Chapter 14

Unified Procedures for Quality Controls in Analogue and Digital Mammography

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Additional information is available at the end of the chapter

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1. Introduction

Breast cancer is the most commonly diagnosed cancer in women [1]. Current attempts to control breast cancer concentrate on early detection by means of massive screening campaign, via periodic mammography and physical examination, because ample evidence indicates that such screening indeed can be effective in lowering the death rate [2]. Early diagnosis of breast cancer plays a leading role in reducing the mortality and improving the prognosis of this disease [3].

Mammography consists in imaging the female breast using X-rays with low contrast (to keep the delivered dose low), but at the same time high resolution (especially used for early detection).

The goal of mammography is to achieve the image quality required for a given detection task, while ensuring that the patient-absorbed dose is kept as low as reasonably achievable [4]. As practised now, it normally requires a dedicated X-ray tube with special anode materials such as molybdenum or rhodium, small focal spots, operating at a tube voltage around 25 to 32 kV, and carefully chosen films and screens in dedicated cassettes. Stationary or moving grids are used as in other branches of plain film radiography. Present-day mammography can be described as a low-dose procedure [5]. In recent years, advances in screen-film technology and film-processing techniques have contributed to major improvements in the quality of mammographic images. At present, two distinct mammographic techniques exist:

- Analogue mammography in which the image is recorded on a film.

- Digital mammography in which the image is digitalised.

The production of analogue or digital mammography images is based on two distinct concepts of image formation [6].

The analogue image is a continuous representation of spatial and intensity variations of the X-ray pattern transmitted by the tissue under analysis. Traditionally, the mammographic image is analogue, obtained using conventional screen-film image receptors as the standard detector [7]. The advantages of screen-film mammography are: high spatial resolution and low contrast sensitivity achieved through improvements in X-ray tube design, screen-film combinations, grids, and film processing [8]. Thus, analogue mammography permits high image quality, low patient dose, and most importantly, the ability to detect small, nonpalpable breast cancers.

In digital systems, image acquisition and display are two independent processes [4]. In such systems images are captured as a digital signal, making electronic transfer and storage of images possible. Digital systems offer a large dynamic range of operation, improving visualization of all areas of the breast and increasing exposure latitude. Also, the digital format allows grayscale adjustment to optimize contrast for any imaging task.

In addition, with the digitalization of the diagnostic image, new medical applications have now emerged, such as Computer-Aided Diagnosis (CAD), stereo mammography, tomosynthesis, contrast medium imaging and dual energy imaging [7].

For a successful screening function the mammograms should contain sufficient diagnostic information to be able to detect breast cancer, using a radiation dose as low as reasonably achievable (ALARA principle). In this context, it is necessary to establish and actively maintain regular and adequate Quality Assurance (QA) procedures that take into account medical, organisational and technical aspects. The QA procedure should include periodic tests to ensure accurate target and critical structure localization. Such tests are referred to as Quality Controls (QC). They are fundamental for the QA procedure because they help ascertain that the equipment performs consistently at a high quality level.

However, whilst the requirement for standardisation is impelling, the Italian legislation (D.L.vo 187/00) is not keeping pace with the advances in mammographic technology. Indeed, at present both analogue and digital formats are used in an un-regulated way, without introducing a proper regulation especially for digital mammography. As a consequence, the QA protocols have been adapted ad hoc to the new digital technology, thus resulting in multiple protocols, some of which valid only for specific machines, resulting in high costs of operation.

On the other hand, at the European level, QA procedures for both analogue and digital mammography systems have been properly addressed and defined, [European guidelines for quality assurance in mammography screening – 4th Edition, Section 2]. In both cases, in fact, the QC of the physical and technical aspects must guarantee the best possible diagnostic information obtainable and image quality stability, within the limits imposed by the ALARA principle.

However, for the case of digital systems the imaging chain can be divided into three independent parts, as cited in [9]:

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a. Image acquisition, including X-ray generation system, image receptor and (in some systems) image receptor corrections;

b. Image processing software;

c. Image presentation, including monitor, imaging presentation software, printer and viewing box.

To produce images with adequate quality, each part of the imaging chain must function within the limits dictated by the standards of screen-film mammography [9], although the definition of such limits for digital systems is still in progress.

In the EUREF protocol it is assumed that digital mammography should perform at least as screen-film mammography.

In this context, a unified protocol is proposed here that can be used with either analogue or digital mammography systems, with the view of reducing the volume of verification procedures to test the operation of such equipment. The advantage of the proposed protocol is that it can be applied as is to both analogue and digital mammography. The results obtained from the application of this protocol to analogue and digital mammography are presented in Section 3, with particular emphasis on image quality. The remaining part of this Section is dedicated to a review of mammographic techniques.

1.1. Screen-film mammography

In screen-film mammography, the film is used as the medium for both image acquisition and display. However, whilst providing excellent spatial resolution in high contrast structures, screen-film mammography has limited detection capability for low-contrast lesions in dense breasts [10]. On phantoms, the highest spatial resolution can be as high as 15–20 lp/mm but with a very low associated contrast. In addition, noise can limit the reliability of detection, especially for the small or subtle structures [11]. Although considerable advances in film-screen mammography have occurred over the past 20 years, some inherent limitations to further technical improvement exist [12]. One such limitation results from the trade - off between dynamic range (latitude) and contrast resolution (gradient) [13]. The relationship between X-ray exposure, image density, and contrast is illustrated by the Hurter and Driffield (H&D) sigmoid curve (Fig. 1) which uniquely characterises a given type of screen-film system under specific conditions [14].

Because of the sigmoid shape of the characteristic curve, the range of X-ray exposures over which the film display gradient is significant, i.e., the image latitude, is limited. The parts of the H&D curve where the slope is flat indicate poor contrast (i.e. over- or under-exposed images) [12, 16].

In screen-film mammography, the automatic exposure control (AEC) has the critical role of ensuring that the appropriate amount of radiation reaches the image receptor to produce a target optical density on the processed film [16]. In AEC systems, an ion chamber or other radiation detector is placed beneath the film cassette and connected electrically to the exposure time control circuit. When a pre-set amount of radiation has been detected, the expo-

sure is automatically terminated. Other limitations of film-screen mammography include (a) noise caused by the random fluctuation of X-ray quantum absorption by the fluorescent screen and the film emulsion, which can limit the detection of subtle structures, (b) the trade-off between spatial resolution and detection efficiency of the film and screen, and (c) the inefficiency of rejection of scatter radiation by the mammographic grid [12].

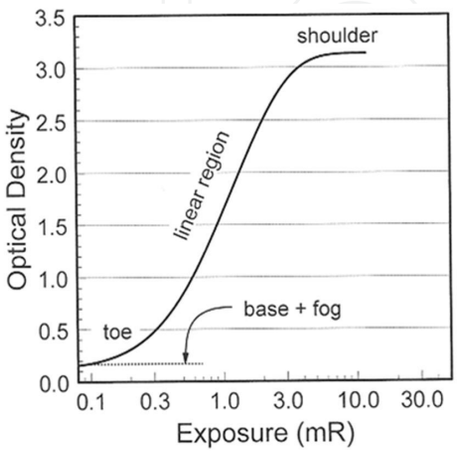

Figure 1. The Hurted & Driffield (H&D) curve describes optical density (OD) vs. the logarithm (base 10) of exposure [15].

1.2. Digital mammography

Digital mammography is an emerging technology, first approved in January 2000 [17], in which the image acquisition, display and storage functions can be performed independently, allowing for optimisation of each function. It offers several potential advantages including wider dynamic range, improved contrast, increased signal to noise ratio for overcoming the limitations of the film–screen combination (limited latitude, limited display contrast, low detection efficiency and noise), and therefore, increasing the sensitivity and specificity of breast cancer detection [18, 19]. Moreover, digital images offer a variety of new and improved applications. The digital image will provide image archiving and retrieval advantages over film, and will facilitate the use of computer-aided diagnosis [11, 20]. Other advanced applications made possible through digital imaging, such as dual energy and 3D tomosynthesis are expected to further improve diagnostic sensitivity and specificity.

In particular, Full Field Digital Mammography (FFDM) offers the promise of revolutionizing the practice of mammography through its superior dose and contrast performance [20]. In FFDM the screen-film is substituted by a fixed or removable digital detector. The digital image is obtained by sampling the X-ray pattern at discrete increments of spatial position and image signal intensity. Any digital image is a 2-dimensional grid of picture elements (pixels), which is defined by its size and bit depth. The size of an image is given by the length by width (in pixels) product. The bit depth is the number of shades of gray that can be displayed [1].

In a digital imager a detector absorbs the X-rays and produces an electronic signal at each pixel. The signal is then translated into a digital value by an analog-to-digital converter

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(ADC). Once the digital image is stored in the computer memory it can be displayed with contrast independent of the detector properties [12].

Digital mammography systems, unlike screen-film mammography systems, allow manipulation of fine differences in image contrast by means of image processing algorithms [10]. The physical properties of the digital image (contrast, resolution and noise) can vary noticeably according to the detection technology used. There are two methods of image capture used in digital mammography that represent different generations of technology: indirect conversion and direct conversion [20].

Indirect conversion digital detectors uses a two step process for X-rays detection, similar to screen-film [1].

Direct conversion should not be confused with "direct readout", which is a capability of all electronic detectors.

Fully digital mammography (FDM) detectors are the final class of detectors. These detectors are sealed units that are permanently mounted to a mammography system. FDM detectors are electronic devices that directly capture X-ray images. In general, such devices require that a new mammography system be installed [8].

1.2.1. Photostimulable phosphors (Computed Radiography systems)

Computed Radiography (CR) is at this moment the most common digital radiography modality in radiology departments, in place of conventional screen film systems [21].

CR for mammography system employ as the X-ray absorber a storage photostimulable phosphor imaging plate (typically $BaFBr:Eu^{+2}$, where the atomic energy levels of the europium activator determine the characteristics of light emission), that replaces the traditional screen-film combination [22]. In this case, the removable detector or the Imaging Plate (IP) is inserted as a cassette in a conventional mammography unit. So, the IP can be used in a standard mammography machine without modification [7].

X-ray absorption mechanisms are identical to those of conventional phosphors. The peculiarity here is that the useful optical signal is not derived from the light that is emitted in prompt response to the incident radiation, but rather from the subsequent emission.

CR digital phosphor plates have shown promise in mammographic imaging because of the wide exposure latitude and linear response [23].

The potential advantages of this technology are the small detector-element size, the fact that the plates can be used also in conventional mammography units, the ease of having multiple plate sizes, and the relatively low cost. In addition the plates are reusable since they can be readily erased optically [8].

However scattering of the light within the phosphor causes the release of traps over a greater area of the image than the size of the incident laser beam. This results in loss of spatial resolution [24].

1.2.2. Optical detector

The detector consists of a phosphor screen, a charged coupled device (CCD) camera, and a fiberoptic taper to couple the light from the screen to the camera. It now represents the most widely used digital mammography technique for cassette-free imaging [8].

The imaging performance of these systems depends on a number of factors, including the characteristics of the phosphor screen, the choice of CCD and the method used to optically couple the phosphor to the CCD.

A CCD is an integrated circuit formed by depositing a series of electrodes, called 'gates' on a semiconductor substrate to form an array of metal-oxide-semiconductor (MOS) capacitors [22].

CCDs are particularly well suited to digital radiography because of their high spatial resolution capability, wide dynamic range and high degree of linearity with incident signal.

1.2.3. Flat panel

The active matrix flat panel technology is the most promising digital radiographic technique [25, 26].

The active matrix detector is based on large glass substrates on which imaging pixels are deposited.

This flat panel plate consists of a matrix of approximately 5 million photodiodes that form the readout for each image. The charge produced on the diode in response to light emitted from the phosphor surface is collected and digitized [1].

2. Quality Control (QC)

QCs are fundamental to guarantee that the radiological equipment performs consistently, with standard and constant physical and technical operational parameters.

The technological advances of the past ten years have revolutionised imaging techniques for diagnostics. As a consequence, QC procedures need to be updated to suit the new technologies and related protocols. This is particularly true for mammographic equipment, for which the physical parameters to be monitored to guarantee high-quality imaging are identified in specific documents.

The European Protocol for "Quality Control of the Physical and Technical Aspects of Mammography Screening" [9] gives guidance on physical, technical and dose measurements, and the periodicity of the corresponding tests to be performed as part of mammography screening programmes.

On the other hand, in the case of the Italian regulation, the relevant legislation (D.L.vo 187/00) was approved before the commercialisation of CR and digital mammography. Therefore, guidelines and procedures for CR and digital mammography are missing.

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This shortcoming is particularly relevant in the case of mammography because it is well known that both image quality and breast dose depend on the equipment used and the radiographic technique employed.

For a complete and accurate estimate of image quality and delivered dose, the following components and system parameters should be monitored [9]:

- X-ray generation and exposure control system
- Bucky and image receptor
- Film processing (for screen-film systems)
- Image processing (for digital systems)
- System properties (including dose)
- Monitors and printers (for digital systems)
- Viewing conditions

		Screen-film mammography	**Digital mammography**	
X-ray generation	X-ray source	Focal spot size		
		Source-to-image distance		
		Alignment of X-ray field/image receptor		
		Film/bucky edge		
		Radiation leakage		
		Output		
	Tube voltage	Reproducibility		
		Accuracy		
		HVL		
	AEC	Central opt. dens. control settings	Exposure control steps: central value	
		Opt. dens. control step	Exposure control steps: difference per step	
		Target opt. dens. control settings	------	
		Short-term reproducibility	Short-term reproducibility	
		Long-term reproducibility	Long-term reproducibility	Variation in SNR
				Variation in dose

		Screen-film mammography	**Digital mammography**
		Object thickness and tube voltage compensation	Object thickness and tube voltage compensation; CNR per PMMA thickness
		Adjustable range	-----
		Spectra	-----
		Correspondence between AEC sensors	------
		Back-up timer and security cut-off	
Compression		Compression force	
		Maintain force for 1 minute	
		Compression force indicator	
		Compression plate alignment, symmetric	
Bucky and image receptor	Anti scatter grid	Grid system factor	
	Screen-film	Inter cassette sensitivity variation (mAs)	-----
		Inter cassette sensitivity variation (OD range)	-----
		Screen-film contact	-----
	Response function	-----	Linearity
		-----	Noise evaluation
	Missed tissue at chest wall side detector homogeneity	-----	Variation in mean pixel value (on image)
		-----	Variation in SNR (on image)
		-----	Variation in mean SNR (between images)
		-----	Variation in dose (between images)
	Detector element failure	-----	Number of defective dels
		-----	Position of defective dels
	Uncorrected dels	-----	Number of uncorrected defective dels
		-----	Position of uncorrected defective dels

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	Screen-film mammography	Digital mammography
Inter plate sensitivity variations	-----	Variation in SNR
	-----	Variation in dose
Dosimetry	Glandular dose per PMMA thickness	
Image quality	Threshold contrast visibility	
	Exposure time	
	Spatial resolution	MTF and NPS
	-----	Scanning time
	-----	Geometric distortion
	-----	Artifact evaluation
	-----	Ghost image factor

Table 1. Operational parameters relevant to analogue and digital mammographs [9].

Some of the above components are suitable only for analogue systems, others only for digital ones, and some are common to both systems although requiring dedicated QC procedures.

With reference to QCs for mammography, the EU legislation is subdivided in two parts: Section 2a for screen-film mammography, Section 2b for digital mammography. In both cases, several measurements should be undertaken by medical physicists. The components that are common to both analogue and digital mammographic systems are listed in Table 1 with corresponding operational parameters specific for the two cases. As expected, the methodology to be used for QC in the two different cases are substantially different particularly with respect to image quality monitoring.

For example, in the case of traditional, analogue mammography, spatial resolution and threshold contrast visibility can be used to uniquely characterise the image quality. On the other hand, in digital mammography image quality is assessed by monitoring the Modulation Transfer Function (MTF), Noise Power Spectrum (NPS) and Nyquist frequency. MTF represents the efficiency or fan imaging system in reproducing subject contrast at various spatial frequencies [7, 20, 27]. The Nyquist frequency, instead, indicates the maximum spatial resolution that can be visualized in an image. NPS provides information on noise at different spatial frequencies. In digital mammography, in fact, spatial resolution is obtained from MTF and Nyquist frequency.

The combination of MTF and NPS gives the Detective Quantum Efficiency (DQE), regarded as the best overall indicator of the image quality of digital radiographic systems. DQE is the efficiency with which a detector uses the incident photons to form an image [28]. Systems with higher DQE can produce higher quality images, at the same dose. Further, there are also other parameters that need to be monitored in digital techniques to defined the image quality. These are listed in Table 2.

Metric	Performance attribute
MTF	Resolution properties of the image/detector/system
NPS	Noise properties of the image/detector/system
DQE	SNR transfer properties of the detector
eDQE	SNR transfer properties of the system
Dark noise	Noise in the absence of signal
Uniformity	Signal uniformity in the absence of an object
Exposure Indicator	Accuracy of exposure indication by the system
Linearity	Exposure response behavior of the system
High-contrast resolution	Ability of the system to represent high-contrast patterns
Low-contrast resolution	Ability of the system to represent low-contrast patterns
Distortion	Geometrical accuracy of images
Artifact	Non-uniform artifactual features in the images
Ghosting	Appearance of shadows of prior images on subsequent images
Throughput	Speed by which a system can sequentially capture images
Normal exposure	Target exposure values for clinical use reflecting system speed

Table 2. List of parameters for digital image quality control [27].

The problem is to define a unified protocol that can be applied to any (analogue, CR, digital) type of mammographic system.

On the basis of procedures developed previously [29, 30], and to minimise problems arising from the use of different QC procedure to monitor different physical parameters for analogue and digital mammographs it is proposed here to monitor only parameters related to the beam at the output of the RX tube. The resulting QC procedure is then flexible and applicable universally to any type of mammograph.

The only additional pieces of equipment needed to execute the proposed QC is a phantom coupled to a solid-state exposure meter (PHAN-EX).

The phantom is a 4.5 cm thick block of PMMA, simulating a standard breast, including details simulating those of clinical interest (micro-calcification, tumoral mass, fibrous structures). This is coupled to an RX exposure meter composed of a photodiode and a digital counter, thus capable of measuring the exposure and the quality of the mammographic image [31]. The proposed protocol was tested on different (analogue and digital) mammographs, to assess its versatility and accuracy, independent of the physical characteristics of the mammographic system. Results on AEC tests obtained from the implementation of the proposed protocol implemented on analogue and digital mammographs, are presented and discussed in Section 3.

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Acoustic and light signaling	Acceptance test, status test and constancy test. The acoustic and light signals should function properly. Operating procedure: The test of acoustic and light signalling will be performed with the exposure. Frequency: Daily
Security cut-off	Acceptance test, status test and constancy test. The security cut-off should function properly. Operating procedure: To verify the correct functioning of the security cut-off produce an exposure with a high mAs value and report the measured dose. Then, produce a second exposure releasing the switch before the set time and report the new measured dose. This value had to be considerably smaller than the previous one. Frequency: Daily
Source-to-image distance	Acceptance test. Manufacturers specification, typical ≥ 600 mm. Operating procedure: if the focal spot is indicated, measure the distance between the focal spot indication mark on the tube housing and the top surface of the bucky. Add the distance between bucky surface and the top of the image receptor to the resulting value. Alternatively, calculate the source-to-image distance by the magnification of an object of known dimension.
Long-term reproducibility	Constancy test. Deviations from the reference value of exposures ≤ ± 2%. Operating procedure: the long term reproducibility of the AEC system is calculated by determining the deviation of the exposures obtained from the phan-ex and from the reference value (45 mm PMMA test block), with the exposure meter accurately placed on the plate holder. The measured counts per second (cps) should be recorded. Frequency: Yearly
Short term reproducibility	Acceptance test, status test and constancy test. Deviations from the mean value of exposures < ± 5%. Operating procedure: the short term reproducibility of the AEC system is calculated by the deviation of the 3 routine exposures (45 mm PMMA test block) of the phan-ex, with the exposure meter accurately placed on the plate holder. The measured counts per second (cps) should be recorded. Frequency: Yearly
Object thickness compensation	Acceptance test, status test and constancy test. Deviations from the reference value of exposures (45 mm PMMA test block) ≤ ± 15%. Operating procedure: the object thickness compensation of the AEC is calculated by determining the deviation of exposures of the phan-ex detector, accurately placed on PMMA plates of 30, 45 and 60 mm thickness, from the reference value (45 mm PMMA) at 28 kV. The measured counts per second (cps) should be recorded. Frequency: Yearly
Tube voltage compensation	Acceptance test, status test and constancy test. Deviations from the reference value of exposures (45 mm PMMA test block, imaged at 28 kV) ≤ ± 15%.

	Operating procedure: the tube voltage compensation of the AEC is calculated by imaging the 45 mm PMMA test block, setting the tube voltage at 26 kV, 28 kV and 30 kV, with the exposure meter of the phan-ex accurately placed on the test block. The measured counts per second (cps) should be recorded. Frequency: Yearly
Difference per step	Acceptance test, status test and constancy test. All the deviation in the measured exposures between successive steps: 0.1 - 0.2 per step. Operating procedure: The optical density control step can be determined by placing the phan-ex on a 45 mm PMMA plate and taking an exposure at all possible steps, setting the operating voltage at 28 kV. The measured counts per second (cps) should be recorded. Frequency: Yearly
Uniformity	Acceptance test, quality control. Parallel to the axis tube, the exposure value should decrease by 30-35 % at a height of 12 cm from the chest wall. Perpendicularly to the axis tube, a typical value of exposure decrease is < 7% from the centre of the X-ray field to 10 cm, for each side. Operating procedure: Beam uniformity can be determined by positioning the exposure meter on a 45 mm PMMA plate, first at the centre of the PMMA plate and, successively, at the top, right, bottom and left of the test block. Image the plate and report the measured counts per second (cps). Frequency: Yearly
Spatial resolution (at high frequency)	Acceptance test, status test and constancy test. Spatial resolution should be ≥ 12 line pairs per mm (lp/mm) Operating procedure: It can be estimated by imaging two resolution lead bar patterns, up to 20 line pairs per mm (lp/mm) each, placed on a 45 mm-thick PMMA plate. Image the patterns using a Mo/Mo target-filter combination at 28 kV. Frequency: Yearly
Threshold contrast visibility	Acceptance test, status test and constancy test. Minimum detectable contrast for a 5-6 mm detail < 1.3%. Operating procedure: It can be estimated by imaging a suitable phantom containing 5-6 mm circular details. The phantom is accurately placed on a 45 mm PMMA plate. Image the phantom using a Mo/Mo target-filter combination at 28 kV. Frequency: Yearly
Alignment of X-ray field/image receptor	Acceptance test, status test and constancy test. X-rays must cover the film by no more than 5 mm outside the film parallel to the axis tube, laterally X-rays must totally cover the film. Operating procedure: The alignment of the X-ray field and image receptor at the chest wall side can be determined by using two loaded cassettes and two X-ray absorbers. Produce an exposure Frequency: Every three months
Tube Voltage Accuracy	Acceptance test, status test. Accuracy for the range of clinically used tube voltages (25 –31 kV): < ± 1 kV. Operating procedure: The equipment should be tested over the range of clinically used settings (typically 25 – 31 kV) at intervals of 1 kV. To determine the tube voltage accuracy, the kV-meter

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	should be accurately placed. The resulting measured kV should be recorded. After having assessed that the differences between measured and nominal tube voltage values are within 1 kV, the exposures can be repeated at 1 kV intervals, after positioning the exposure meter, by recording the resulting counts per second (cps). Constancy test. Accuracy for the range of clinically used tube voltages (25 –31 kV): measured mGy vs nominal kV curve should be within the error bar. Operating procedure: Adequately position the exposure meter and report the counts per second (cps) measured at intervals of 1 kV. Frequency: Yearly
Tube Voltage Reproducibility	Acceptance test, status test and constancy test. Reproducibility (at 28 kV): < ± 0.5 kV. Operating procedure: To determine tube voltage reproducibility, accurately position the kV-meter and make at least three exposures at a fixed tube voltage that is normally used clinically (e.g. 28 kV). When the deviation from the mean value is < ± 0.5 kV and repeat the exposures, after positioning the exposure meter, and record the resulting counts per second (cps). Constancy test. Reproducibility (at 28 kV): < ± 2 %. Operating procedure: Adequately position the exposure meter. Make at least three exposure at a fixed tube voltage that is normally used clinically (e.g. 28 kV) and report the measured counts per second (cps). Frequency: Yearly
Exposure time	Acceptance test, status test and constancy test. Exposure time needed to image a 45 mm PMMA phantom: < 2 sec. Operating procedure: After accurately positioning the PMMA phantom and the sensor, the time for a routine exposure is measured. Frequency: Yearly
Reference dose	Acceptance test, status test and constancy test. Entrance dose: ≤10 mGy (40 mm PMMA test block); ≤ 12 mGy (45 mm PMMA test block); ≤ 20 mGy (50 mm PMMA test block). Operating procedure: Accurately position the exposure meter on the PMMA test block of known thickness. Report the counts per second (cps) measured at the entrance. Frequency: Yearly
Output rate	Acceptance test, status test and constancy test. Output rate must be < / 7.5 mGy/s (at the focus-to-film distance). Operating procedure: The output rate should be measured using a Mo/Mo target-filter combination at 28 kV, in the absence of scatter material and attenuation, and reporting the counts per second (cps). After calculating the exposure value, calculate the output rate at a distance equal to the focus-to-film distance (FFD). Frequency: Yearly
Average glandular dose (AGD)	Acceptance test, quality control. AGD (45 mm PMMA): < 2 mGy.

	Operating procedure: After determining the tube load (mAs) necessary to image the phan-ex, accurately position the exposure meter on the 45 mm PMMA test block and report the measured counts per second (cps), without backscattering. After calculating the exposure value, calculate the output rate at a distance equal to the focus-to-film distance (FFD) and convert this value into the average glandular dose. Frequency: Yearly
Grid system factor	At acceptance and when dose or exposure time increases suddenly. Grid system factor must be ≤ 3. Operating procedure: The grid system factor can be estimated by accurately positioning the phan-ex and measuring counts per second (at 28 kV), without compression, and with and without the grid system.
Grid imaging	Acceptance test, status test and constancy test. No significant non uniformity Operating procedure: image the bucky at the lowest position of the AEC-selector, without PMMA. Verify the image uniformity. Frequency: Yearly
Back-up timer	Acceptance test, quality control. The back-up timer should function properly. Operating procedure: Make an exposure of a 1 mm lead sheet and verify if the AEC system terminates the exposure. Frequency: Yearly
Half Value Layer (HVL)	Acceptance test, status test and constancy test. For 28 kV Mo/Mo target-filter combination the HVL must be between 0.30 and 0.40 mm Al equivalent. Operating procedure: Position the exposure detector at the reference ROI (since the HVL is position-dependent) on top of the bucky. Place the compression device halfway between focal spot and detector. Select a Mo/Mo target/filter combination, 28 kV tube voltage and an adequate tube loading (mAs-setting), and expose the detector directly. The filters can be placed on the compression device and must intercept the whole radiation field. Use the same tube load (mAs) setting and expose the detector through each filter. Frequency: Yearly
Focal spot size	At acceptance and when resolution has changed, quality control. For 28 kV Mo/Mo target-filter combination, focal spots size are reported in the following table. **Focal spot size** / **Reference values** — Length (cm) / Width (cm) 1 × 1 — 0.1 ÷ 0.15 / 0.1 ÷ 0.15 2 × 2 — 0.2 ÷ 0.3 / 0.2 ÷ 0.3 3 × 3 — 0.45 ÷ 0.65 / 0.3 ÷ 0.45 4 × 4 — 0.6 ÷ 0.85 / 0.4 ÷ 0.6 Operating procedure: Produce a magnified image of the pinhole and measure, on the image, the length and the width, in cm. Repeat for all available focal spots. Frequency: Yearly
Compression force	Acceptance test, status test and constancy test.

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	Maximum automatically applied force: 130 - 200 N. Operating procedure: The compression force can be estimated using a compression force test device or a bathroom scale. Frequency: Yearly
Compression plate alignment	Acceptance test, status test and constancy test. The difference between the measured distances at the left and right side of the compression paddle should be ≤ 5 mm for symmetrical load. Operating procedure: The alignment of the compression device at maximum force can be visualized and measured when a piece of foam-rubber is compressed. Frequency: Yearly

Table 3. Proposed protocol for mammography QC and technical specification of the parameters to be monitored.

3. Results and discussion

The chosen protocol can be used equally for acceptance, status and constancy tests. It was successfully implemented for both analogue and digital mammographs.

In particular, it was implemented for constancy tests of all parameters relevant to the exposure, utilising the same phantom-exposure meter pair.

In addition to the protocol, Table 3, the QC report worksheet is proposed in which the raw results (counts per second, cps) can be reported, Fig. 2-3. The raw data is then elaborated to estimate the entrance dose.

The proposed protocol and QC report were tested on different (analogue and digital) mammographs, to assess their versatility and accuracy, independent of the physical characteristics of the mammograph.

As an example, the AEC test results obtained for a digital mammographic system are reported in Figs. 4-6 to show that the same protocol can also be used on digital instruments.

The results obtained from the object thickness compensation are represented in Fig. 4. In particular, in Fig. 4 (a), the value of the dose (mGy) normalised to the tube load value (mAs) for the reference PMMA test block thickness (45 mm), is constant and within the error bar (± 15 %). The dose as a function of the PMMA plate thickness is presented in Fig. 4 (b). This curve shows that, with increasing dose, the normalised dose is constant, indicating the correct operation of the AEC system.

The results obtained from the tube voltage compensation are presented in Fig. 5 (a). Differently from the previous test, where the tube voltage was kept constant (28 kVp) varying only the tube load, in this type of test two parameters are varied: tube voltage and tube load. Therefore, in this test the parameter chosen to assess the tube voltage compensation is the logarithm (base 10) of the dose. Also in this case the results show that the logarithm of the dose is within the limit values (± 15 % calculated for a reference tube voltage of 28 kVp and for a 45 mm PMMA test block).

TEST RESULTS

DATE ___/___/___

QC REPORT

(A) ACCEPTANCE TEST ❒
(B) STATUS TEST ❒
(C) CONSTANCY TEST ❒

Monitored parameters

1) Acoustic and light signalling [(A), (B), (C)]

Acoustic signal functions properly: *yes* ❒ *no* ❒
Light signal functions properly: *yes* ❒ *no* ❒

2) Security cut-off [(A), (B), (C)]

Exposure value _____ cps;
Terminated exposure: _____ cps;

3) Source-to-image distance [(A), (B)]

Nominal value: manufacturers specification: _____ *cm*
Focus indication to Bucky: _____ cm
Bucky to cassette (or receiver image) _____ cm
Source-to-image distance: _____ cm

4) AEC-system [(A), (B), (C)]

- **Long term reproducibility [(C)] and short term reproducibility [(A), (B), (C)]**

Limit: ≤ ± 2% (long term reproducibility)
≤ ± 5 % (short term reproducibility)

- **Difference per step [(A), (B), (C)]**

Limit: 0.1 – 0.2 per step

PMMA test block: 45 mm; *Tube voltage: 28 kVp;*

Step	*Tube load (mAs)*	*Counts per second (cps)*
-2		
-1		
0		
+1		
+2		

5) Uniformity [(A), (B), (C)]

Limit: < 30-35 % (parallel to the axis tube)
< 7 % (perpendicular to the axis tube)

Exposure meter position	*Counts per second (cps)*
Centre	
Top	
Right	
Bottom	
Left	

6) Spatial resolution [(A), (B), (C)]

Limit: ≥ 12 lp/mm

Target-filter combination: Mo/Mo
Tube voltage: 28 kVp Tube load: _____ mAs
Resolution: ____ lp/mm

PMMA test block: 45 mm; *Tube voltage: 28 kVp;*

exposure	*Tube load (mAs)*	*Counts per second (cps)*
1		
2		
3		
4		
5		

- **Object thickness compensation [(A), (B), (C)]**

Limit: ≤ ± 15%

Tube voltage: 28 kVp;

PMMA test block (mm)	*Tube load (mAs)*	*Counts per second (cps)*
30		
45		
60		

- **Tube voltage compensation [(A), (B), (C)]**

Limit: ≤ ± 15%

PMMA test block: 45 mm;

Nominal tube voltage (kV)	*Tube load (mAs)*	*Counts per second (cps)*
26		
28		
30		

7) Threshold contrast visibility [(A), (B), (C)]

Limit: ≥ 1,3 %

Target-filter combination: Mo/Mo
Tube voltage: 28 kVp Tube load: _____ mAs

Diameter disc: _____ mm Contrast: ____ %
Diameter disc: _____ mm Contrast: ____ %
Diameter disc: _____ mm Contrast: ____ %
Diameter disc: _____ mm Contrast: ____ %

8) Alignment of X-ray field/image receptor [(A), (B), (C)]

Limit: < 5 mm (chest)
totally cover the film (otherwise)

Left: _____ mm
Nipple: _____ mm
Right: _____ mm
Chest: _____ mm

9) Tube voltage [(A), (B), (C)]

- **Accuracy [(A), (B), (C)]**

Limit: ≤ ± 1 kVp [(A); (B)]
measured mGy vs nominal kV curve should be within the error bar [(C)]

Nominal tube voltage (kVp)	*25*	*26*	*27*	*28*	*29*	*30*	*31*
Measured tube voltage (kVp)							
Counts per second (cps)							
Tube load (mAs)							

- **Precision [(A), (B), (C)]**

Limit: ≤ ± 0.5 kVp [(A); (B)]
≤ ± 2.0 % [(C)]

Nominal tube voltage (kVp)	*28*				
Measured tube voltage (kVp)					
Counts per second (cps)					
Tube load (mAs)					

Figure 2. QC report worksheet for raw data recording (part 1).

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10) **Exposure time [(A), (B), (C)]**

Limit: ≤ 2 second

PMMA test block: 45 mm
Tube voltage: *28 kVp;* *AEC settings:* _____

Exposure time: _____ sec

11) **Reference dose [(A), (B), (C)]**

Limit: ≤ 10 mGy (40 mm PMMA test block)
≤ 12 mGy (45 mm PMMA test block)
≤ 20 mGy (50 mm PMMA test block)

PMMA test block: _____ mm;
Tube voltage: _____ kVp Tube load:_____ mAs
Counts per second:_____ cps

12) **Output rate [(A), (B), (C)]**

Limit: > 7.5 mGy/s (at the focus-to-film distance)
Tube voltage: 28 kVp; Tube load: ____ mAs Exposure time: ____ sec
FFD: _____ cm Counts per second: _____ cps

13) **Average glandular dose [(A), (B), (C)]**

Limit: ≤ 2 mGy (45 mm PMMA test block)
Tube voltage: *28 kVp* Tube load: ____ mAs
FFD= ____ cm Tube output = ____ cps/mAs

14) **Anti scatter grid [(A), (B), (C)]**

- **Grid system factor [(A)]**

Limit: ≤3

Grid	Counts per second (cps)	Tube load
Present		
Absent		

- **Grid imaging [(A), (B), (C)]**

Artefacts are present: *yes* ☐ *no* ☐
Description of artefacts: _____

15) **Back-up timer [(A), (B), (C)]**

Exposure terminates by exposure limit :
yes ☐ no☐

16) **Half-Value Layer (HVL) [(A), (B), (C)]**

Limit: 0.3 mm Al ≤ HVL ≤ 0.4 mmAl (Mo/Mo filter-tube combination).

Tube voltage: 28 KVp; Tube load: ___mAs;

no filter	0 mm	cps = _____
filter 1	____ mm	cps =._____
filter 2	____ mm	cps =._____
filter 3	____ mm	cps =._____
filter 4	____ mm	cps =._____
filter 5	____ mm	cps =._____

17) **Focal spot size [(A), (B), (C)]**

Limits:

Nominal focal spot size (mm)	*Length (cm)*	*Width (cm)*
1 x 1	*0.1 ÷ 0.15*	*0.1 ÷ 0.15*
2 x 2	*0.2 ÷ 0.3*	*0.2 ÷ 0.3*
3 x 3	*0.45 ÷ 0.65*	*0.3 ÷ 0.45*
4 x 4	*0.6 ÷ 0.85*	*0.4 ÷ 0.6*

Nominal focal spot size (mm)	*Measured Length (cm)*	*Measured Width (cm)*
1 x 1		
2 x 2		
3 x 3		
4 x 4		

18) **Compression force [(A), (B), (C)]**

Limit: maximum automatically-applied force 130-200 N
Measured compression force: _____ N
Compression force after 1 min: _____ N

19) **Compression plate alignment [(A), (B), (C)]**

Limit: ≤ 5 mm

	Left (mm)	Right (mm)
Rear		
Front		

Figure 3. QC report worksheet for raw data recording (part 2).

The dose radiated by the AEC system as a function of the tube voltage is presented in Fig. 5 (b), as measured with the phan-ex. From the results of Fig 5 (b) it is noticed that as the tube voltage increases, the dose decreases, further confirming that the AEC system is functioning correctly.

Results from the test on the "difference per step" are reported in Fig. 6. Also in this case, the logarithm of the dose was calculated at each step. The obtained values are within the limit values (0.2 – 0.4 as the step difference was 2), Fig. 6 (a). The corresponding values of the dose per step are reported in Fig. 6 (b).

For the short-term reproducibility test, exposure values were measured, from which the average dose value was determined with respect to the tube load supplied by the AEC system (mGy/mAs), Fig. 7, to show the proposed unified protocol is equally applicable to analogue and digital mammographic system.

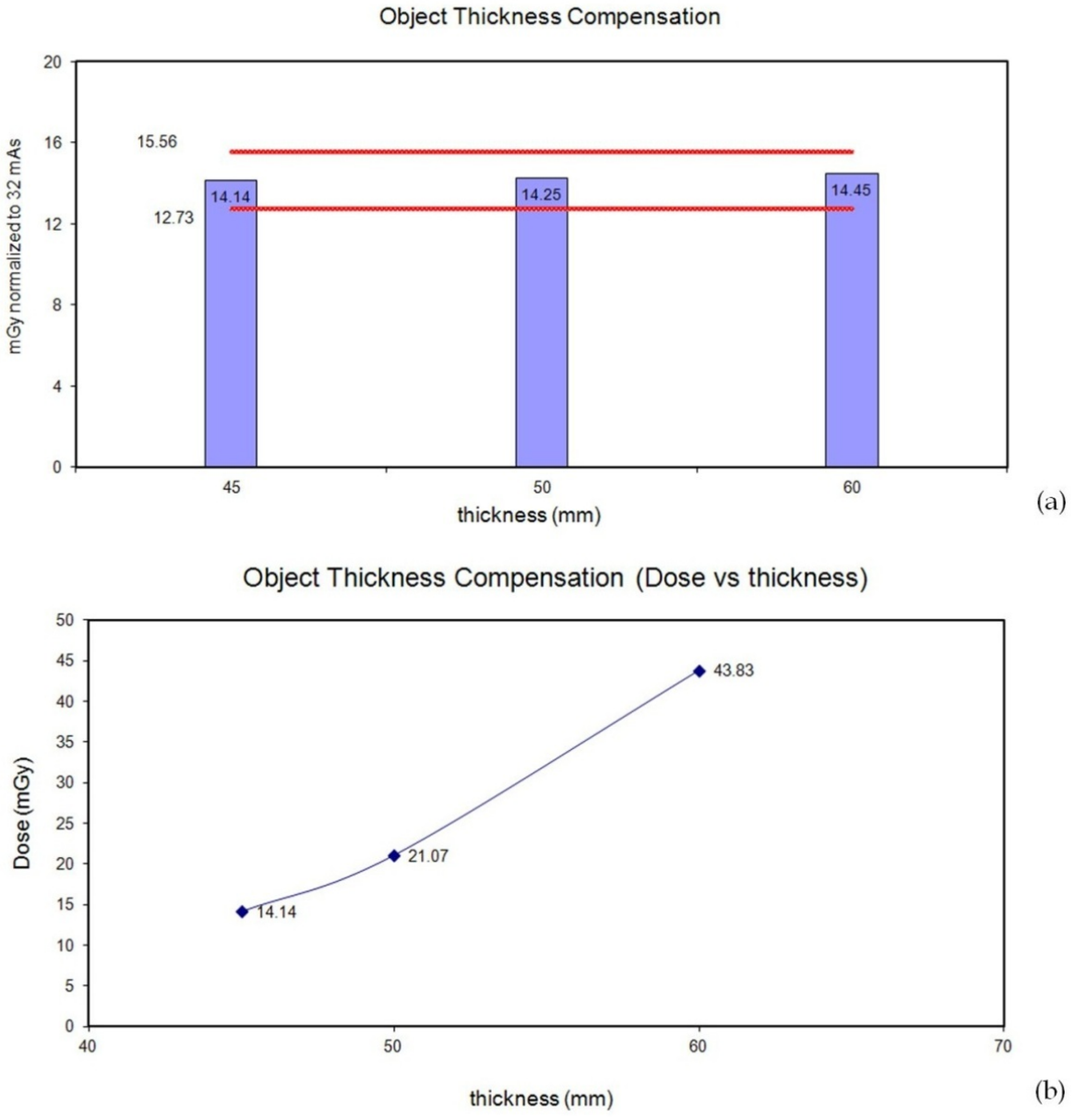

Figure 4. Results of object thickness compensation test: (a) the dose (mGy) normalised to the tube load value (mAs); (b) the dose (mGy) as a function of PMMA plate thickness.

The use of the phan-ex, coupled with the proposed protocol, is useful also to verify parameters related to the exposure such as tube voltage precision and accuracy, and exposure time.

Most importantly the proposed protocol permits the evaluation of the functional parameters of the instruments by utilising a single phantom, thus significantly reducing the number of additional dedicated equipment and simplifying the task of the Medical Physics Expert.

The results obtained from raw data analysis obtained following the proposed protocol were found to be consistent with those obtained from standard procedures [32-35], thus highlighting the usefulness and versatility of the proposed unified protocol to test all relevant param-

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eters in analogue and (direct or indirect) digital instruments. The simplification is even more relevant in the latter type of mammographs for which the QC procedures currently used present considerable difficulties in the interpretation of the measurement protocols.

The applicability of the proposed phantom can be further extended to the measurement of parameters other than those relevant to the exposure even for the next generation of mammographs which are still under development. One such instrument is the SYRMEP, equipped with a Si-based microstrip detector and a synchrotron X-Ray source characterised by superior performance with respect to typical X-Ray tubes [36].

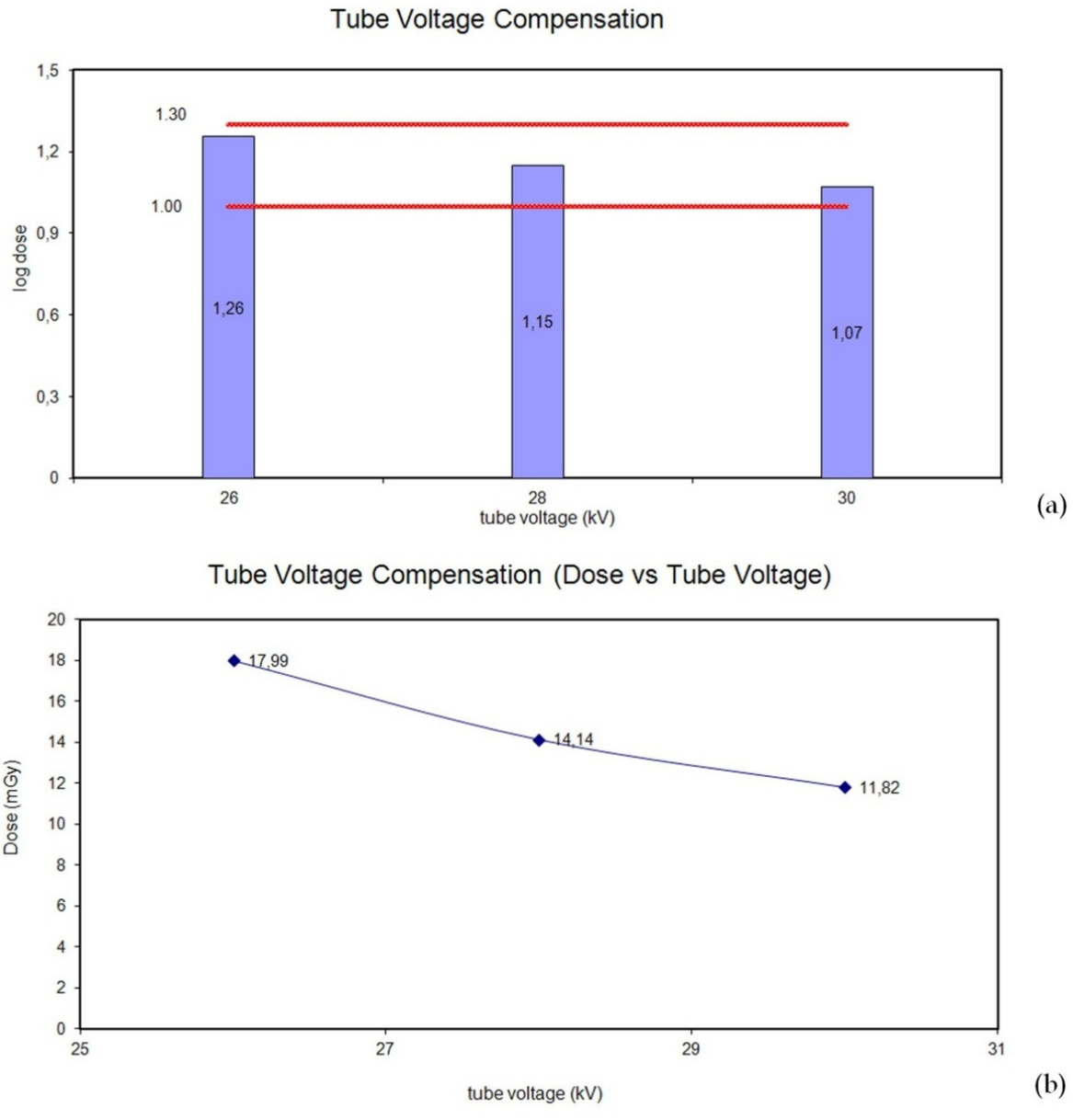
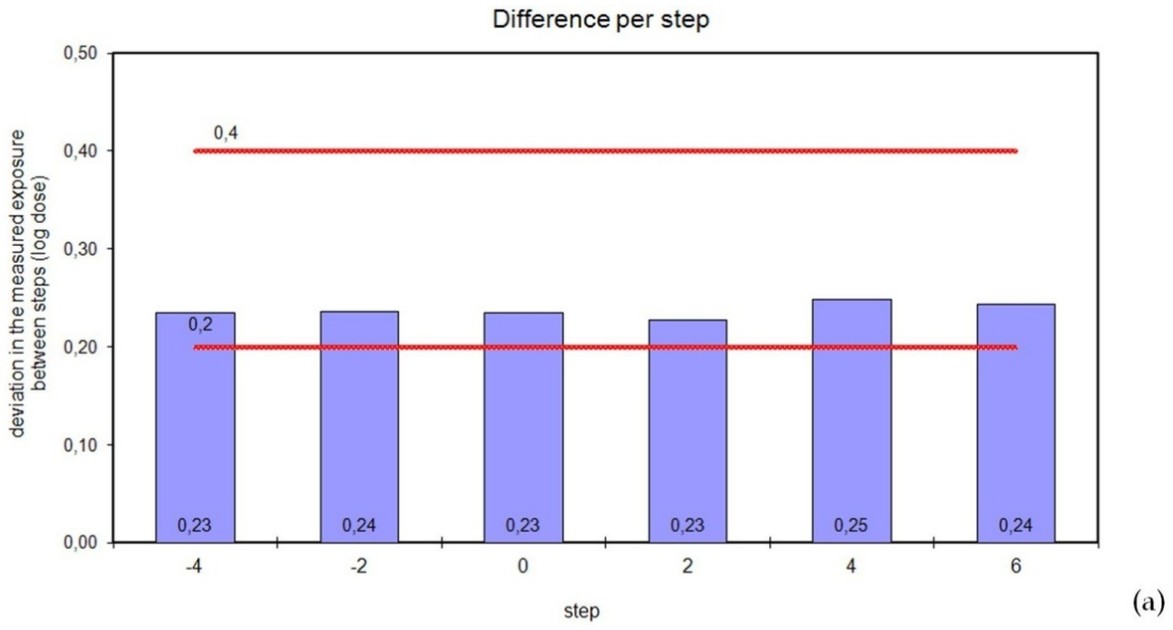
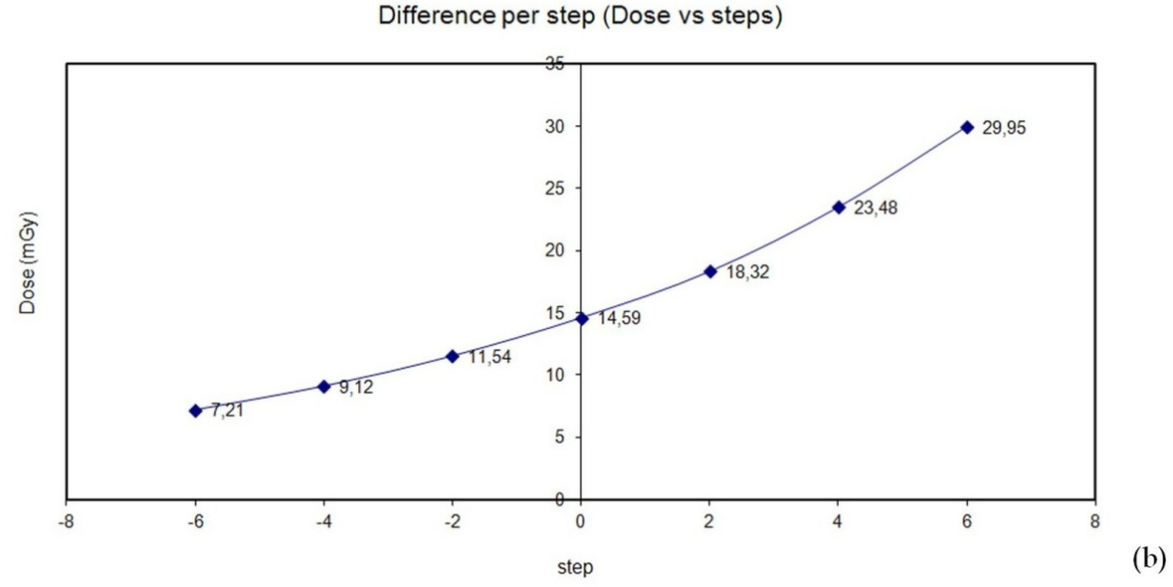


Figure 5. Results of tube voltage compensation test: (a) logarithm of the dose, red lines representing the limit values (± 15 %) with respect to 28 kVp reference tube voltage; (b) the dose (mGy) as a function of tube voltage (kVp).



(a)



(b)

Figure 6. Results of difference per step test: (a) logarithm of the dose, red lines representing the limit values (0.2 – 0.4 per step); (b) the dose (mGy) per step.

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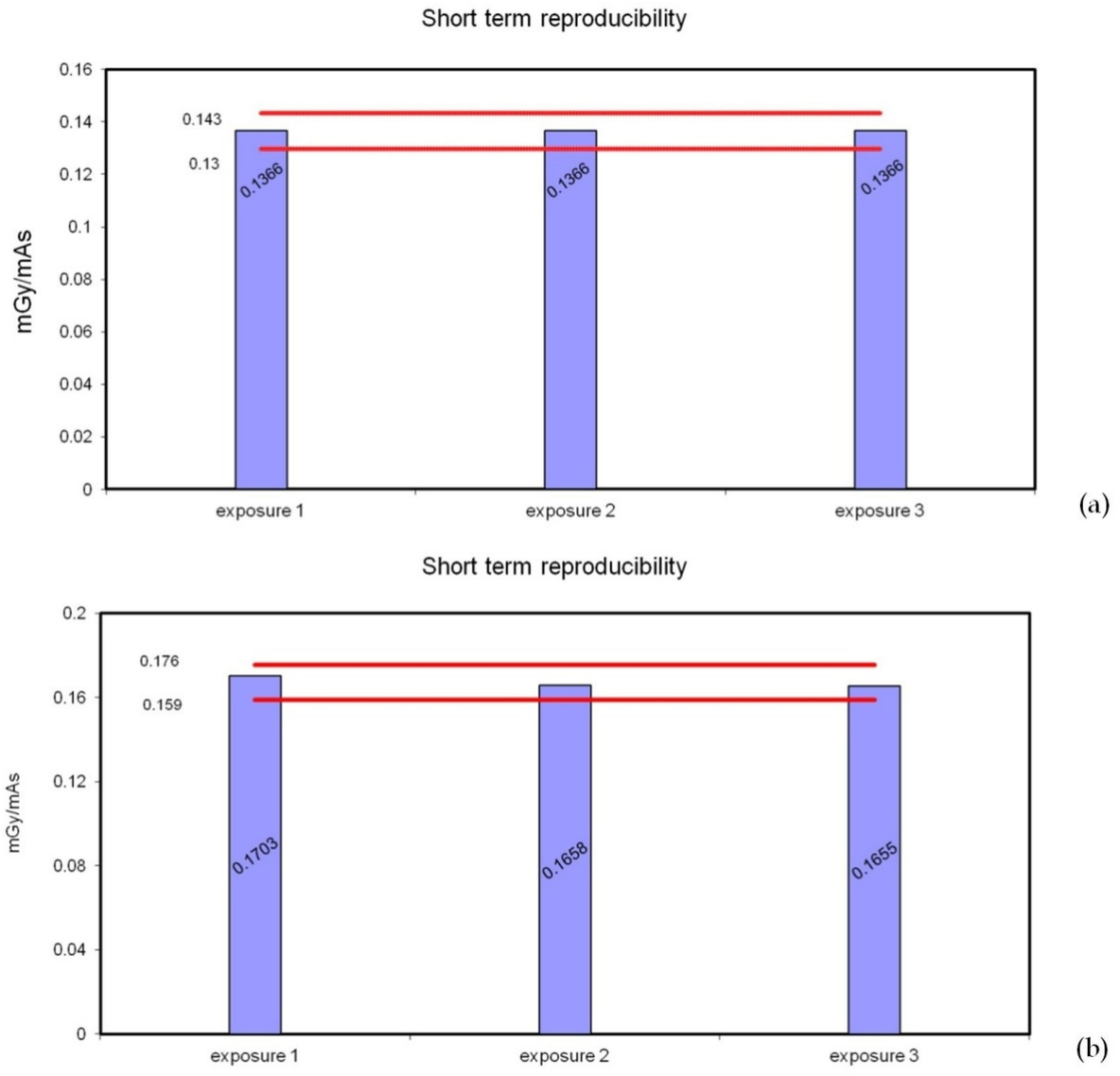

Figure 7. Results of short term reproducibility test, dose to tube load ratio (mGy/mAs) for three different exposures : (a) digital, (b) analogue mammograph;

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