Guideline for Determining the Mean Glandular Dose According to DIN 6868-162 and Threshold Contrast Visibility According to the Quality Assurance Guideline for Digital Mammography Systems

Prüfanleitung für die Bestimmung der mittleren Parenchymdosis nach DIN 6868-162 und des Kontrastauflösungsvermögens nach Qualitätssicherungs-Richtlinie für digitale Mammografieeinrichtungen – Leitfaden der deutschen Referenzzentren für Mammographie Version 2.0

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Abstract
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As part of the physico-technical quality assurance of the German breast cancer screening program, the threshold contrast visibility and the average glandular dose of every digital mammography system have to fulfill the requirements of the "European guidelines for quality assurance in breast cancer screening and diagnosis" (4th Edition). To accomplish uniform measurements in all federal states of Germany, the physical board of the reference centers developed a special guideline in 2009. Due to recent changes in the guidelines and standards, a second version of the guideline was developed by the reference centers. This guideline describes the determination of the average glandular dose as well as the CDMAM image acquisition and the CDMAM image evaluation. The determination of the threshold contrast visibility can be performed visually or automatically. The determination of the average glandular dose is based on DIN 6868 – 162 and the threshold contrast visibility test is based on the German "Quality Assurance Guideline".

Key Points:
▸ Update of the first guideline due recent changes in the national standards
▸ Description of the procedure for determining the average glandular dose according to DIN 6868-162
▸ Description of the procedure for determining the threshold contrast visibility according to the Quality Assurance Guideline
▸ In addition to the visual evaluation of the threshold contrast visibility, an automatic evaluation method can be used

Zusammenfassung
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Im Rahmen der physikalisch-technischen Qualitätssicherung muss nach Beschluss des Bundesministeriums für Umwelt, Naturschutz und Reaktorsicherheit an allen eingesetzten digitalen Mammographiesystemen die Prüfung des Kontrastauflösungsvermögens sowie die Bestimmung der mittleren Parenchymdosis auf Grundlage der „European guidelines for quality assurance in breast cancer screening and diagnosis" 4th Edition durchgeführt werden. Um eine weitgehende Homogenisierung dieser Messungen in Deutschland zu erreichen, wurde von den Referenzzentren für Mammographie bereits 2009 eine gemeinsame Prüfanleitung publiziert. Aufgrund von aktuellen Veränderungen in den Richtlinien und der Normung wurde eine zweite Version durch die Referenzzentren erarbeitet. In dieser Prüfanleitung werden sowohl die einzelnen Schritte zur Bestimmung der mittleren Parenchymdosis als auch die Anfertigung und Auswertung der Prüfkörperaufnahmen für die Ermittlung des Kontrastauflösungsvermögens beschrieben. Die Auswertung der Prüfkörperaufnahmen zur Bestimmung des Kontrastauflösungsvermögens kann hierbei sowohl visuell als auch automatisiert erfolgen. Die Prüfung der Parenchymdosis erfolgt nach den Vorgaben der DIN 6868 – 162 und die Prüfung der Kontrastauflösung nach Vorgaben der Qualitätssicherungs-Richtlinie.

1. Introduction
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This guideline describes the procedure for determining the average glandular dose (AGD) according to the standard DIN 6868 – 162:2013 Section 9.12 [1] and the threshold contrast visibility (CDMAM test) according to the currently valid Quality Assurance Guideline for digital mammography systems [2 – 4]. The procedure described here is used both in quality assurance for the German mammography screening program as well as for systems used for diagnostic mammography [5 – 7]. This guideline replaces guideline version 1.4 of the German reference centers for mammography [8].

The described tests are based on the specifications of the 4th edition of the "European guidelines for quality assurance in breast cancer screening and diagnosis" (EPQC 4th edition) [9] and the EPQC Supplement [10].

The test and measurement equipment of DIN 6868 – 162 is to be used for determining the AGD. The test of the threshold contrast visibility is to be performed using a test object in accordance with EPQC 4th edition.

This guideline was coordinated among all German mammography reference centers.

The original text of the guideline contains various appendices with practical procedures and examples of the individual test positions.

2. Determination of the average glandular dose according to DIN 6868 – 162 Number 9.12 [1]
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The AGD is determined according to the following procedure:
1. Determination of the imaging conditions with automatic exposure control (AEC)
2. Determination of the entrance surface air kerma using manual exposure settings
3. Determination of the half-value layer (HVL)
4. Determination of the factors g, c, and s
5. Calculation of the AGD

If a mammography system has more than one breast support table, each with a different AEC-detector attached, then each AEC system must be assessed separately.

2.1 Determination of the imaging conditions

The exposure factors (target-filter combination, x-ray tube voltage, tube loading) are determined using the test blocks of polymethyl methacrylate (PMMA) specified in DIN 6868 – 162 Appendix A d) [1].

For each of seven different PMMA thicknesses, one x-ray is acquired using the AEC exposure settings that are normally used clinically for the particular equivalent breast thickness according to ⊙ **Table 1** (⊙ **Fig. 1a**).

If a correction switch is provided for clinical operation, it must be set to the position that is normally used clinically. The imaging conditions including the tube loading (mAs) set by the automatic exposure control are recorded for every X-ray.

2.1.1 Positioning of the AEC-detector

In mammography systems with a manually selectable AEC-detector position of the automatic exposure control, the detector must be positioned near the chest wall. The effective measurement field of the detector must be completely under the particular attenuation body and remain in the same position during every exposure. An automatically selected measurement field position AEC is only per-

Table 1   Limiting values of the average glandular dose.

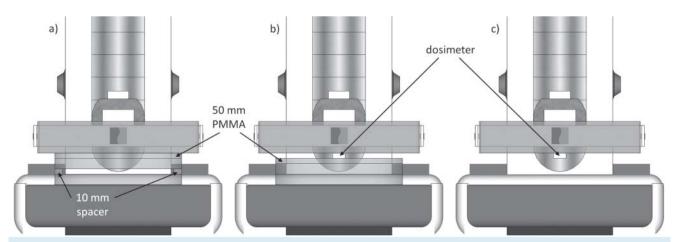| object thickness PMMA (mm)	equivalent breast thickness (mm)	limit value of the average glandular dose (mGy)
20 mm	21 mm	1.0
30 mm	32 mm	1.5
40 mm	45 mm	2.0
46 mm	53 mm	2.5
50 mm	60 mm	3.0
60 mm	75 mm	4.5
70 mm	90 mm	6.5

Fig. 1   Example for 50-mm PMMA thickness according to Table 1: Determination of the exposure conditions with a) 50-mm PMMA attenuation body and 10-mm spacer for simulation of 60-mm breast tissue, b) measurement of the entrance surface air kerma KE with 50-mm PMMA attenuation body and c) measurement of the entrance surface air kerma KE without a PMMA attenuation body.

mitted for mammography systems that do not allow selection of the AEC-detector position.

2.1.2 Spacer

For mammography systems that select the exposure parameters in AEC mode as a function of the object thickness, the total thickness must be corrected to the equivalent breast thickness according to ○ **Table 1** in order to simulate the conditions in clinical operation. Spacers that do not interfere with radiography can be used for this purpose (○ **Fig. 1a**).

2.2. Determination of the entrance surface air kerma K_E

For all seven PMMA thicknesses according to ○ **Table 1**, the entrance surface air kerma K_E is determined at the upper surface of the PMMA test object (without spacers) in manual mode (○ **Fig. 1b**).

The measurement chamber of the dosimeter is to be positioned 6 cm from the chest wall side and laterally centered. The radiation detector of the dosimeter and the bottom of the compression plate must be in contact during the measurements. Scattered radiation from the test objects must not contribute to the measurement results.

The target-filter combination, tube voltage, and the tube loading used in manual mode are to be taken from the corresponding exposures in AEC mode with automatic exposure control (see 2.1). The selectable tube loading closest to the mAs value (Q) of the corresponding PMMA thickness determined under 2.1 is to be used for the tube loading.

If the nearest selectable tube loading deviates more than 5 % from the mAs value determined according to 2.1, the entrance surface air kerma is determined twice for the corresponding PMMA thickness, once with the next high mAs value and once with the next low mAs value. The entrance surface air kerma K_E is then calculated via linear interpolation for the tube loading determined in 2.1.

Example 1: Linear interpolation of entrance surface air kerma K_E

Assumption: An mAs value of Q = 74.8 was determined for a PMMA thickness of 50 mm according to section 2.1.

1. Determination of the deviation from the nearest selectable tube loading.

In manual mode, the nearest selectable tube loading is 70 mAs. Since 70 mAs deviates more than 5 % from 74.8 mAs, the entrance surface air kerma is measured for both $Q_1 = 70$ mAs (next low selectable mAs value) and $Q_2 = 80$ mAs (next high selectable mAs value).

2. Linear interpolation of entrance surface air kerma K_E

The measurements result in an entrance surface air kerma of $K_{E,1} = 4.586$ mGy for $Q_1 = 70$ mAs and $K_{E,2} = 5.241$ mGy for $Q_2 = 80$ mAs. Using linear interpolation entrance surface air kerma dose K_E for Q = 74.8 mAs is determined to be:

$$K_E = K_{E,1} + \frac{K_{E,2} - K_{E,1}}{Q_2 - Q_1} \cdot (Q - Q_1) \qquad (1)$$

$$K_E = 4.586 \text{ mGy} + \frac{5.241 \text{ mGy} - 4.586 \text{ mGy}}{80 \text{ mAs} - 70 \text{ mAs}} \cdot (74.8 \text{ mAs} - 70 \text{ mAs})$$

Alternatively, the measurements can be performed without PMMA test objects. The measurement chamber of the dosimeter is positioned in contact with the bottom of the compression plate (6 cm from the edge on the chest wall side, in

the center of the side). The distance between the breast support table and the bottom of the dosimeter must correspond to the PMMA thickness according to ○ **Table 1** (○ **Fig. 1c**).

2.3 Determination of the half-value layer (HVL)

The half-value layer (HVL) must be determined for the exposure factors (target-filter combination, X-ray tube voltage, tube loading) determined in 2.1. A compression plate must be located in the beam.

The HVL must be determined using one of the following procedures:
▶ Direct measurement of the HVL with a digital HVL-meter (see section 2.3.1)
▶ Polynomial interpolation using tabulated values (see section 2.3.2).

2.3.1 Direct measurement of the HVL

Direct measurement of the HVL can be performed in combination with the determination of the entrance surface air kerma according to 2.2 (for all seven PMMA thicknesses).

2.3.2 Polynomial interpolation of the HVL

Alternatively, the corresponding HVL values can be determined using the procedure described by Robson [11]. This includes a two-step method based on the parameters of ○ **Table 2**:

$$HVL = a \cdot U^2 + b \cdot U + d \qquad (2)$$

with

a: Factor 1 (mm Al/ kV²),
b: Factor 2 (mm Al/kV),
d: Intercept point (mm Al)
U: X-ray tube voltage (kV)

1. Determination of d for the HVL measured according to DIN 6868 – 162 test point 9.2 [1]. Equation (2) must be solved for d and the corresponding values from ○ **Table 2** are to be entered (see example 2).
2. Interpolation of the HVL for the required X-ray tube voltage via equation (2). The corresponding X-ray tube voltage is used for this purpose and the value determined in step 1 for d is entered in equation (2) (see example 2).

Example 2: Interpolation of the *HVL* for 30 kV Mo/Mo with a measured *HVL* of 0.35 mm Al for 28 kV Mo/Mo.

1. Determination of d for 28 kV Mo/Mo

$$d = HVL - a \cdot U^2 - b \cdot U$$

$$d = \left(0.35 \text{ mm Al} - \left(-0.00027778 \frac{\text{mm Al}}{\text{kV}^2} \cdot (28 \text{ kV})^2\right) - \left(0.02605556 \frac{\text{mm Al}}{\text{kV}} \cdot 28 \text{ kV}\right)\right)$$

$$d = -0.16178 \text{ mm AL}$$

Table 2 Factors *a* and *b* for polynomial interpolation of the HVL as a function of the voltage according to equation 2. The factors were based on DIN 6868 – 162 [1], Table 2.

target and filter	factor 1 [a] (mm Al/kV²)	factor 2 [b] (mm Al/kV)
Mo + 30 μm Mo	– 0.00027778	0.02605556
Mo + 25 μm Rh	– 0.00027778	0.02538889
Rh + 25 μm Rh	– 0.00083333	0.06483333
W + 50 μm Rh	0.00000000	0.01000000
W + 50 μm Ag	– 0.00111111	0.08222222
W + 0.5 mm Al	–0.00027778	0.03538889

Table 3 *g*-factors for breast simulation with PMMA (conversion to 50 % glandular tissue) [12, 13].

PMMA thickness (mm)	equivalent breast thickness (mm)	glandularity of the equivalent breast thickness	*g*-factors (mGy/mGy) HVL (mm Al)										
			0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80
20	21	97	0.378	0.421	0.46	0.496	0.529	0.559	0.585	0.609	0.631	0.65	0.669
30	32	67	0.261	0.294	0.326	0.357	0.388	0.419	0.448	0.473	0.495	0.516	0.536
40	45	41	0.183	0.208	0.232	0.258	0.285	0.311	0.339	0.366	0.387	0.406	0.425
45	53	29	0.155	0.177	0.198	0.22	0.245	0.272	0.295	0.317	0.336	0.354	0.372
50	60	20	0.135	0.154	0.172	0.192	0.214	0.236	0.261	0.282	0.3	0.317	0.333
60	75	9	0.106	0.121	0.136	0.152	0.166	0.189	0.21	0.228	0.243	0.257	0.272
70	90	4	0.086	0.098	0.111	0.123	0.136	0.154	0.172	0.188	0.202	0.214	0.227
80	103	3	0.074	0.085	0.096	0.106	0.117	0.133	0.149	0.163	0.176	0.187	0.199

Table 4 *c*-factors for breast simulation with PMMA (correction for typical breast tissue at the age of 50 – 64 years) [12, 13].

PMMA thickness (mm)	equivalent breast thickness (mm)	glandularity of the equivalent breast thickness	*c*-factors HVL (mm Al)										
			0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80
20	21	97	0.889	0.895	0.903	0.908	0.912	0.917	0.921	0.924	0.928	0.933	0.937
30	32	67	0.94	0.943	0.945	0.946	0.949	0.952	0.953	0.956	0.959	0.961	0.964
40	45	41	1.043	1.041	1.040	1.039	1.037	1.035	1.034	1.032	1.030	1.028	1.026
45	53	29	1.109	1.105	1.102	1.099	1.096	1.091	1.088	1.082	1.078	1.073	1.068
50	60	20	1.164	1.160	1.151	1.150	1.144	1.139	1.134	1.124	1.117	1.111	1.103
60	75	9	1.254	1.245	1.235	1.231	1.225	1.217	1.207	1.196	1.186	1.175	1.164
70	90	4	1.299	1.292	1.282	1.275	1.270	1.260	1.249	1.236	1.225	1.213	1.200
80	103	3	1.307	1.299	1.292	1.287	1.283	1.273	1.262	1.249	1.238	1.226	1.213

Table 5 *s*-factors for clinically used target-filter combinations (correction for the X-ray spectrum). Right (column 3 and 4): s-factors for systems with W/Al combination filtered with 0.5 mm Al [12, 14].

target and filter	*s*-factors	PMMA (mm)	*s*-factors for W/Al
Mo + 30 µm Mo	1.000	20	1.075
Mo + 25 µm Rh	1.017	30	1.104
Rh + 25 µm Rh	1.061	40	1.134
W + 50 µm Rh	1.042	45	1.149
W + 50 µm Ag	1.042	50	1.160
		60	1.181
		70	1.198
		80	1.208

2. Interpolation of HVL for 30 kV Mo/Mo

$HVL = a \cdot U^2 + b \cdot U + d$

$HVL = 0,37$ mm AL

$$HVL = ((-0,00027778 \frac{mm\,Al}{kV^2} \cdot (30\,kV)^2) + (0,02605556 \frac{mm\,Al}{kV} \cdot 30\,kV) + (-0,16178\,mm\,Al))$$

2.4 Calculation of the average glandular dose

The AGD values are to be calculated for the seven entrance surface air kerma K_E measured according to section 2.2 by applying the following equation (3) [12]:

$$AGD = K_E \cdot g \cdot c \cdot s \qquad (3)$$

with

K_E Entrance surface air kerma determined according to section 2.2

g Factor for the conversion to 50 % glandular tissue,

c Factor for the correction of the deviation of the composition of real breasts from the 50 % glandular tissue proportion,

s Factor for the correction of the deviation based on the selection of the target-filter combination with significant influence on the X-ray spectrum.

The factors *g*, *c* and *s* can be taken from ❍ **Table 3 – 5**. Factors *g* and *c* are selected for the HVLs determined in section 2.3. For HVL values that are not contained in ❍ **Table 3** and ❍ **Table 4**, factors *g* and *c* are calculated via polynomial interpolation.

2.5 Requirements and evaluation

The AGD values determined in section 2.4 must not exceed the limiting values of the average glandular dose according to ❍ **Table 1**.

3. Determination of the threshold contrast visibility according to the Quality Assurance Guideline [2]
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The threshold contrast visibility is determined using the CDMAM test object according to the 4th edition of the "European guidelines for quality assurance in breast cancer screening and diagnosis" (EPQC) from 2006 (❍ **Fig. 2**) [9]. The test procedure described in EPQC Section 2b.2.4.1 [9] (test procedure A) or alternatively the test procedure speci-
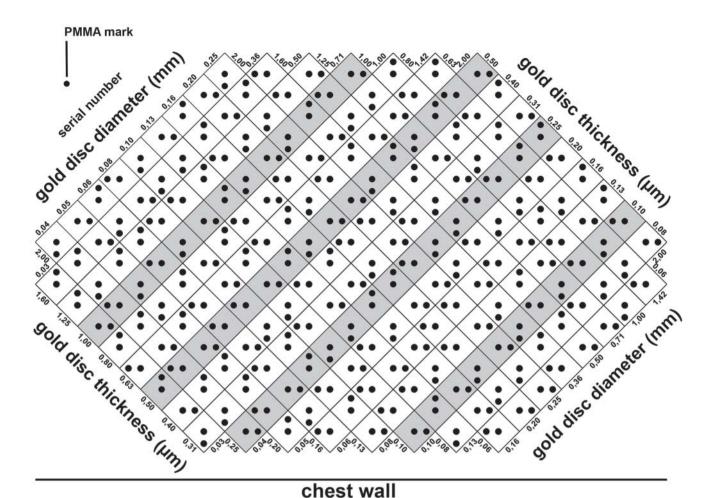
Fig. 2 Schema and alignment of the CDMAM phantom [17].

fied in EPQC Supplement S1 Part 1 Section 2b.2.4.1 [10] (test procedure B) is to be used for the evaluation of the acquired images.

3.1 Requirements for the determination of the threshold contrast visibility

The AGD determined in section 2.4 for a 50 mm PMMA must not exceed the value of 3 mGy according to DIN 6868 – 162 (o **Table 1**).

According to a memorandum of the Federal Ministry for the Environment, Nature Conservation, and Nuclear Safety dated 2/27/2008 [15], one of the observers must be an appropriately trained expert (certified CDMAM training course as of 4/1/2008, right of continuance for CDMAM courses prior to 4/1/2008).

The visual evaluation of the test object images is to be performed on site using image display devices that meet the specifications of DIN V 6868 – 57 [16] and the Quality Assurance Guideline. The evaluation may only be performed on other image display devices that meet the above specifications if a diagnostic workstation is not available on site (e. g. Mammobil, reporting at an external location).

3.2 Determination of the exposure factors

The absorption behavior of the CDMAM test object (45 mm thickness) corresponds to 50 mm of homogeneous PMMA.

Therefore, the test object images are acquired in manual mode with the parameters determined in section 2.1. for a PMMA thickness of 50 mm (60 mm equivalent breast thickness).

If the tube loading determined under 2.1 for 50 mm PMMA, is not in AEC mode manually selectable, the next smaller mAs value has to be used.

3.3 Arrangement of the test object

The 5-mm contrast detail plate is to be covered above and below with 20-mm PMMA using the four included 10-mm PMMA plates. The markings of the PMMA plates and the serial number of the contrast detail plate must be positioned on the left side distal from the chest wall. The phantom must be aligned with the chest wall edge of the breast support table and be positioned laterally centered.

3.4 Test procedure A (visual evaluation)
3.4.1 Acquisition of the phantom images

Six X-rays of the CDMAM phantom are to be acquired using the same exposure parameters determined under 3.2 for all images. The test object is to be moved a few millimeters along the longitudinal and transverse axis of the breast support table between the individual exposures.

The images acquired for the visual evaluation must be processed with the same image processing method used for clinical mammograms.

3.4.2 Visual evaluation of the phantom images

The six CDMAM phantom images are evaluated by three different observers meeting the following criteria:
1. One of the observers must be a trained expert [15].
2. The two other observers must both have experience with radiological applications (e. g. radiology specialist, medical physics expert, physician with mammography experience).

After receiving instructions from the expert, each observer independently evaluates two of the six images under the supervision of the expert. Not all rows of the CDMAM test object need to be evaluated. The following rows of the gold disc diameter required in EPQC 4th edition Part B must be evaluated: 0.10 mm; 0.25 mm; 0.50 mm und 1.00 mm.

In every field of the four indicated rows, the central and peripheral gold discs must be visible. The individual fields of the rows must be continuously correctly seen starting from the thickest gold disc.

To optimize the visibility of the individual gold discs, it is permitted to use the digital postprocessing options available for interpreting mammograms (e. g. windowing, magnification, inversion, etc.).

Neighbor correction

Each field of the CDMAM test object has a maximum of four directly adjacent fields. For a gold disc thickness to be considered "seen", the following rules must be followed:
1. A detected field is only evaluated as "seen" if at least two directly adjacent fields were also correctly detected.
2. An undetected field can nonetheless be rated as "seen" if at least 3 directly adjacent fields were also correctly detected.
3. An exception to rules 1 and 2 is permitted when a field has less than 4 directly adjacent fields due to its position in the test object.

Example for rules 1 and 3:
4 directly adjacent fields are present = 2 adjacent fields must be correctly detected;
3 directly adjacent fields are present = only 1 adjacent field must be correctly detected;
2 directly adjacent fields are present = the field can be evaluated as "seen" without any additional correctly detected adjacent fields.

Example for rules 2 and 3:
4 directly adjacent fields = 3 adjacent fields must be correctly detected;
3 directly adjacent fields = 2 adjacent fields must be correctly detected;
2 directly adjacent fields = only 1 adjacent field must be correctly detected;
The smallest visible (i. e., evaluated as "seen") gold disc thicknesses determined according to this principle are to be documented for each of the four rows and for each of the six exposures (● **Table 6**).

Table 6 Exemplary documentation, mean value calculation, and evaluation.

gold disc (GD) Ø	0.10 mm	0.25 mm	0.50 mm	1.00 mm
exposure 1 GD thickness (µm)	2.00	0.25	0.13	0.08
exposure 2 GD thickness (µm)	2.00	0.25	0.13	0.08
exposure 3 GD thickness (µm)	2.00	0.50	0.16	0.10
exposure 4 GD thickness (µm)	1.42	0.36	0.13	0.08
exposure 5 GD thickness (µm)	1.42	0.36	0.13	0.10
exposure 6 GD thickness (µm)	1.42	0.25	0.13	0.08
mean value GD thickness (µm):	1.710	0.328	0.135	0.087
limit value EPQC 4th Ed. (µm):	1.680	0.352	0.150	0.091
condition met [1]):	no	yes	yes	yes

Table 7 Minimum requirement for the smallest visible gold disc thickness (µm) according to EPQC 4th edition [9].

gold disc diameter (mm)	limiting value: Gold disc thickness (µm) according to EPQC 4th edition	next smaller gold disc thickness (µm) compared to the limit value
0.10	≤ 1.680	1.42
0.25	≤ 0.352	0.25
0.50	≤ 0.150	0.13
1.00	≤ 0.091	0.08

3.4.3 Requirements and evaluation

The mean is calculated for each gold disc diameter from the six determined smallest visible gold disc thicknesses (● **Table 6**).

The threshold contrast visibilty test is considered to have been passed when the mean values of the smallest visible gold disc thicknesses for the four gold disc diameters (0.10 mm; 0.25 mm; 0.50 mm; 1.00 mm) do not exceed the limiting values of ● **Table 7**.

In the case of a negative contrast resolution test result, it is allowed to repeat the test with the original data (DICOM for processing) in order to rule out interfering structures possibly caused by image processing. In the case of a positive result with the original data, the test is considered to have been passed.

3.4.4 Documentation according to test procedure A

The following data are to be documented:
1. Exposure factors (target-filter combination, kV, mAs, format)
2. Postprocessing method used
3. Serial number of the test object
4. Certified expert
5. Observers
6. Image display devices or diagnostic workstation used for visual evaluation
7. Position of the detected gold structures
8. Determined contrast detail resolution per tested diameter incl. neighbor correction (refer to 3.4.2)
9. Overall test result (passed/failed).

3.5 Test procedure B (automatic evaluation)
3.5.1 Acquisition of the test object images

At least sixteen X-rays of the CDMAM phantom are to be acquired using the same exposure parameters determined under 3.2 for all images. The phantom is moved a few milli-

Table 8 Sample automatic evaluation results.

Diameter (mm)	Automatic threshold gold thickness (µm)	Predicted human gold thickness (µm)	Fit to predicted gold thickness (µm)
0.08	1.111	1.650	1.217
0.10	0.579	0.893	0.867
0.13	0.343	0.554	0.583
0.16	0.233	0.394	0.433
0.20	0.187	0.329	0.316
0.25	0.148	0.270	0.236
0.31	0.100	0.190	0.181
0.40	0.064	0.128	0.135
0.50	0.049	0.102	0.107
0.63	0.038	0.084	0.086
0.80	0.031	0.072	0.071
1.00	0.026	0.063	0.062

meters along the longitudinal and transverse axis of the patient positioning aid between the individual exposures. Original data of the phantom images (DICOM for processing) are used for the evaluation according to test procedure B. All exposures are evaluated automatically.

In addition, a plausibility test is performed by analysing one of the images according to test procedure A (see 3.4).

3.5.2 Automatic evaluation of the test object exposures
The "CDMAM analysis" software is used for the automatic evaluation (www.euref.org/downloads). Version v1.5.5 or higher must be used. Information regarding the installation and use of the software is available in the software user manual.

Since the results of the automatic evaluation (automatic threshold gold thickness) cannot be directly compared to the visual detection of the gold discs, the result is adapted to a typical human observer (predicted human gold thickness) using the CDMAM Analysis Software Tool. The contrast detail curve is then calculated by curve fitting (fit to predicted gold thickness) via a 3rd degree polynomial. The software uses the method of Young et al. (UK method) for this [18].

3.5.3 Determination of threshold contrast visibility
The results of the adapted and fitted automatic evaluation (fit to predicted gold thickness) are documented for the four rows of the gold disc diameters (0.10 mm; 0.25 mm; 0.50 mm; and 1.00 mm) required by the EPQC Supplement (○ **Table 8**).

3.5.4 Requirements and evaluation
A check must be performed to ensure that the results documented under 3.5.3 do not exceed the limiting values in ○ **Table 7**. In the case of a negative result, the contrast resolution test is considered to have failed. In the case of a positive result of the automatic evaluation, this must be subjected to a visual plausibility check according to test procedure A. The contrast resolution test is considered to have been passed when the next lower gold disc thickness for every examined row according to ○ **Table 7** was "seen" in the comparison to the limit value in one of the 16 exposures (refer to section 3.4.2). The test can be performed using the origi-

nal data with a corresponding adaptation of brightness and contrast.

In case of justified suspicion regarding the plausibility of the results of the automatic evaluation, a complete test according to procedure A has to be performed (refer to 3.4).

3.5.5 Documentation according to test procedure B
The following data are to be documented:
1. Exposure factors (target-filter combination, kV, mAs, format)
2. Postprocessing used for the image evaluated according to test procedure A
3. Serial number of the test object
4. Certified expert
5. Version of the CDMAM analysis sofware
6. Determined contrast detail resolution per tested diameter
7. Results of visual check according to test procedure A
8. Image display devices or diagnostic workstation used for visual evaluation
9. Overall test result (passed/failed).

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