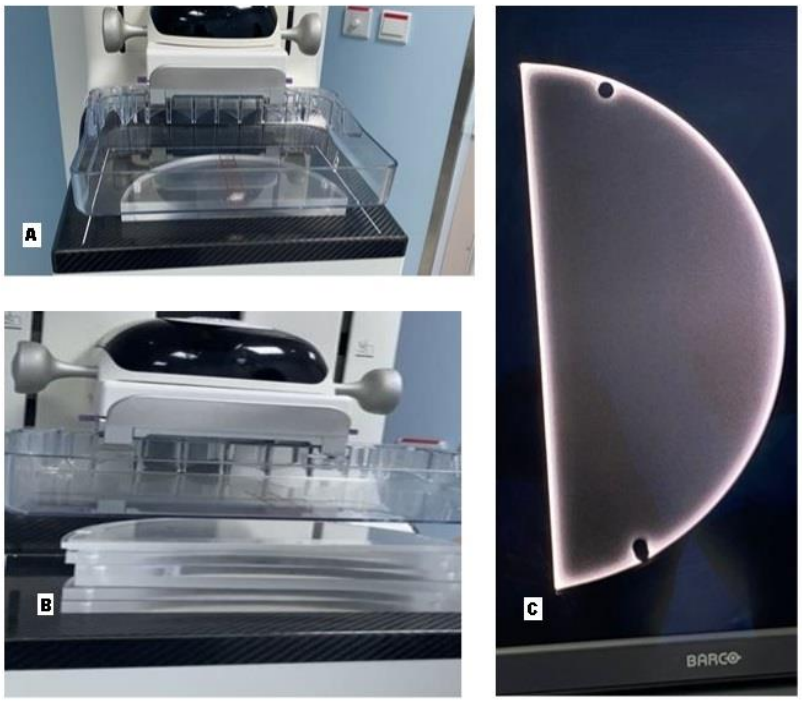

Figure 3: **(A) shows 20 mm PMMA slabs, (B) shows 60 mm PMMA slabs during AEC, (C) shows slabs after exposure.**

SNR= (Mean BG Signal –DC offset) /SD of BG (Eq.5)

Guidance documents should be checked to see if there are DC offset values that should be used for the calculation of the SNR. SNR is recommended to be ≥40.0 for the 4.0 cm phantom in 2D contact mode, and within ±15% of the last MEE's SNR for each thickness and mode tested [16]. Table 3 shows that values of SNR have met the recommended standard.

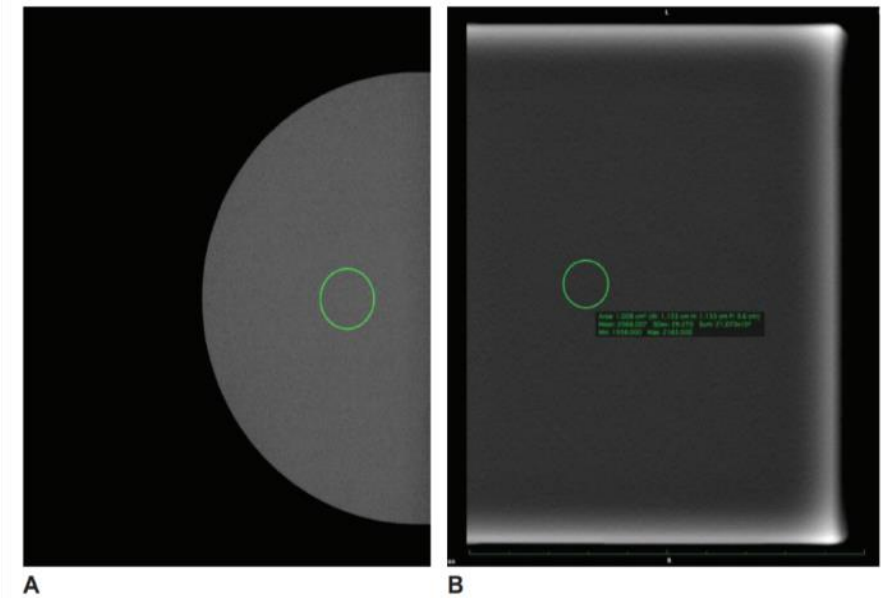

Figure 4: (A) shows ROI drawn on image, (B) shows Mean and SD values.

Table 4: Result of MGD.

#	mGy	mAs
Exposure 1	6.296	166
Exposure 2	6.699	176
Exposure 3	6.603	174
Exposure 4	6.623	165
Average dose	6.552	
MGD	1.89	

Radiation Output and Output Rate

Variation in X-ray mammography output and quality during a diagnostic exposure may result in unnecessary dose to the patient. Exposure rate is defined as the amount of ionizing radiation per hour in a person's vicinity (measured in milliRoentgen per hour, mR/h). on the other hand dose rate is the biological effect on the body from exposure to that radiation (measured in nanoSieverts per hour, nSv/h). At source/image distance 70 cm, dose measurements were taken by detector, at 28 kVp and 50 mAs for measuring the tube output settings. The dose found to be 2.032 mGy, In consequence, the radiation output dose of 50 mAs was 40.64 µGy/mAs. Such output was within the accepted value between 40–75 µGy/mAs [21]. The radiation output rate for same parameters at 0.5 sec was 4.064 mGy y/s.

Phantom Image Quality Evaluation

ACR DM Phantom was required in the test, to evaluate the image quality. This phantom has been designed to stimulate the breast tissue and it approximates a 4.2 cm thick compressed breast consisting of 50% glandular and 50% adipose tissue. Such ACR phantom demonstrated in Figure 5 [14] contain 6 fibers, 5 speck groups, and 5 masses. At the end of the test, 2 fibers, 3 specs and 3 masses, were previewed and met the criteria of ACR standards [16]. It is worth pointing out that phantom images should be read under optimal viewing conditions. General lighting should be at a low level and diffuse. View boxes should be positioned to avoid light from windows, other view boxes, and other sources of bright light, either direct or reflected. Images should be masked to eliminate extraneous light. One should use a magnifying glass of 2X or higher for scoring speck groups as well as any other appropriate test objects. For data analysis and interpretation and when scoring the image of one of the ACR-approved accreditation phantoms, each object type is scored separately. We then count the number of visible objects from the largest object of a given type (i.e., fiber, speck group, or mass) downward until a score of 0 or 0.5 is reached, then stop counting for that object type. We then count each fiber as one point if the full length of the fiber is visible and the location and orientation of the fiber are correct. We count a fiber as 0.5 point if not all, but more than half, of the fiber is visible, and its location and orientation are correct. We then add each

full or partial fiber score to the total fiber score, from the largest down to the smallest visible, until a score of 0 or 0.5 is reached. We then record the "raw" fiber scores before artifact deduction. Then after determining the last fiber to be counted, look at the overall background for artifacts. If a fiber-like artifact appears anywhere in the wax insert area of the image, but not in an appropriate location or orientation, we deduct the "artifactual" fiber from the last "real" half or whole fiber scored if the artifactual fiber is equally or more apparent. We deduct only from the last real fiber, not from additional fibers. We record the final score after artifact deduction in the appropriate space on the form. In addition, we use a large field-of-view magnifying lens (approximately 2X or higher) to assist in the visualization of specks. Starting with the largest speck group, count each speck group as 1 point if four or more of the six specks in the group are visible in the proper locations. Count a speck group as 0.5 if 2 or 3 of the six specks in the group are visible in the proper locations. Add each full or partial speck group score to the total speck group score, from the largest down to the smallest visible group, until a score of 0 or 0.5 is reached. Record this "raw" speck score before artifact deduction. After determining the last speck group to be counted, look at the overall background for artifacts. If noise or speck-like artifacts are visible in the wrong locations within the area of the wax insert, and are as apparent as the "real" specks, deduct them one for one from the individual specks counted in the last whole or half speck group scored, and adjust the score of the last group appropriately. We record the final score after artifact deduction in the appropriate space on the form. We then count each mass as 1 point if a minus density object is visible in the correct location and the mass appears to be generally circular against the background (i.e., greater than ¾ of the perimeter is visible). A mass is counted as 0.5 point if a minus density object is visible in the correct location, but the mass does not have a generally circular appearance. We then add each full or partial mass to the total mass score, from the largest mass down and until a score of 0 or 0.5 is reached. We finally record the "raw" mass score before artifact deduction. After determining the last mass to be counted, we look at the overall background for artifacts. If a mass-like artifact is seen in the wrong location within the area of the wax insert, we deduct the "artifactual" mass from only the last "real" whole or half mass scored if the artifactual mass is equally or more apparent. The final score record after artifact deduction on the appropriate space on the form.

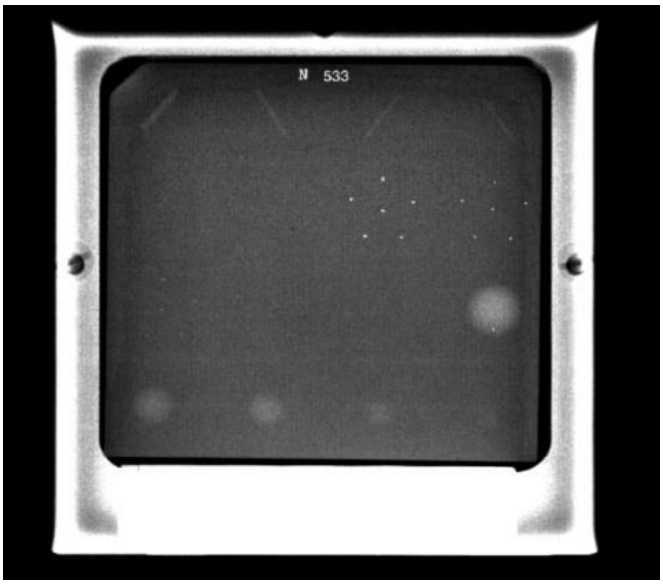

Figure 5: An image of the ACR phantom after exposure showing 2 fibers, 3 specs and 3 masses, were previewed and met the criteria of ACR standards [16].

Half Value Layer (HVL) Measurement

HVL testing is used to determine the quality of an x-ray beam. HVL is defined as the absorber material thickness necessary to reduce the X-ray beam intensity to half its incident magnitude, under proper geometry conditions using multiple exposures. HVL is the width of a material required to reduce the air Kerma of an X-ray or gamma ray to half its original value. This applies to narrow beam geometry only. With broad-beam geometry, a greater amount of scatter will reach the detector, falsely overestimating the degree of attenuation. The quantity half-value thickness ($d_{½}$) is the amount of material that reduces the intensity to half the original value. Instead of the linear half-value thickness (in m), often the mass half-value thickness $\rho d_{½}$ (in kg/m^2) is given. Here, ρ is the density (in kg/m^3) of the material. HVL is an important index of the image quality or radiation risk in mammography. Radiation risk of the breast tissue is evaluated with the average glandular dose. The HVL index is indispensable for the average glandular dose computations. Precise measurement of the half value layer (HVL) is required to allow the estimate of the Mean Glandular Dose (MGD). HVL with (compression paddle) should only be measured for target/filter and kVp settings related to MGD calculations [21]. After entering the target/filter settings into the unit base , HVL was easy to get. The half value layer was measured over the 28 kVp and 50 mAs for 70 cm SID . The obtained result was 0.502 mm Al, which is met the Criteria; HVL ≥ 0.3 mm Al [16]. It indicates that the quality of beam being produced from the tube is consistent at different kVp. HVL could be calculated manually by using Eq. 6 [21];

$$HV\ L < (kV\ p/\ 100\ ) + C \qquad \text{(Eq. 6)}$$

Where C of W/Rh = 0.30 mm Al. The results of equation(6) and RaySafe equipment show very similarity values .

Table 5: Values of the g and c factors.

g-factor*c-factor*8.76 mGy/R for Acrylic							
Breast Thickness	**HVL(mm Al)**						
(cm)	**0.3**	**0.35**	**0.4**	**0.45**	**0.5**	**0.55**	**0.6**
2	2.94	3.30	3.64	3.95	4.23	4.49	4.72
4	1.76	1.90	2.11	2.35	2.59	2.82	3.07
4.2	1.61	1.83	2.04	2.26	2.49	2.74	2.97
6	1.16	1.32	1.47	1.64	1.78	2.02	2.22
8	0.85	0.97	1.09	1.20	1.32	1.48	1.65

Mean Glandular Dose (MGD)

The MGD is an estimate of the average absorbed dose to the glandular tissues of a breast during mammography. It is a quantity used to describe the absorbed dose of radiation to the breast and it is based on a measurement of air Kerma and conversion factors. MGD can be calculated from measurements made with poly(methyl methacrylate) (PMMA) blocks. It is often used to compare typical doses to patients between different centers or internationally, and is the preferred measure of the potential risk from mammography. It was estimated that the average MGD uses the entrance air Kerma without back scattering (Figure 6). This procedure uses the factors that result from the ACR Digital Mammography (DM) Phantom Image Quality test. These factors must be the same as that used clinically for a 4.2-cm thick compressed breast consisting of 50% glandular and 50% adipose tissue, as defined by the FDA [14]. The mean glandular dose was calculated using Eq. 7 [7].

$$MGD = K \cdot g \cdot c \cdot s \qquad \text{(Eq.7)}$$

Where K is the incident air Kerma (without back scatter) at the upper

surface of the breast, g is the incident air Kerma to mean glandular dose conversion factor (g-factor), c corrects for any difference in breast composition from 50% glandularity and the factor s corrects for any difference due to the use of a different X-ray spectrum. The conversion factors g, c and s were extrapolated from the work of Dance [22]. The MGD to different equivalent breast thicknesses was calculated and compared with the acceptable standard, with ACR phantom results should be no more than 3mGy for 28 kVp and HVL value of 502 mm Al. The results are presented in Table 4. The calculated MGD was within the acceptable level. Table 5 and 6 show the numeric values of (g, c and s) factor [16].

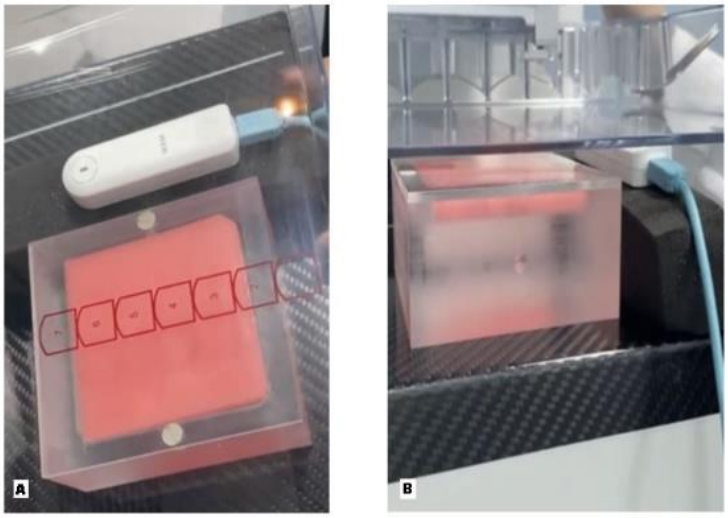

Figure 6 :(A) shows ACR phantom with detector, (B) shows the detector height set at around 4.2cm.

Spatial Resolution

Spatial resolution is defined as the ability to distinguish two neighboring structures as separated. In digital mammography, the pixel size typically ranges between 50 and 100 μm, so that the corresponding limiting spatial resolution ranges between 10 and five line pairs per millimeter. A requirement of Line pair (lp) pattern with frequencies up to 10 lp/mm, are essential to measure the limiting spatial resolution as an indicator of detector performance. With compression paddle, one exposure was taken, after placing the line pair pattern at a 45° angle to stimulate the CC position of the breast (Figure 7). The result was 4 lp/mm, as recommended [14].

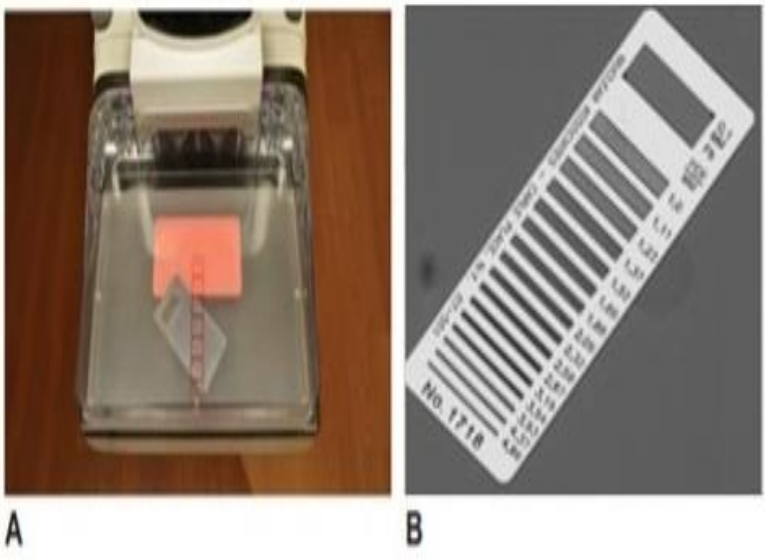

Figure 7: (A) shows Line pair pattern, (B) shows line pair after exposure.

CONCLUSION

Overall performance of a 3D breast tomosynthesis mammography system was evaluated by examining parameters and measurements including kVp accuracy, reproducibility, mAs linearity, AEC performance, radiation output, quality of image, SNR evaluation, and MGD. The results gained passed all the tests and were close to international standards and recommended values. Thus, this system can meet the image quality and dosage standards in the ACR for mammography and American Association of Physicists in Medicine. The system is acceptable for utilization in the field of 3D breast imaging.

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ABBREVIATION

QC: Quality Control; MGD: Mean Glandular Dose; 3D: Tree-Dimensions; ACR: American College of Radiology; W/ Rh: Tungsten/Rhodium; HVL: Half Value Layer; FDA: Food and Drug Administration; CC: Craniocaudal; FCC: Federal Communications Commission; PMMA: Polymethyl methacrylate; TFT: Thin Film Transistor; mGy: milligray; µGy: microgray; mAs: Milliamperage-Seconds; kVp: Kilo voltages peak.

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