SLOVENSKI STANDARD
SIST EN 61676:2003/A1:2009

01-junij-2009

Medicinska elektriļ na oprema - Dozimetrijska oprema za posredno merjenje napetosti rentgenske elektronke v diagnostiļ ni radiologiji (IEC 61676:2002/A1:2008)

Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology (IEC 61676:2002/A1:2008)

Medizinische elektrische Geräte - Geräte für die nicht-invasive Messung der Röntgenröhrenspannung in der diagnostischen Radiologie (IEC 61676:2002/A1:2008)

Appareils électromédicaux - Instruments de dosimétrie pour la mesure non invasive de la tension du tube radiogène dans la radiologie de diagnostic (IEC 61676:2002/A1:2008)

Ta slovenski standard je istoveten z: **EN 61676:2002/A1:2009**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
17.240	Merjenje sevanja	Radiation measurements

SIST EN 61676:2003/A1:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61676/A1

April 2009

ICS 11.040.50; 11.040.55

English version

Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology
(IEC 61676:2002/A1:2008)

Appareils électromédicaux -
Instruments de dosimétrie
pour la mesure non invasive
de la tension du tube radiogène
dans la radiologie de diagnostic
(CEI 61676:2002/A1:2008)

Medizinische elektrische Geräte -
Geräte für die nicht-invasive Messung
der Röntgenröhrenspannung
in der diagnostischen Radiologie
(IEC 61676:2002/A1:2008)

This amendment A1 modifies the European Standard EN 61676:2002; it was approved by CENELEC on 2009-03-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 61676:2002/A1:2009 E

Foreword

The text of document 62C/445/CDV, future amendment 1 to IEC 61676:2002, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as amendment A1 to EN 61676:2002 on 2009-03-01.

The following dates were fixed:

– latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2009-12-01
– latest date by which the national standards conflicting with the amendment have to be withdrawn	(dow)	2012-03-01

Endorsement notice

The text of amendment 1:2008 to the International Standard IEC 61676:2002 was approved by CENELEC as an amendment to the European Standard without any modification.

IEC 61676

Edition 1.0 2008-11

INTERNATIONAL STANDARD

AMENDMENT 1

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

PRICE CODE D

ICS 11.040.50; 11.040.55

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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.