

Quality assurance and control in digital mammography

In the last two decades, comprehensive guidelines on quality control in mammography have been developed worldwide. At the advent of digital mammography, efforts were made to revise quality assurance guidelines for mammography and adapt them in line with technological advancements. However, transposition of quality control guidelines to procedures that comply with regulations varies across countries. The variations include the tests performed, phantoms used, image quality criteria and limit values. Therefore, we aimed to investigate appropriate quality control guidelines and optimize the routine tests and protocols.

KEYWORDS: Digital mammography = Quality control - Quality tests

Introduction

The employment of digital technologies in mammography started in 2000s. Today, digital mammography has replaced analogue systems. The most important advantage of digital imaging systems is that the window and contrast adjustments can be made on the image using a wide dynamic range. This way, the re-imaging needs stemming from wrong irradiation are eliminated, thereby preventing unnecessary irradiation exposure for the patient [1-6].

In the last two decades, comprehensive guidelines on quality control in mammography have been developed worldwide [2]. It is therefore very critical that the quality control and acceptance tests of digital systems such as conventional mammography systems are conducted carefully and periodically. At the advent of digital mammography, efforts were made to revise quality assurance guidelines for mammography and adapt them in line with technological advancements. Specifically, the criteria used in the phantom-based image quality assessment, which were previously followed, were revised and new phantom designs were created in some cases. At the end of these efforts, which lasted approximately 10 years, a conclusion was reached on the protocol revision. However, transposition of quality control guidelines to procedures that comply with regulations varies across countries. The variations include the tests performed, phantoms used, image quality criteria and limit values. The variations at these points may result in non-homogeneous test results, hence differing results in different countries using the same equipment [7-11].

The quality assurance guidelines that are currently available for use were adapted from the American College of Radiology (ACR) and European Union Guidelines. While there may be some variations in the method and details, the quality controls are implemented in the light of these guidelines [3].

According to ACR, the primary aim of quality control is to reduce the irradiation exposure of patient and personnel, ensure a suitable and consistent image quality and identify and correct potential problems before they impact the patient's image quality. A detailed technical evaluation of products, measurement of the limit of the unit or optimization of the unit are not the primary aims; however, they are important. The test designated by ACR and the frequency at which they should be contacted are summarized in TABLE 1 [12].

The European Quality Assurance Guideline was drafted with a multidisciplinary approach. The 4th edition of the Guideline was published in the year 2006. It consisted of 12 sections and 400 pages and it was contributed by more than 200 authors and assistants [1]. The quality control approach is performed independently from the brand and type of the system. The primary objective of this protocol is to define the least number of control tests, which can be easily applied and assure system performance within the acceptable interval for digital mammography systems. This protocol contains detailed explanations targeted at minimizing personal performance variations and misinterpretations as much as possible.

Filiz Çelebi*

"Department of Raalology, Gayrettepe Florence Nightingale Hospital, Cemil Aslan Güder Sk, No: 8 Gayrettepe/ Beşiktaş, 34349 Istanbul, Turkey

*Author for correspondence : elbuken.filiz@gmail.com

Table 1. ACR Digital Mammography Quality Control Tests.								
Test	The lowest frequency of implementation	Time of correction						
Technician tests								
ACR DM phantom image quality	Weekly	Prior to clinical use						
CR cassette erasure	Weekly	Prior to clinical use						
	The lowest frequency of implementation							
Test	The lowest frequency of implementation	Time of correction						
Compression thickness indicator	Monthly	Within 30 days						
Visual checklist	Monthly	Prior to clinical use for critical items and within the first 30 days for less critical ones						
Scanning work station monitor quality control	Monthly	Within 30 days; prior to clinical use in case of serious problems						
Radiologist work station quality control	Monthly	Within 30 days; prior to clinical use in case of serious problems						
Film pressure quality control (if applicable)	Monthly	Prior to clinical use						
View box cleaning (if applicable)	Monthly	Prior to clinical use						
Facility quality control evaluation	Four times per year	Not applicable						
Compression power	Twice per year	Prior to clinical use						
Manufacturer detector calibration (if applicable)	Manufacturer Recommendation	Prior to clinical use						
Optional re-analysis	As needed	Within 30 days post-analysis						
Optional - system quality control for the radiologist	As needed	Within the first 30 days, prior to use in case of a serious problem						
Optional - feedback by the radiologist based on quality control	As needed	Not applicable						
Testing by Medical Physicist								
As per the requirements for mammography equipment evaluation (MEE)-MQSA	MED	Prior to clinical use						
ACR DM phantom image quality	MED and annually	Prior to clinical use						
Spatial Resolution	MED and annually	Within 30 days						
Automatic Exposure Control (AEC) System Performance	MED and annually	Within 30 days						
Mean Glandular Dose	MED and annually	Prior to clinical use						
Unit checklist	MED and annually	Prior to clinical use for critical items and within the first 30 days for less critical ones						
Computerized Radiography (if applicable)	MED and annually	Prior to clinical use						
Scanning work station monitor quality control	MED and annual	Within 30 days; prior to clinical use in case of serious problems						
Radiologist work station quality control	MED and annual	Within 30 days; prior to clinical use in case of serious problems						
Film pressure quality control (if applicable)	MED and once a year	Prior to clinical use						
Field technician quality control program evaluation	Annually	Within 30 days						
Evaluation of the display device in the technician quality control program	Annually	Within 30 days						
MED-troubleshooting-beam quality (Half- Value Layer) evaluation	MED or troubleshooting	Prior to clinical use						
MED-troubleshooting-kVp accuracy and reproducibility	MED or troubleshooting	MED: Prior to clinical use; troubleshooting; within 30 days						
MED-troubleshooting-evaluation of collimation	MED or troubleshooting	MED: Prior to clinical use; troubleshooting; within 30 days						
Troubleshooting-Phantom image evaluation	Troubleshooting	Prior to clinical use						
Troubleshooting-View box Brightness	Troubleshooting	Not applicable						

According to the European Union Guidelines, effective quality control programs need to be practical in conformity with clinical use, be prepared as per many steps in the imaging chain, the quality control test of AEC system should be simple and it should be able to provide required information on the equipment performance. For the digital X-ray system to meet the requirements of the European Union Guideline, it is required that it has an acceptable 'Pass' result on tests related to all the parameters and the frequencies of quality control tests are summarized in TABLE 2 [13].

Several quality criteria exist for the evaluation

of the image quality of mammography systems. Some of the tests conducted for conventional mammography are the same as those for digital mammography systems and computerized radiography systems. These include the tube output value test, repeatability and accuracy of the tube voltage test, Half Value Layer (HVL) test, automatic irradiation control tests and collimation test. In addition to these tests, there are also some additional tests that must be conducted for digital mammography systems. These tests include the detector response test, noise evaluation test, detector homogeneity test, dosimetry test, image quality tests (Modulation Transfer Function-MTF, Noise Power

Table 2. Control Frequencies according to the European Union Guidelines.								
Test object	At acceptance and as needed	Annually	Once every six months	Weekly	Daily			
X-ray generation								
X-ray resource								
Focal spot size	Х							
Resource-image distance	Х		If applicable					
Alignment of x-ray of image field	Х	Х						
Radiation leak	Х							
Radiation output	Х		Х					
Tube voltage and beam quality								
Tube voltage	Х		Х					
Half value layer	Х							
Automated Exposure Control system								
Exposure control steps	Х		Х					
Back-up timer and safety interruption	Х	Х						
Short-term reproducibility	Х		Х					
Long-term reproducibility	Х			Х				
Object thickness and tube voltage	V		V					
compensation	A		Λ					
Compensation	Х	Х						
Anti-scatter grid								
Grid system factor (if available)	Х							
Grid imaging	0	0						
Image receptor								
Image receptor response								
Response function	Х		Х					
Noise Evaluation	Х		Х					
Skipped tissue on the breast side	Х							
Skipped tissue on the breast side	Х							
Detector homogeneity and stability								
Detector homogeneity	Х			Х				
Detector element error	Х		Х					
Dosimetry	Х		Х					
Image quality								
Threshold contrast visibility	Х	Х						
MTF and NPS	0							
Exposure time	Х	Х						
Geometric distortion and artefact evaluation	Х		Х					
Phantom image/deletion integrity	Х	Х						

Spectrum-NPS) and phantom image test. The implementation of a standard protocol in systems is very crucial to be able to compare the studies conducted at different facilities if needed (TABLE 3) [14-18].

Methods and Results

■ Computerized Radiography (CR) Mammography Tests

1. Test for the alignment of the x-ray and the irradiation field

All radiography systems are equipped with a mirrored beam system set up to obtain information on the irradiated field. It ensures that several mirrors can be adjusted at specific angles to illuminate the field to be irradiated with light. The x-rays can be collimated onto the size of the field intended for imaging. The aim of this test is to determine whether there is a problem in the mirror system or not. Even minor deviations in the orientation of mirrors may result in deviations of the x-rays, thereby irradiation of the wrong part of the body. For the CR systems, this test is conducted by employing the method used in film-screen systems.

2. Radiation leakage test

Even though absorbent materials of a suitable

thickness are used to prevent leakage of x-rays in mammography systems, a certain amount of x-ray is leaked from the tube. The intention of this test is to identify the level of leakage and determine whether it is within acceptable limits. ACR cassette is required to perform the leakage test.

3. Detector homogeneity test

A different evaluation is performed for CR systems. 3 areas of interest are identified on the image. The average pixel value within the identified areas is calculated. To remain within acceptable limits, the difference between the average pixel values on the areas of interest on the sides and the central values should not exceed 10%.

4. Sensitivity change test for CR cassettes

It is examined whether the CR cassettes used in the clinic show a difference or not. A standard test block is irradiated using the AEC settings used in the clinic and the input air Kerma value and mAs value are noted. The CR cassette is read. The monitor's image processing feature should be turned off for as long as possible. Furthermore, the image post-processing feature should not be used, either. A reference area of interest is drawn on the image and the standard deviation is measured based on the average pixel

Table 3. Image Display.							
Test object	At admission and as needed	Annually	Once every six months	Weekly	Daily		
Monitors							
Ambient light	Х		Х				
Geometric distortion	Х				Х		
Contrast visibility	Х				Х		
Definition	Х		X				
Display artefacts	Х				Х		
Luminessence range	Х		X				
DICOM grey scale display function	Х		X				
Luminessence uniformity	Х		X				
Printers							
Geometric distortion	Х				Х		
Contrast visibility	Х				Х		
Definition	Х						
Printer artefacts	Х				Х		
Optic density range	0	0					
DICOM GSDF	Х		Х				
Density uniformity	Х		Х				
View boxes	Х	Х					
O: Optional test, X: Compulsory t	est						

value within this area of interest. Then, SNR is calculated. These processes are repeated for all the cassettes. The homogeneity of each and every image is identified. As for the acceptable limits, the deviation in SNR for every cassette should be lower than 15% and the deviation in the input air Kerma should be lower than 10%.

5. Test to determine the effect of other irradiation resources on the CR cassettes

Firstly, the CR cassette is erased. After that, one coin is placed on each side of the cassette and it is stored for a while, for example throughout the acceptance test, under normal storage conditions. Then, the cassette is read; the display image processing feature should be turned off for as long as possible and no image post-processing should be performed. If the coins are not visible on the image, it can be concluded that it is within acceptable limits.

6. Test for the fading of the occult image on CR cassettes

The phosphor within CR cassettes has the characteristic of absorbing the x-rays and harboring the occult image within its body. Naturally, this occult image will disappear over time. However, this process needs to unfold slowly over time. If it happens quickly, there will be a loss of image. The aim of this test is to have information on this disappearance. A standard test block is irradiated under the irradiation conditions used in a clinic and the cassette is read after it is kept waiting for a minute. An area of interest is drawn on the image and the average pixel value is read. Then, this process is repeated for different durations (2,5,10,30 minute). There are no acceptable limits identified for this test. The values obtained in acceptance tests are taken as reference values.

7. Square wave contrast transfer function

The line pair is used as a test object in the square wave contrast function test. The test object needs to include line pairs that are sufficient to cover the Nyquist frequency of the detector based on one line pair per millimeter. The test object is placed on the CR cassette and irradiated. To obtain the background on the derived image, an area of interest is drawn on the brightest spot of the image and the average pixel value within this area of calculated. Then, the same procedure is performed with the same area of interest, this time on a less bright area. After that, an area of interest, which encompasses the outer line pairs but excludes the background, is drawn and the standard deviation value within this area of interest is calculated. As for the acceptable limits for this test, it is stipulated that the deviation from the value calculated at the device acceptance should be lower than 10%.

Digital detector tests

1. Detector response test

Detector response is the measure of response generated by the detector in response to rising mAs values. This feature makes it possible to switch to different dose values by using the average pixel value obtained on the image. In the protocol entitled 'European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services (EUREF)', which is used by the European Union, a kVp that is widely used in clinics is set and fixed. Then, irradiations are performed in 10 different mAs values, which would include the mAs values used in routine practices, as well as other values that amount to 20 times these values. The dose values are read with an ionisation chamber placed on the detector and corrected with a reverse square at a distance of one meter. The standard test block is then irradiated at the same mAs values. A reference area of interest is selected among the images obtained and the average pixel values and standard deviations in this area of interest are calculated.

2. Noise evaluation test

The average pixel value and standard deviation value within a specific reference area of interest on the images are calculated as part of the response test. For systems with linear response, the SNR is obtained by using these values.

Detector homogeneity and stability testsDetector homogeneity test

Detector homogeneity is an important parameter that influences image quality. There are different methods recommended by different protocols within this test. In the EUREF protocol, the detector homogeneity is tested by means of irradiation of the standard test block that covers the entire detector under clinical conditions. Once irradiation is completed, the irradiation settings and mAs are registered. After that, an area of interest of 1 cm² is drawn on the unprocessed image and the average pixel value within the area of interest is evaluated. Then, this area of interest is scanned on the entire image. The average pixel value of the entire

image is calculated and an average SNR value is calculated based on all areas of interest. This average value is compared against the values that are read individually in areas of interest. There are some software programs available for this procedure. When the homogeneity image is evaluated using these programs, the program output provides the average pixel value on the image, the highest and lowest count values and the maximum deviation from the average value. In the evaluation phase, it is checked whether this maximum deviation is within the acceptable limits. The deviation of the average pixel values and SNRs within the areas of interest from the average pixel value and SNR of the total image should not be more than 15%.

■ Test for the operation of detector elements

This test is exclusively specific to DR systems. First of all, the latest malfunctioning pixel map obtained by the manufacturer should be examined. This map identifies the locations of all the pixels that are not functioning. This malfunctioning pixel map should be always readily accessible by the user.

The map that is obtained should be compared with the map provided by the manufacturer and the locations of malfunctioning pixels should be checked. If there are clusters composed of malfunctioning pixels, the film display contact test object can be used to overcome these problems.

Test for uncorrected and dysfunctional detector elements

This test is exclusively specific to DR systems. To identify the number and locations of dysfunctional pixels, an image of the standard test block is obtained, a reference area of 1cm² is identified and the average pixel value is read. After that, the area of interest is scanned on the entire image and the areas of interest, which have a pixel value that is 20% different than the pixel value of the entire image, are identified. This procedure is repeated on all 4 images to increase reliability. Pixels that show a deviation of more than 20% on all 4 images are potentially dysfunctional pixels. Various software programs are available for use in this procedure. When the variance image of a homogeneous image is examined, problems on the detector such as dead pixel defects can be visualized.

■ Modulation Transfer Function (MTF) and Image Power Spectrum (NPS) Test

MTF is a parameter which defines the differentiation strength of the system in the frequency space. The detector receives information in different frequencies; for example: very small structures on the breast and sharp edges are represented by high frequency. The modular transfer function is expressed as the decrease, which occurs in the output amplitudes of signals received by the imaging system at varying frequencies. The higher the frequencies, the lower the output amplitudes. Beyond a certain high frequency level, the system is unable to let any amplitudes pass through. This point is defined as the cut-off frequency.

In order to be able to calculate the MTF directly, a system with a linear response is required. In systems that do not provide linear responses (CR systems), the image should first be made linear. The values obtained in the acceptance test are determined as reference values. The measurements can be repeated in case of doubt regarding the detector quality.

As for the Noise Power Spectrum (NPS) it is the analysis of noise in the frequency space. Each of the phases that elapse in the process of obtaining the image in digital systems adds a certain amount of noise onto the image. The noise power spectrum is the most generalized and total expression of all these noises relative to the signal to noise ratio because the NPS also provides information on frequency-related noise.

Phantom image test

Phantom image is the residual image that is left on the obtained image from the previous image. On this measurement, a phantom image factor will be obtained with the help of contrast difference above 0.1 mm Al.

Firstly, the standard test block is irradiated in such a way as to cover half the detector. After that, the standard test block is placed in such a way as to cover the entire detector this time and an image is obtained with an AI object exactly in the center of the block. The interval between these two images should be approximately one minute. The acceptable limits for this test were identified based on a phantom image factor smaller than 0.3.

Dosimetry

In the dosimetry test, PMMA plates with a thickness of 20 mm are irradiated. The input

air Kerma values and AEC-selected irradiation parameters are registered. This procedure is repeated for 30, 40, 45, 50, 60 and 70 mm. Then, the input air Kerma values obtained in the first phase of the test are used to calculate the average glandular dose (15-18).

Discussion

It is very important that the quality control and acceptance tests of digital systems are performed carefully and periodically. At the advent of digital mammography, efforts were

REFERENCES

- Perry N, Broeders, Wolf Cde *et al.* European guidelines for quality assurance in breast cancer screening and diagnosis. *Ann. Oncol.* 19, 614-622, (2008).
- Marshall NW, Mackenzie AHI. Quality control measurements for digital x-ray detectors. *Phys. Med. Biol.* 56, 979-999, (2011).
- Cláudia Reis, Ana Pascoal, Taxiarchis Sakellari et al. Quality assurance and quality control in mammography: a review of available guidance worldwide. *Insights Imaging.* 4, 539-553, (2013).
- Skaane P, Young K, Skjennald A. Populationbased mammography screening: comparison of screen-film and full-field digital mammography with soft-copy reading–Oslo I study. *Radiology*. 229, 877-884, (2003).
- 5. Skaane P, Skjennald Α. Screen-film mammography versus full-field digital mammography with soft-copy reading: randomized trial in a population-based screening program-the Oslo II Study. Radiology. 232, 197-204, (2004).

made to revise quality assurance guidelines for mammography and adapt them in line with technological advancements.

Conclusion

The quality assurance guidelines that are currently available for use are implemented from the American College of Radiology (ACR) and European Union Guidelines as mentioned in our review. However, there may be some variations in the methods and details for different countries and systems.

- Pisano ED, Gatsonis C, Hendrick E et al. Diagnostic performance of digital versus film mammography for breast-cancer screening. N. Engl. J. Med. 353, 1773–1783, (2005).
- Heras GH, Schöfer F, Tiller B *et al.* A phantom using titanium and Landolt rings for image quality evaluation in mammography. *Phys. Med. Biol.* 58, 17-30, (2013).
- https://screening.iarc.fr/doc/ ND7306954ENC_002.pdf
- 9. https://www-pub.iaea.org/MTCD/publications/ PDF/TRS457_web.pdf
- 10. https://cdn.drg.de/media/document/8158/ EFOMP-MAMMO-PROTOCOL-Mar15.pdf
- Gennaro G, Avramova CS, Azzalini A et al. Quality Controls in Digital Mammography protocol of the EFOMP Mammo Working group. *Phys. Med.* 48, 55-64, (2018).
- 12. https://www.acr.org/Media-Center/ACR-News-Releases/2018/2018-ACR-Digital-Mammography-Quality-Control-Manual-with-DBT-is-now-available

- 13. h t t p s : / / w w w . e u r e f . o r g / downloads?download=24:european-guidelinesfor-quality-assurance-in-breast-cancer-screeningand-diagnosis-pdf
- 14. Şanlı R, Gündoğdu Ö. Dijital Mamografi Cihazi Kalite Kontrol Ölçümleri Ve Görüntü Kalitesinin Değerlendirilmesi. KOU. Sag. Bil. Derg. 4, 88-94, (2018).
- Marshall NW. Retrospective Analysis of A Detector Fault for a Full Field Digital Mammography System. *Phys. Med. Biol.* 51, 5655-5673, (2006).
- Marshall NW. A Comparison Between Objective And Subjective Image Quality Measurements For A Full Field Digital Mammography System. *Phys. Med. Biol.* 51, 2441-2463, (2006).
- Marshall NW. Early Experience In The Use of Quantitative Image Quality Measurements for the Quality Assurance of Full Field Digital Mammography X-Ray Systems. *Phys. Med. Bio.* 52, 5545-5568, (2007).
- Rampado O, Isoardi P, Ropolo R. Quantitative assessment of computed radiography quality control parameters. *Phys. Med. Biol.* 51, 1-17, (2006).