

INTERNATIONAL STANDARD

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First edition
2003-10

Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1: Determination of the detective quantum efficiency

*Appareils électromédicaux –
Caractéristiques des appareils d'imagerie à rayonnement X –
Partie 1: Détermination de l'efficacité quantique de détection*



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**MEDICAL ELECTRICAL EQUIPMENT –
CHARACTERISTICS OF DIGITAL X-RAY IMAGING DEVICES –**

Part 1: Determination of the detective quantum efficiency

FOREWORD

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International Standard IEC 62220-1 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this standard is based on the following documents:

FDIS	Report on voting
62B/493/FDIS	62B/506/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, terms printed in SMALL CAPITALS are used as defined in IEC 60788, in Clause 3 of this standard or other IEC publications referenced in Annex B. Where a defined term is used as a qualifier in another defined or undefined term it is not printed in SMALL CAPITALS, unless the concept thus qualified is defined or recognized as a “derived term without definition”.

NOTE Attention is drawn to the fact that, in cases where the concept addressed is not strongly confined to the definition given in one of the publications listed above, a corresponding term is printed in lower-case letters.

The committee has decided that the contents of this publication will remain unchanged until 2006-12. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

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Withdrawn

INTRODUCTION

DIGITAL X-RAY IMAGING DEVICES are increasingly used in medical diagnosis and will widely replace conventional (analogue) imaging devices such as screen-film systems or analogue X-RAY IMAGE INTENSIFIER television systems in the future. It is necessary, therefore, to define parameters that describe the specific imaging properties of these DIGITAL X-RAY IMAGING DEVICES and to standardize the measurement procedures employed.

There is growing consensus in the scientific world that the DETECTIVE QUANTUM EFFICIENCY (DQE) is the most suitable parameter for describing the imaging performance of an X-ray imaging device. The DQE describes the ability of the imaging device to preserve the signal-to-NOISE ratio from the radiation field to the resulting digital image data. Since in X-ray imaging, the NOISE in the radiation field is intimately coupled to the exposure level, DQE values can also be considered to describe the dose efficiency of a given imaging device.

NOTE 1 In spite of the fact that the DQE is widely used to describe the performance of imaging devices, the connection between this physical parameter and the decision performance of a human observer is not yet completely understood [1], [3].¹⁾

NOTE 2 The standard IEC 61262-5 specifies a method to determine the DQE of X-RAY IMAGE INTENSIFIERS at nearly zero SPATIAL FREQUENCY. It focuses only on the electro-optical components of X-RAY IMAGE INTENSIFIERS, not on the imaging properties as this standard does. As a consequence, the output is measured as an optical quantity (luminance), and not as digital data. Moreover, IEC 61262-5 prescribes the use of a RADIATION SOURCE ASSEMBLY, whereas this standard prescribes the use of an X-RAY TUBE. The scope of IEC 61262-5 is limited to X-RAY IMAGE INTENSIFIERS and does not interfere with the scope of this standard.

The DQE is already widely used by manufacturers to describe the performance of their equipment. The specification of the DQE is also required by regulatory agencies (such as the Food and Drug Administration (FDA)) for admission procedures. However, there is presently no standard governing either the measurement conditions or the measurement procedure with the consequence that values from different sources may not be comparable.

This standard has therefore been developed in order to specify the measurement procedure together with the format of the conformance statement for the DETECTIVE QUANTUM EFFICIENCY of DIGITAL X-RAY IMAGING DEVICES.

In the DQE calculations proposed in this standard, it is assumed that system response is measured for objects that attenuate all energies equally (task-independent) [5].

The standard will be beneficial for manufacturers, users, distributors and regulatory agencies. It can be regarded as the first of a series describing all the relevant parameters of DIGITAL X-RAY IMAGING DEVICES.

¹⁾ Figures in square brackets refer to the bibliography.

MEDICAL ELECTRICAL EQUIPMENT – CHARACTERISTICS OF DIGITAL X-RAY IMAGING DEVICES –

Part 1: Determination of the detective quantum efficiency

1 Scope

This part of IEC 62220 specifies the method for the determination of the DETECTIVE QUANTUM EFFICIENCY (DQE) of DIGITAL X-RAY IMAGING DEVICES as a function of exposure and of SPATIAL FREQUENCY for the working conditions in the range of the medical application as specified by the MANUFACTURER.

This part of IEC 62220 is applicable to projection DIGITAL X-RAY IMAGING DEVICES producing IMAGES in digital format that are used for medical diagnosis. It is restricted to DIGITAL X-RAY IMAGING DEVICES that are used for radiographic imaging, such as CR systems, selenium-based systems, flat panel detectors, optically coupled CCD detectors, and digital X-RAY IMAGE INTENSIFIERS used for single exposures.

This part of IEC 62220 is not applicable to

- DIGITAL X-RAY IMAGING DEVICES intended to be used in mammography or in dental radiography;
- COMPUTED TOMOGRAPHY;
- systems in which the X-ray field is scanned across the patient; and
- devices for dynamic imaging (where series of images are acquired, as in fluoroscopic or cardiac imaging).

NOTE The devices noted above are excluded because they contain many parameters (for instance, beam qualities, geometry, time dependence, etc.) which differ from those important for general radiography. It is intended to treat some of these techniques in separate standards as has been done for other topics, for instance for speed and contrast, in IEC and ISO standards.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60336:1993, *X-ray tube assemblies for medical diagnosis – Characteristics of focal spots*

IEC 60601-2-7: *Medical electrical equipment – Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators*

IEC 60788:1984, *Medical radiology – Terminology*

IEC 61267:1994, *Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics*

ISO 12232:1998, *Photography – Electronic still-picture cameras – Determination of ISO speed*

3 Terminology and definitions

For the purposes of this part of IEC 62220 the following terms and definitions apply.

3.1

CENTRAL AXIS

line perpendicular to the ENTRANCE PLANE passing through the centre of the entrance field

3.2

CONVERSION FUNCTION

plot of the large area output level (ORIGINAL DATA) of a DIGITAL X-RAY IMAGING DEVICE versus the number of exposure quanta per unit area (Q) in the DETECTOR SURFACE plane

NOTE 1 Q is to be calculated by multiplying the measured exposure excluding back scatter by the value given in column 2 of Table 2.

NOTE 2 Usually AIR KERMA is substituted for exposure.

NOTE 3 Many calibration laboratories, such as national metrology institutes, calibrate RADIATION METERS to measure AIR KERMA.

3.3

DETECTIVE QUANTUM EFFICIENCY

$DQE(u,v)$

ratio of two NOISE POWER SPECTRUM (NPS) functions with the numerator being the NPS of the input signal at the DETECTOR SURFACE of a digital X-ray detector after having gone through the deterministic filter given by the system transfer function, and the denominator being the measured NPS of the output signal (ORIGINAL DATA)

NOTE Instead of the two-dimensional DETECTIVE QUANTUM EFFICIENCY, often a cut through the two-dimensional DETECTIVE QUANTUM EFFICIENCY along a specified SPATIAL FREQUENCY axis is published.

3.4

DETECTOR SURFACE

area which is closest to the IMAGE RECEPTOR PLANE with all protecting parts (including the ANTI-SCATTER GRID and components for AUTOMATIC EXPOSURE CONTROL, if applicable) that can be safely removed out of the RADIATION BEAM without damaging the digital X-ray detector

3.5

DIGITAL X-RAY IMAGING DEVICE

device consisting of a digital X-ray detector including the protective layers installed for use in practice, the amplifying and digitizing electronics, and a computer providing the ORIGINAL DATA (DN) of the image

3.6

IMAGE MATRIX

arrangement of matrix elements in a preferably Cartesian coordinate system

3.7

LAG EFFECT

influence from a previous image on the current one

3.8

LINEARIZED DATA

ORIGINAL DATA to which the inverse CONVERSION FUNCTION has been applied

NOTE The LINEARIZED DATA are directly proportional to the exposure.

3.9**MODULATION TRANSFER FUNCTION***MTF(u,v)*

modulus of the generally complex optical transfer function, expressed as a function of SPATIAL FREQUENCIES u and v

3.10**NOISE**

fluctuations from the expected value of a stochastic process

3.11**NOISE POWER SPECTRUM (NPS)***W(u,v)*

modulus of the Fourier transform of the NOISE auto-covariance function. The power of NOISE, contained in a two-dimensional SPATIAL FREQUENCY interval, as a function of the two-dimensional frequency

NOTE In literature, the NOISE POWER SPECTRUM is often named "Wiener spectrum" in honour of the mathematician Norbert Wiener.

3.12**ORIGINAL DATA***DN*

RAW DATA to which the corrections allowed in this standard have been applied

3.13**PHOTON FLUENCE***Q*

mean number of photons per unit area

3.14**RAW DATA**

pixel values read directly after the analogue-digital-conversion from the DIGITAL X-RAY IMAGING DEVICE without any software corrections

3.15**SPATIAL FREQUENCY***u or v*

inverse of the period of a repetitive spatial phenomenon. The dimension of the SPATIAL FREQUENCY is inverse length

4 Requirements**4.1 Operating conditions**

The DIGITAL X-RAY IMAGING DEVICE shall be stored and operated according to the MANUFACTURER'S recommendations. The warm-up time shall be chosen according to the recommendation of the MANUFACTURER. The operating conditions shall be the same as those intended for clinical use and shall be maintained during evaluation as required for the specific tests described herein.

Ambient climatic conditions in the room where the DIGITAL X-RAY IMAGING DEVICE is operated shall be stated together with the results.

4.2 X-RAY EQUIPMENT

For all tests described in the following subclauses, a CONSTANT POTENTIAL HIGH-VOLTAGE GENERATOR shall be used (IEC 60601-2-7). The PERCENTAGE RIPPLE shall be equal to, or less than, 4.

The NOMINAL FOCAL SPOT VALUE (IEC 60336) shall be not larger than 1,2.

For the measurement of exposure, calibrated RADIATION METERS shall be used. The uncertainty (coverage factor 2)[2] of the readings shall be less than 5 %.

NOTE 1 “Uncertainty” and “coverage factor” are terms defined in the ISO Guide to the expression of uncertainty in measurement [2].

NOTE 2 RADIATION METERS to read AIR KERMA are, for instance, calibrated by many national metrology institutes.

4.3 RADIATION QUALITY

The RADIATION QUALITIES shall be one or more out of four selected RADIATION QUALITIES specified in IEC 61267 (see Table 1). If only a single RADIATION QUALITY IS used, RADIATION QUALITY RQA5 should be preferred.

For the application of the RADIATION QUALITIES, refer to IEC 61267:1994.

NOTE 1 According to IEC 61267, RADIATION QUALITIES are defined by a fixed ADDITIONAL FILTRATION and a HALF-VALUE LAYER that is realized with this filtration by a suitable adaptation of the X-RAY TUBE VOLTAGE, starting from the approximate X-RAY TUBE VOLTAGE (Table 1).

Table 1 – RADIATION QUALITY (IEC 61267:1994) for the determination of DETECTIVE QUANTUM EFFICIENCY and corresponding parameters

RADIATION QUALITY No.	Approximate X-RAY TUBE VOLTAGE	HALF-VALUE LAYER (HVL)	ADDITIONAL FILTRATION
	kV	mm Al	mm Al
RQA 3	50	4,0	10,0
RQA 5	70	7,1	21,0
RQA 7	90	9,1	30,0
RQA 9	120	11,5	40,0

NOTE 2 The additional filtration is the filtration added to the inherent filtration of the X-RAY TUBE.

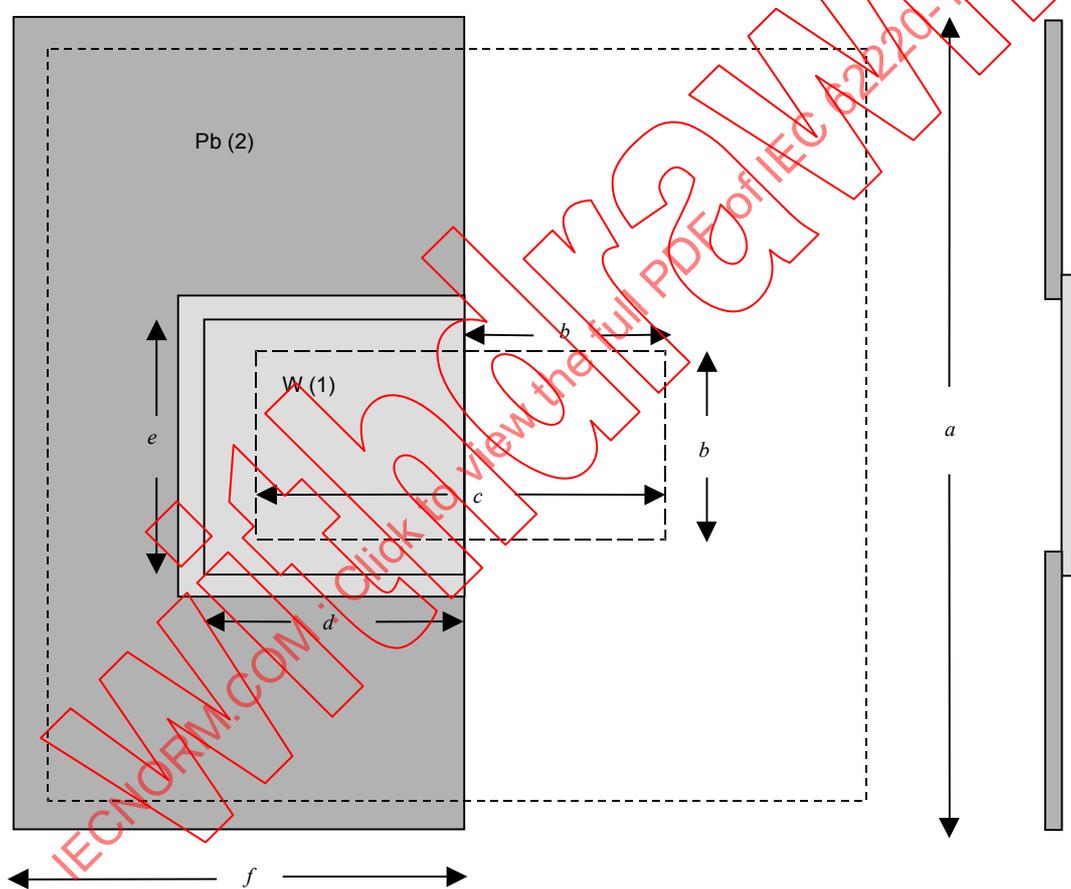
NOTE 3 The capability of X-RAY GENERATORS to produce low exposure levels may not be sufficient, especially for RQA9. In this case, it is recommended that the distance FOCAL SPOT to DETECTOR SURFACE be increased.

4.4 TEST DEVICE

The TEST DEVICE for the determination of the MODULATION TRANSFER FUNCTION and the magnitude of LAG EFFECTS shall consist of a 1,0 mm thick tungsten plate (purity higher than 90 %) 100 mm long and at least 75 mm wide (see Figure 1). Inadequate purity of tungsten shall be compensated by increased thickness.

The tungsten plate is used as an edge TEST DEVICE. Therefore, the edge which is used for the test IRRADIATION shall be carefully polished straight and at 90° to the plate. If the edge is irradiated by X-rays in contact with a screenless film, the image on the film shall show no ripples on the edge larger than 5 μm.

The tungsten plate shall be fixed on a 3 mm thick lead plate (see Figure 1). This arrangement is suitable to measure the MODULATION TRANSFER FUNCTION of the DIGITAL X-RAY IMAGING DEVICE in one direction.



IEC 2253/03

NOTE The TEST DEVICE consists of a 1,0 mm thick tungsten plate (1) fixed on a 3 mm thick lead plate (2).

Dimension of the lead plate: a : 200 mm, d : 70 mm, e : 90 mm, f : 100 mm.

Dimension of the tungsten plate: 100 mm × 75 mm.

The region of interest (ROI) used for the determination of the MTF is defined by $b \times c$, 50 mm × 100 mm (inner long dashed line).

The irradiated field on the detector (outer dashed line) is at least 160 mm × 160 mm.

Figure 1 – TEST DEVICE

4.5 Geometry

The geometrical set-up of the measuring arrangement shall comply with Figure 2. The X-RAY EQUIPMENT is used in that geometric configuration in the same way as it is used for normal diagnostic applications. The distance between the FOCAL SPOT of the X-RAY TUBE and the DETECTOR SURFACE should be not less than 1,50 m. If, for technical reasons, the distance cannot be 1,50 m or more, a smaller distance can be chosen but has to be explicitly declared when reporting results.

The TEST DEVICE is placed immediately in front of the DETECTOR SURFACE. The centre of the edge of the TEST DEVICE should be aligned to the CENTRAL AXIS of the X-ray beam. Displacement from the CENTRAL AXIS will lower the measured MTF. The CENTRAL AXIS can be located by maximizing the MTF as a function of TEST DEVICE displacement.

The recommended procedure is that the TEST DEVICE and the X-ray field be centred on the detector. If this is not done, the position of the centre of the X-ray field and of the TEST DEVICE needs to be stated.

In the set-up of Figure 2, the DIAPHRAGM B1 and the ADDED FILTER shall be positioned near the FOCAL SPOT of the X-RAY TUBE. The diaphragms B2 and B3 should be used, but may be omitted if it is proven that this does not change the result of the measurements. The DIAPHRAGMS B1 and - if applicable - B2 and the ADDED FILTER shall be in a fixed relation to the position of the FOCAL SPOT. The DIAPHRAGM B3 - if applicable - and the DETECTOR SURFACE shall be in a fixed relation at each distance from the FOCAL SPOT. The square DIAPHRAGM B3 - if applicable - shall be 120 mm in front of the DETECTOR SURFACE and shall be of a size to allow an irradiated field at the DETECTOR SURFACE of at least 160 mm × 160 mm. The RADIATION APERTURE of DIAPHRAGM B2 may be made variable so that the beam remains tightly collimated as the distance is changed. The irradiated field at the DETECTOR SURFACE shall be at least 160 mm × 160 mm.

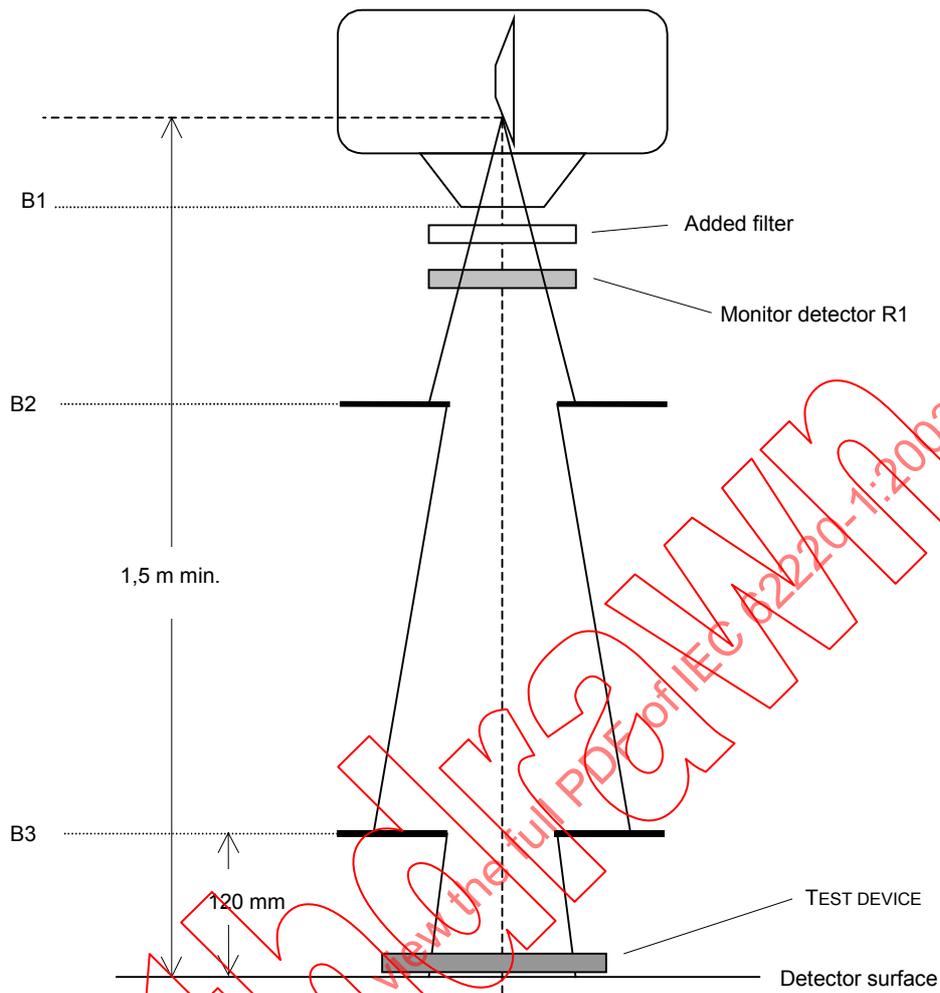
The attenuating properties of the DIAPHRAGMS shall be such that their transmission into shielded areas does not contribute to the results of the measurements. The RADIATION APERTURE of the DIAPHRAGM B1 shall be large enough so that the PENUMBRA of the RADIATION BEAM will be outside the sensitive volume of the monitor detector R1 and the RADIATION APERTURE of DIAPHRAGM B2 - if applicable.

A monitor detector should be used to assure the precision of the X-RAY GENERATOR. The monitor detector R1 may be inside the beam that irradiates the DETECTOR SURFACE if it is suitably transparent and free of structure; otherwise, it shall be placed outside the beam. The precision (standard deviation 1σ) of the monitor detector shall be better than 2 %. The relationship between the monitor reading and the exposure at the DETECTOR SURFACE shall be calibrated for each RADIATION QUALITY used (see also 4.6.2). To minimize the effect of back-scatter from layers behind the detector a minimum distance of 500 mm to other objects should be provided.

NOTE The calibration of the monitor detector may be sensitive to the positioning of the ADDED FILTER and to the adjustment of the shutters built into the X-RAY SOURCE. Therefore, these items should not be altered without re-calibration of the monitor detector.

This geometry is used either to irradiate the DETECTOR SURFACE uniformly for the determination of the CONVERSION FUNCTION and the NOISE POWER SPECTRUM or to irradiate the DETECTOR SURFACE behind a TEST DEVICE (see 4.6.6). For all measurements, the same area of the DETECTOR SURFACE shall be irradiated. The centre of this area, with respect to either the centre or the border of the digital X-ray detector, shall be recorded.

For the determination of the NOISE POWER SPECTRUM and the CONVERSION FUNCTION, the TEST DEVICE shall be moved out of the beam.



IEC 2254/03

NOTE No TEST DEVICE is used for the measurement of the CONVERSION FUNCTION and the NOISE POWER SPECTRUM.

Figure 2 – Geometry for exposing the DIGITAL X-RAY IMAGING DEVICE in order to determine the CONVERSION FUNCTION, the NOISE POWER SPECTRUM and the MODULATION TRANSFER FUNCTION

4.6 IRRADIATION conditions

4.6.1 General conditions

The calibration of the digital X-ray detector shall be carried out prior to any testing, i.e., all operations necessary for corrections according to Clause 5 shall be effected. No re-calibration of the digital X-ray detector shall be allowed between any measurement of the series.

The exposure level shall be chosen as that used when the digital X-ray detector is operated for the intended use in clinical practice. This is called the "normal" level and shall be specified by the MANUFACTURER. At least two additional exposure levels shall be chosen, one 3,2 times the normal level and one at 1/3,2 of the normal level. No change of system settings (such as gain etc.) shall be allowed when changing exposure levels.

NOTE 1 A factor of three in the exposure above and below the "normal" level approximately corresponds to the bright and dark parts within one clinical radiation image.

To cover the range of various different clinical examinations, additional "normal" levels may be chosen. For these additional "normal" levels other system settings may be chosen and kept constant during the test procedure.

Each IRRADIATION shall be made without interruption. The variation of exposure shall be carried out by variation of the X-RAY TUBE CURRENT or the IRRADIATION TIME or both. The IRRADIATION TIME and exposure level shall be similar to the conditions for clinical application of the digital X-ray detector. LAG EFFECTS shall be avoided (see 4.6.3).

The IRRADIATION conditions shall be stated together with the results (see Clause 7).

The RADIATION QUALITY shall be assured when varying the X-RAY TUBE CURRENT or the IRRADIATION TIME and shall be checked at the lowest exposure level.

4.6.2 Exposure measurement

The exposure at the DETECTOR SURFACE is measured with an appropriate RADIATION METER. For this purpose, the digital X-ray detector is removed from the beam and the RADIATION DETECTOR of the RADIATION METER is placed behind APERTURE B3 in the DETECTOR SURFACE plane. Care shall be taken to minimize the back-SCATTERED RADIATION. The correlation between the readings of the RADIATION METER and the monitoring detector, if used, shall be noted, and shall be used for the exposure calculation at the DETECTOR SURFACE when irradiating the DETECTOR SURFACE to determine the CONVERSION FUNCTION, the NOISE POWER SPECTRUM and the MODULATION TRANSFER FUNCTION. It is recommended that about five exposures be monitored and that the average be used for the correct exposure.

NOTE 2 To reduce back-SCATTERED RADIATION, a lead screen of 4 mm in thickness may be placed 450 mm behind the RADIATION DETECTOR. It has been proven by experiments that, under these conditions, the back-SCATTERED RADIATION is not more than 0,5 %. If the lead screen is at a distance of 250 mm, the back-SCATTERED RADIATION is not more than 2,5 %.

If it is not possible to remove the digital X-ray detector out of the beam, the exposure at the DETECTOR SURFACE may be calculated via the inverse square distance law. For that purpose, the exposure is measured at different distances from the FOCAL SPOT in front of the DETECTOR SURFACE. For this measurement, radiation, back-scattered from the DETECTOR SURFACE, shall be avoided. Therefore, a minimum distance between the DETECTOR SURFACE and the RADIATION DETECTOR of 450 mm is recommended.

If a monitoring detector is used, the following equation shall be plotted as a function of the distance d between the FOCAL SPOT and the RADIATION DETECTOR:

$$f(d) = \sqrt{\frac{\text{monitor detector reading}}{\text{radiation detector reading}}}$$

By extrapolating this approximately linear curve up to the distance between the FOCAL SPOT and the DETECTOR SURFACE r_{SID} , the ratio of the readings at r_{SID} can be obtained and the exposure at the DETECTOR SURFACE for any monitoring detector reading can be calculated.

If no monitoring detector is used, the square root of the inverse RADIATION METER reading is plotted as a function of the distance between the FOCAL SPOT and the RADIATION DETECTOR. The extrapolation etc. is carried out as in the preceding paragraph.

NOTE 3 To reduce back-SCATTERED RADIATION, a lead shield of 4 mm thickness may be placed in front of the DETECTOR SURFACE.

4.6.3 Avoidance of LAG EFFECTS

LAG EFFECTS may influence the measurement of the CONVERSION FUNCTION and the NOISE POWER SPECTRUM. They may, therefore, influence the measurement of DETECTIVE QUANTUM EFFICIENCY.

The influence may be split into an additive component (additional offset) and a multiplicative component (change of gain). The magnitude of both components shall be estimated.

For the determination of possible LAG EFFECTS, the digital X-ray detector shall be operated according to the specifications of the MANUFACTURER. The minimum time interval between two successive exposures (as determined by the tests given in Annex A) must be maintained to prevent the contaminating LAG EFFECTS on the measurement of the DETECTIVE QUANTUM EFFICIENCY.

NOTE The following parameters may contribute to LAG EFFECTS: time of IRRADIATION relative to read-out, method of erasure of remnants of previous IRRADIATION, time from erase to re-IRRADIATION, time from read-out to re-IRRADIATION, or the inclusion of intervening "dummy" read-outs used to erase the effects of a previous IRRADIATION.

To test the magnitude of LAG EFFECTS, the test procedures as given in Annex A shall be used.

4.6.4 IRRADIATION to obtain the CONVERSION FUNCTION

The settings of the DIGITAL X-RAY IMAGING DEVICE shall be the same as those used when exposing the TEST DEVICE. The IRRADIATION shall be carried out using the geometry of Figure 2 but without any TEST DEVICE in the beam. The exposure is measured according to 4.6.2. The CONVERSION FUNCTION shall be determined from exposure level zero up to four times the normal exposure level.

The CONVERSION FUNCTION for exposure level zero shall be determined from a dark image, realized under the same conditions as an X-ray image. The minimum X-ray exposure level shall not be greater than one-fifth of the normal exposure level.

Depending on the form of the CONVERSION FUNCTION the number of different exposures varies; if only the linearity of the CONVERSION FUNCTION has to be checked, five exposures, uniformly distributed within the desired range, are sufficient. If the complete CONVERSION FUNCTION has to be determined, the exposure shall be varied in such a way that the maximum increments of logarithmic (to the base 10) exposure is not greater than 0,1. The RADIATION QUALITY for all exposure levels shall be assured and shall be checked at the lowest exposure level. In case of deviations from this requirement, the FOCAL SPOT to DETECTOR SURFACE distance may have to be increased.

4.6.5 IRRADIATION for determination of the NOISE POWER SPECTRUM

The settings of the DIGITAL X-RAY IMAGING DEVICE shall be the same as those used when exposing the TEST DEVICE. The IRRADIATION shall be carried out using the geometry of Figure 2 but without any TEST DEVICE in the beam. The exposure is measured according to 4.6.2.

A square area of approximately 125 mm × 125 mm located centrally behind the 160 mm square DIAPHRAGM is used for the evaluation of an estimate for the NOISE POWER SPECTRUM to be used later on to calculate the DQE.

For this purpose, the set of input data shall consist of at least four million independent image PIXELS arranged in one or several independent flat-field images, each having at least 256 PIXELS in either spatial direction. If more than one image is necessary, all individual images shall be taken at the same RADIATION QUALITY and AIR KERMA. The standard deviation of the IRRADIATIONS used to get the different images shall be less than 10 % of the mean.

NOTE The minimum number of required independent image PIXELS is determined by the required accuracy which defines the minimum number of ROIs. For an accuracy of the two-dimensional NOISE POWER SPECTRUM of 5 %, a minimum of 960 (overlapping) ROIs are needed meaning 16 million independent image pixels with the given ROI size. The averaging and binning process applied afterwards to obtain a one-dimensional cut reduces the minimum number of required independent image PIXELS to four million, still assuring the necessary accuracy.

Care shall be taken that there is no correlation between the subsequent images (LAG EFFECT; see 4.6.3). No change of system setting is allowed when making the IRRADIATIONS.

The images for the determination of the NOISE POWER SPECTRUM shall be taken at three exposure levels (see 4.6.1): the normal one and two others, each differing by a factor of 3,2 from the normal one.

4.6.6 IRRADIATION with TEST DEVICE in the RADIATION BEAM

The IRRADIATION shall be carried out using the geometry of Figure 2. The TEST DEVICE is placed directly on the DETECTOR SURFACE. The TEST DEVICE is positioned in such a way that the edge is tilted by an angle α relative to the axis of the PIXEL columns or PIXEL rows, where α is between 1,5° and 3°.

NOTE 1 The method of tilting the TEST DEVICE relative to the rows or columns of the IMAGE MATRIX is common in other standards (ISO 15529 and ISO 12233) and reported in numerous publications when the pre-sampling MODULATION TRANSFER FUNCTION has to be determined.

The TEST DEVICE has to be adjusted in such a way that it is perpendicular to the CENTRAL AXIS of the RADIATION BEAM and the edge of the TEST DEVICE is aligned as closely as possible to the CENTRAL AXIS of the RADIATION BEAM.

NOTE 2 Deviations from this ideal set-up will result in a lower measured MTF.

Two IRRADIATIONS shall be made with the TEST DEVICE in the RADIATION BEAM, one with the TEST DEVICE oriented approximately along the columns, the other with the TEST DEVICE approximately along the rows of the IMAGE MATRIX. The positions of the other components shall not be changed. For the new position, a new adjustment of the TEST DEVICE shall be made.

The images for the determination of the MTF shall be taken at one of the three exposure levels (see 4.6.1).

5 Corrections of RAW DATA

The following linear and image-independent corrections of the RAW DATA are allowed in advance of the processing of the data for the determination of the CONVERSION FUNCTION, the NOISE POWER SPECTRUM, and the MODULATION TRANSFER FUNCTION:

- The RAW DATA of bad or defective pixels may be replaced by appropriate data as in normal clinical use.
- A flat-field correction comprising
 - correction of the non-uniformity of the radiation field,
 - correction for the offset of the individual pixels and
 - gain correction for the individual pixels
 may be applied as in normal clinical use.
- A correction for geometrical distortion may be made as in normal clinical use.

NOTE Some detectors execute linear image processing due to their physical concept. As long as this image processing is linear and image-independent, these operations are allowed.

6 Determination of the DETECTIVE QUANTUM EFFICIENCY

6.1 Definition and formula of $DQE(u,v)$

The equation for the frequency-dependent DETECTIVE QUANTUM EFFICIENCY $DQE(u,v)$ is :

$$DQE(u,v) = G^2 MTF^2(u,v) \frac{W_{in}(u,v)}{W_{out}(u,v)} \quad (1)$$

The source for this equation is the Handbook of Medical Imaging I (equation 2.153) [4],

In this standard, the NOISE POWER SPECTRUM at the output $W_{out}(u,v)$ and the MODULATION TRANSFER FUNCTION $MTF(u,v)$ of the DIGITAL X-RAY IMAGING DEVICE shall be calculated on the LINEARIZED DATA. The LINEARIZED DATA are calculated by applying the inverse CONVERSION FUNCTION to the ORIGINAL DATA (according to subclause 6.3.1) and are expressed in number of exposure quanta per unit area. The gain G of the detector at zero SPATIAL FREQUENCY (equation (1)) is part of the conversion function and does not need to be separately determined.

Therefore the working equation for the determination of the frequency-dependent DETECTIVE QUANTUM EFFICIENCY $DQE(u,v)$ according to this standard is :

$$DQE(u,v) = MTF^2(u,v) \frac{W_{in}(u,v)}{W_{out}(u,v)} \quad (2)$$

where

$MTF(u,v)$ is the pre-sampling MODULATION TRANSFER FUNCTION of the DIGITAL X-RAY IMAGING DEVICE, determined according to subclause 6.3.3;

$W_{in}(u,v)$ is the NOISE POWER SPECTRUM of the radiation field at the DETECTOR SURFACE, determined according to subclause 6.2;

$W_{out}(u,v)$ is the NOISE POWER SPECTRUM at the output of the DIGITAL X-RAY IMAGING DEVICE, determined according to subclause 6.3.2.

6.2 Parameters to be used for evaluation

For the determination of the DETECTIVE QUANTUM EFFICIENCY, the value of the input NOISE POWER SPECTRUM $W_{in}(u, v)$ shall be calculated:

$$W_{in}(u, v) = K_a \cdot SNR_{in}^2 \quad (3)$$

where

K_a is the measured AIR KERMA, unit: μGy ;

SNR_{in}^2 is the squared signal-to-NOISE ratio per AIR KERMA, unit: $1/(\text{mm}^2 \cdot \mu\text{Gy})$ as given in column 2 of Table 2.

The values for SNR_{in}^2 in Table 2 shall apply for this standard.

Table 2 – Parameters mandatory for the application of this standard

RADIATION QUALITY No.	SNR_{in}^2 1/($\text{mm}^2 \cdot \mu\text{Gy}$)
RQA 3	21759
RQA 5	30174
RQA 7	32362
RQA 9	31077

Background information on the calculation of SNR_{in}^2 is given in Annex C.

6.3 Determination of different parameters from the images

6.3.1 Linearization of data

The LINEARIZED DATA are calculated by applying the inverse CONVERSION FUNCTION to the ORIGINAL DATA on an individual PIXEL basis. Since the CONVERSION FUNCTION is the output level (ORIGINAL DATA) as a function of the number of exposure quanta per unit area, the linearized data have units of exposure quanta per unit area.

NOTE In case of a linear CONVERSION FUNCTION this calculation reduces to the multiplication by a conversion factor.

The CONVERSION FUNCTION is determined from the images generated according to 4.6.4.

The output is calculated by averaging 100×100 pixels of those ORIGINAL DATA in the centre of the exposed area. The PIXEL values shall be the ORIGINAL DATA, meaning the RAW DATA values which are corrected according to Clause 5 only. This output is plotted against the input signal being the number of exposure quanta per unit area Q calculated by multiplying the AIR KERMA by the value given in column 2 of Table 2 (see 6.2).

The experimental data points shall be fitted by a model function. If the CONVERSION FUNCTION is assumed to be linear (only 5 exposures made according to 4.6.4) only a linear function shall be fitted. The fit-result has to fulfil the following requirements:

- Final $R^2 \geq 0,99$; and
- no individual experimental data point deviates from its corresponding fit result by more than 2 % relatively.

6.3.2 The NOISE POWER SPECTRUM (NPS)

The NOISE POWER SPECTRUM at the output of the DIGITAL X-RAY IMAGING DEVICE ($W_{out}(u, v)$) shall be determined from the images generated according to 4.6.5.

The portion of the uniformly exposed area of the digital X-ray detector used for NPS analysis shall be divided into square areas, called ROIs. Each ROI for calculating an individual sample for the NOISE POWER SPECTRUM shall be 256×256 PIXELS in size. These areas shall overlap by 128 PIXELS in both, the horizontal and vertical direction (see Figure 3). Let the first area be the one in the upper left corner of the total region analysed. The next is produced by moving the rectangular area 128 PIXELS in the horizontal direction to the right-hand side, generating a second area, which overlaps half with the first one. The next is defined by moving the second one by 128 PIXELS again. This is repeated up to the end of the first horizontal “band”. Starting again at the left-hand side of the image and simultaneously moving by 128 PIXELS in the vertical direction, a second horizontal “band” is generated. The movement in the vertical direction generates further bands until the whole area of about $125 \text{ mm} \times 125 \text{ mm}$ is covered by ROIs.

Trend removal may be performed by fitting a two-dimensional second-order polynomial to the LINEARIZED DATA of each complete image used for calculating the spectra and subtracting this function ($S(x_i, y_j)$, see equation (4)) from the LINEARIZED DATA. Without applying any windowing, the two-dimensional Fourier transform is calculated for every ROI.

The two-dimensional Fourier transform is applied using equation (4). Starting with equation 3.44 as given in the Handbook of Medical Imaging I [4], the working equation for the determination of the NOISE POWER SPECTRUM according to this standard is :

$$W_{out}(u_n, v_k) = \frac{\Delta x \Delta y}{M \cdot 256 \cdot 256} \sum_{m=1}^M \left| \sum_{i=1}^{256} \sum_{j=1}^{256} (I(x_i, y_j) - S(x_i, y_j)) \exp(-2\pi i(u_n x_i + v_k y_j)) \right|^2 \quad (4)$$

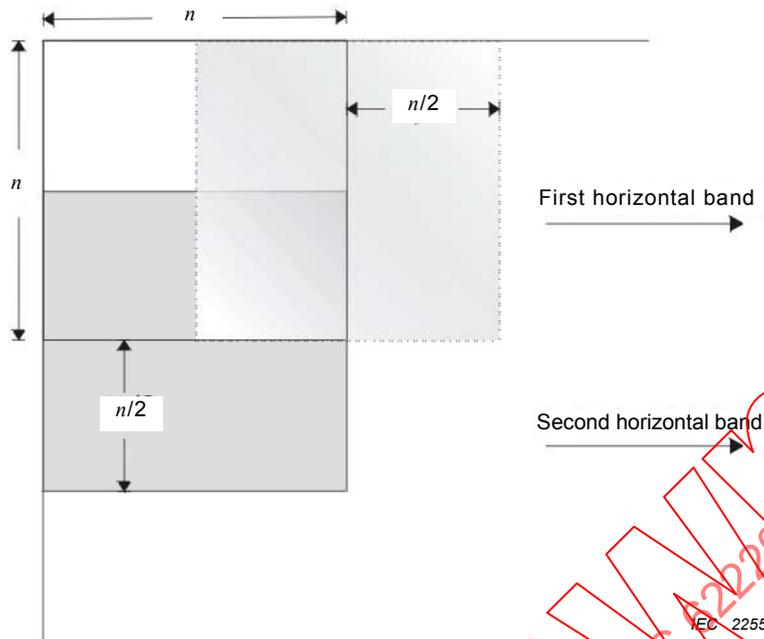
where

$\Delta x \Delta y$ is the pixel spacing in respectively the horizontal and vertical direction;

M is the number of ROIs;

$I(x_i, y_j)$ is the LINEARIZED DATA;

$S(x_i, y_j)$ is the optionally fitted two-dimensional polynomial.



NOTE The size of the ROIs shall be $n = 256$.

Figure 3 – Geometric arrangement of the ROIs

An average two-dimensional NOISE POWER SPECTRUM is obtained by averaging the samples of all the spectra.

In order to obtain one-dimensional cuts through the two-dimensional NOISE POWER SPECTRUM along the axis of the SPATIAL FREQUENCY plane, 15 rows or columns of the two-dimensional spectrum around each axis are used. However, only the data of the NOISE POWER SPECTRUM of seven rows or columns on both sides of the corresponding axis (a total of 14), omitting the axis itself, are averaged. For all data points the exact SPATIAL FREQUENCIES in the sense of radial distance from the origin shall be calculated. Smoothing shall be obtained by averaging the data points within the 14 rows and columns that fall in a frequency interval of f_{int} ($f - f_{int} \leq f \leq f + f_{int}$) around the SPATIAL FREQUENCIES which shall be reported (see Clause 7).

f_{int} is defined by $f_{int} = \frac{0,01}{\text{pixelpitch(mm)}}$.

NOTE Making the binning frequency interval dependent on pixel pitch assures that a similar number of data points is always used in the binning process, independent of the pixel pitch. This assures a constant accuracy.

The dimension of the NOISE power spectral density is the squared LINEARIZED DATA per two-dimensional SPATIAL FREQUENCY, that means inverse length squared.

In order to estimate if quantization effects influence the NOISE POWER SPECTRUM, the variance of the ORIGINAL DATA $\text{var}(\text{DN})$ which are used for the calculation of the NOISE POWER SPECTRUM shall be calculated for one image. If the variance is larger than 0,25 (see 6.2.5 in ISO 12232), it may be assumed that quantization NOISE is negligible. If the variance is smaller than 0,25, the data is considered to be not suitable for the determination of the NOISE POWER SPECTRUM.

NOTE Generally, the variance of the ORIGINAL DATA is larger than a quarter of the quantization interval. Only if the number of bits for quantization is very small, may the variance be smaller. For the calculation of the quantization variance i. e. $1/12$, it is assumed that the analogue values which are digitized have a uniform or rectangular distribution with respect to each quantization interval [2].

If the NOISE POWER SPECTRUM is determined along a diagonal (45° with respect to the horizontal or vertical axis), the averaging of single samples shall be carried out in a similar way as described in the preceding paragraph but including the values along the diagonal.

These measurements at 45° may also require averaging of adjacent 45° cuts in order to improve the precision of NPS determination.

6.3.3 Determination of the MODULATION TRANSFER FUNCTION (MTF)

The pre-sampling MODULATION TRANSFER FUNCTION shall be determined along two mutually perpendicular axes which are parallel to the rows or to the columns of the IMAGE MATRIX, respectively.

For the determination of the MTF, the complete length of the edge spread function (ESF) as defined by the ROI shown in Figure 1 shall be used.

The integer number N of lines (i.e. rows or columns) leading to a lateral shift of the edge in line direction which most closely matches the value of 1 PIXEL is determined. Different methods may be applied. One is to determine the angle α between the edge and the columns or rows of the IMAGE MATRIX and to calculate N as $N = \text{round}(1/\tan\alpha)$, where "round" denotes the rounding to the nearest integer value. N should be accurate to integer precision.

NOTE The range of values for the angle α means that N is between about 20 and 40.

The pixel values of the LINEARIZED DATA (see 6.3.1) of N consecutive lines (i.e. rows or columns) across the edge are used to generate an oversampled edge profile or (ESF). The value of the first PIXEL in the first line gives the first data point in the oversampled ESF, the first PIXEL in the second line the second data point, and the first PIXEL in the N^{th} line the N^{th} data point. This procedure is repeated for the other PIXELS in the N consecutive lines, for example, the value of the second PIXEL in the first line gives the $(N + 1)^{\text{th}}$ data point, the second PIXEL in the second line the $(N + 2)^{\text{th}}$ data point, etc.

The sampling distance in the oversampled ESF is assumed to be constant and is given by the PIXEL spacing Δx divided by N , i.e. $\text{ESF}(x_n)$ with $x_n = n(\Delta x/N)$. The oversampled ESF is differentiated using a $[-1, 0, 1]$ or $[-0,5, 0, 0,5]$ kernel yielding the oversampled line spread function LSF. The spectral smoothing effect of the finite-element differentiation may be corrected [6]. A digital Fourier transform of the line-spread function is calculated, and the modulus of this Fourier transform yields the MTF. The MTF is normalized to its value at zero frequency. Since the distance of the individual PIXELS to the edge is calculated along the line direction and not in a direction perpendicular to the edge, a frequency axis scaling (scaling factor: $1/\cos\alpha$) may be performed for correction.

NOTE The error of the SPATIAL FREQUENCY is $\leq 0,1\%$ if no correction by $1/\cos\alpha$ is done.

To calculate the average MTF, this procedure is repeated for other groups of N consecutive lines along the edge. Alternatively, and especially suited for noisier images, the average of all edge spread functions is determined, and the MTF is calculated based on this average ESF.

To obtain the MTF at the SPATIAL FREQUENCIES which shall be reported (see Clause 7), binning of the data points in a frequency interval of $f_{\text{int}} \text{ mm}^{-1}$ ($f - f_{\text{int}} \leq f \leq f + f_{\text{int}}$, see 6.3.2 for f_{int}) around these SPATIAL FREQUENCIES shall be performed.

7 Format of conformance statement

When stating the DETECTIVE QUANTUM EFFICIENCY, the following parameters shall be stated:

- RADIATION QUALITY according to Table 1;
- exposure (AIR KERMA);
- distance between FOCAL SPOT and DETECTOR SURFACE if less than 1,5 m;
- deviations from recommended centred geometry (see 4.5);
- method used for MTF determination and its validation, if a method different from the standardized edge method is used;

– ambient climatic conditions.

The measurement results for DQE shall be given as numbers in a table (see Table 3 as an example). The DQE shall be reported for SPATIAL FREQUENCIES of $0,5 \text{ mm}^{-1}$, 1 mm^{-1} , $1,5 \text{ mm}^{-1}$ up to the highest SPATIAL FREQUENCY which is just below the Nyquist frequency. Other relevant parameters may be added to the table. Additionally the measurement results may be plotted as values of $DQE(u,v)$ as a function of SPATIAL FREQUENCY, showing the AIR KERMA as parameter using a linear scale on both axes. An example is given in Figure 4.

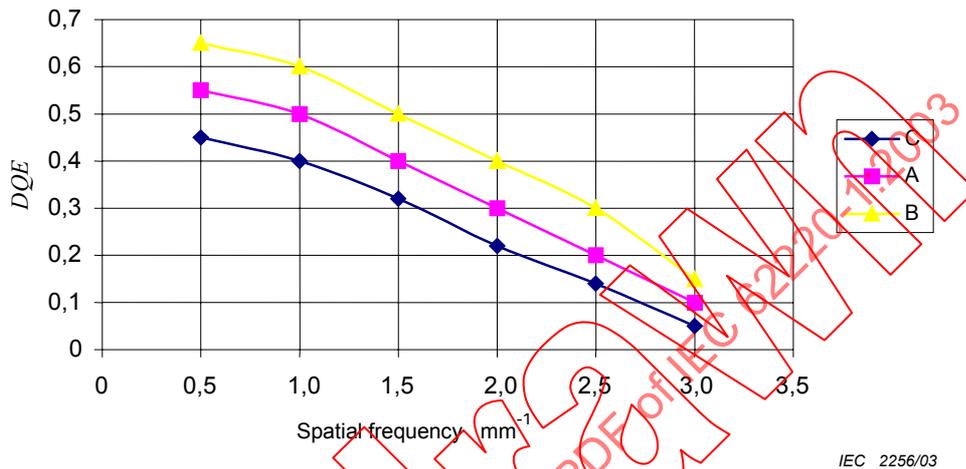


Figure 4 – Example for a plot of $DQE(u,v)$ as a function of SPATIAL FREQUENCY with AIR KERMA (a: $2,5\mu\text{Gy}$, b: $2,5\mu\text{Gy} * 3,2$, c: $2,5\mu\text{Gy} / 3,2$) as parameters

Generally, the $DQE(u,v)$ values shall be given for both axes, the horizontal and vertical axes. If the quotient of ($DQE(u)/DQE(v)$) is within the range of 0,9 to 1,1, the $DQE(u,v)$ values for both axes may be averaged and stated to be valid for both axes.

Additionally, values of DQE may be given along a diagonal axis. It shall be explicitly stated with the results that the DQE refers to the diagonal axis.

Table 3 – Format to state the measurement results

IRRADIATION ROA/ μGy	SPATIAL FREQUENCY mm^{-1}	DQE (horizontal) or (vertical)
5/2,5	0,5	0,65
	1,0	0,6
	1,5	0,5
	2,0	0,4
	2,5	0,3
	3,0	0,15

8 Accuracy

The uncertainty of DQE should be determined following the instructions of GUM [2] using equation (2) as a model equation.

The uncertainty (coverage factor 2 according to [2]) of the DQE values presented shall be less than

$\Delta(DQE(u)) = \pm 0,06$ or

$\Delta(DQE(u))/DQE(u) = \pm 0,10$,

whichever is greater.

The uncertainty should be stated in the data sheets.

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Annex A (normative)

Determination of LAG EFFECTS

A.1 Test of additive LAG EFFECTS

To test the magnitude of additive LAG EFFECTS, the following test procedure shall be performed.

- 1) Following the method as described in 4.6.6, carry out an IRRADIATION of the edge TEST DEVICE. Ensure that the object is properly aligned with the beam as specified in 4.6.6. The IRRADIATION shall be made at the “normal” exposure level as described in 4.6.1.
- 2) Create an image resulting from the IRRADIATION of step 1 following the method proposed by the manufacturer.
- 3) Follow whatever steps are part of the proposed method for the treatment of the digital X-ray detector between IRRADIATIONS.
- 4) Without further irradiating the DETECTOR SURFACE, create a second image following the method of step 2.
- 5) Record the time between the first (irradiated) and the second (non-irradiated) reading of the digital X-ray detector. The larger of this time and the time determined in Clause A.2 shall be the minimum time between successive images used for the determination of the CONVERSION FUNCTION, the NOISE POWER SPECTRUM and the MTF.
- 6) On the (irradiated) image from step 2, measure the average value of LINEARIZED DATA of a rectangular region enclosing at least 1 000 pixels² adjacent to, but not overlapping, the area of the image of the high-contrast object of step 2 (ROI 2, see Figure A.1).
- 7) On the (non-irradiated) image from step 4, measure the average value of LINEARIZED DATA of a rectangular region enclosing at least 1 000 pixels adjacent to, but not overlapping, the area of the image of the high-contrast object of step 2 (ROI 2, see Figure A.1).
- 8) On the (non-irradiated) image from step 4, measure the average pixel value of a rectangular region enclosing at least 1 000 pixels within the area covered by the image of the high-contrast object (ROI 1, see Figure A.1).
- 9) The test will have been passed if the difference of the measurements from steps 6 and 7 divided by the measurement from step 5 is less than 0,005.
- 10) This insures that lag contributes less than 0,5 % of the effective exposure.
- 11) In case the test is not passed, repeat it with an increased time-interval between the exposures/readings of the digital X-ray detector.

² The use of 1 000 pixels is a limit derived from the number of samples necessary to ensure that a relative difference of means of 0,005 is detected at 95 % confidence with a probability of detection of 80 %. The use of 10 000 pixels is preferable.