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INTERNATIONAL STANDARD

AMENDMENT 1

Medical electrical equipment – Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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FOREWORD

This amendment has been prepared by subcommittee 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62, Electrical equipment in medical practice.

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

Enquiry draft	Report on voting
62C/445/CDV	62C/452/RVC

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

NOTE In this amendment, a new influence quantity “Additional tungsten filtration (tube aging)” has been introduced.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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- withdrawn,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

4.3.5 Limits of variation

Replace the existing Table 2 by the following:

Table 2 – Minimum RATED RANGE OF USE, REFERENCE CONDITIONS, STANDARD TEST CONDITIONS, LIMITS OF VARIATION (± *L*) and INTRINSIC ERROR (*E*) over the EFFECTIVE RANGE of use, for the pertaining INFLUENCE QUANTITY

INFLUENCE QUANTITY	Minimum RATED RANGE of use	REFERENCE CONDITIONS	STANDARD TEST CONDITIONS	± *E* kV	± *L* %	Sub-clause
Voltage waveform and frequency: Diagnostic Mammography	Constant potential, 2-, 6-, 12-pulse and medium frequency generators [a] Constant potential	Constant potential	Constant potential, ripple less than 4 %	 0,5	2,0	4.4.2
Anode angle: Diagnostic Mammography	6° to 18° 15° to 24°	12° 20°	REFERENCE VALUE ± 2° REFERENCE VALUE ± 2°	 0,5	0,5	4.4.3
Filtration: Diagnostic Mammography CT Dental	2,5 mm Al to 3,5 mm Al [b] 25 mm Al to 35 µm Mo [c] 4 mm Al to 8 mm Al 1 mm Al to 2 mm Al	3,0 mm Al 30 µm Mo 6 mm Al 1,5 mm Al	REFERENCE VALUE ± 5 % REFERENCE VALUE ± 5 % REFERENCE VALUE ± 5 % REFERENCE VALUE ± 5 %	0,5	1,5 1,5 1,5	4.4.4
Dose rate: Diagnostic Mammography CT Dental Fluoroscopic	20 mGy/s to 200 mGy/s 25 mGy/s to 150 mGy/s 20 mGy/s to 200 mGy/s 5 mGy/s to 50 mGy/s 1 mGy/s to 10 mGy/s	As stated by manufacturer	REFERENCE VALUE ± 20 %	0,5	0,5 0,5 0,5 0,5	4.4.5
Irradiation time: Diagnostic Other	10 ms to 1 000 ms 200 ms to 1 000 ms	100 ms 500 ms	REFERENCE VALUE ± 20 % REFERENCE VALUE ± 20 %		0,5 0,5	4.4.6
Field size: Rated Range Large Field	Length and width stated by manufacturer + 30 % −10 % 30 cm by 30 cm	As stated by manufacturer 30 cm by 30 cm	REFERENCE VALUE ± 2 % REFERENCE VALUE ± 2 %		0,5 2,0	4.4.7.1 4.4.7.2
Detector-Focal distance	32 cm to 60 cm or as stated by Mfg	40 cm or as stated by manufacturer	REFERENCE VALUE ± 1 %		0,5	4.4.8
Angle of incidence Rotation	± 5° ± 180°	0° 0°	REFERENCE VALUE ± 1° REFERENCE VALUE ± 1°		0,5 0,5	4.4.9 4.4.10
Temperature Relative humidity	15 °C to 35 °C ≤ 80 % (max 20 g/m^3)	20 °C 50 %	REFERENCE VALUE ± 2°C 30 % TO 75 %		1,0	4.4.11
Power supply Line voltage and frequency Batteries Rechargeable batteries	 115 V or 230 V + 10 % − 15 % 50 or 60 Hz As stated by Mfg. Fresh to Low	 115 V/230 V 50 Hz/60 Hz as stated Fresh, mains disconnected	 REFERENCE VALUE ± 1 % REFERENCE VALUE ± 1 % REFERENCE VALUE ± 1 %		 0,5 0,5 0,5	 4.4.12.1 4.4.12.2 4.4.12.3
Electromagnetic compatibility	IEC 61000-4-2 IEC 61000-4-3 IEC 61000-4-4 IEC 61000-4-5 IEC 61000-4-6 IEC 61000-4-11	Without any disturbance	Insignificant		1,0	4.4.13
Additional tungsten filtration (tube aging)	0 µm to 10 µm W	3 µm W	0µm W -3 µm W		2,0	4.4.14

[a] Frequency range f = 50 Hz to 50 kHz, VOLTAGE RIPPLE (%) from 0 to (50-10log f), e.g. 0 % to 20 % at 1 000 Hz, 0 % to 3 % at 50 kHz. All frequencies above 50 kHz are treated as constant potential generators.

[b] Filtration outside of MINIMUM RATED RANGE may be met by applying corrections.

[c] X-RAY generator with a molybdenum anode, a beryllium window, and no ADDED FILTRATION other than the 30 µm Mo.

4.4 Performance test procedures

Add a new subclause as follows:

4.4.14 Additional tungsten filtration (tube aging)

Over the RATED RANGE of additional tungsten filtration, the LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

NOTE The higher the age of an X-ray tube, the anode roughens more and more depending on the cumulative heat load during its total operation time. The roughening of the anode results in a hardening of the spectral photon distribution, which can be simulated by additional tungsten filtration, where zero filtration represents a new tube, and 10 μm W an X-ray tube near the end of its lifetime, respectively.

Before performing this test it should be proved that the X-ray tube used for this test is of moderate age, corresponding to an additional filtration of 0 μm W – 3 μm W as required for the standard test conditions. This can be shown under the following conditions: 70 kV tube voltage and 3,0 mm Al total filtration, by measuring the Al-HALF-VALUE LAYER (HVL) which should be less than the values in Table 4, depending on the anode angle of the tube:

Table 4 – Maximum HALF-VALUE LAYER (HVL) depending on anode angle

Anode angle(°)	*6*	*8*	*10*	*12*	*14*	*16*	*18*
HVL (mm Al)	*3,23*	*3,07*	*2,98*	*2,91*	*2,86*	*2,83*	*2,80*

Compliance with the performance requirement shall now be checked by measuring the response of the instrument with the detector of the instrument exposed to the minimum and the maximum rated additional tungsten filtration and compared with a reference set of readings at reference filtration (with 3 μm additional tungsten filtration). Tests shall be made at the minimum test points indicated in Table 3 and in 4.4.1 to show compliance over the effective range of voltages.

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