SLOVENSKI STANDARD
SIST EN 61676:2003

01-april-2003

Medicinska električna oprema - Dozimetrijska oprema za posredno merjenje napetosti rentgenske elektronke v diagnostični radiologiji

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

Medizinische elektrische Geräte - Geräte für die nicht-invasive Messung der Röntgenröhrenspannung in der diagnostischen Radiologie

Appareils électromédicaux - Instruments de dosimétrie pour la mesure non invasive de la tension du tube radiogène dans la radiologie de diagnostic

Ta slovenski standard je istoveten z: **EN 61676:2002**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
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English version

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

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

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

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This European Standard 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

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Foreword

The text of document 62C/340/FDIS, future edition 1 of IEC 61676, 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 EN 61676 on 2002-11-01.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2003-08-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2005-11-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative and annexes A, B and C are informative.
Annex ZA has been added by CENELEC.

In this standard, the following print types are used:
– requirements, compliance with which can be tested, and definitions: roman type;
– notes, explanations, advice, general statements and exceptions: smaller roman type;
– *test specifications: italic type;*
– TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3 OR IN EN 60601-1: SMALL CAPITALS.

Endorsement notice

The text of the International Standard IEC 61676:2002 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60417	Series	Graphical symbols for use on equipment	EN 60417	Series
IEC 60788	1984	Medical radiology - Terminology	-	-
IEC 61000-4-2	1995	Electromagnetic compatibility (EMC) Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	EN 61000-4-2	1995
IEC 61000-4-3	2002	Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	2002
IEC 61000-4-4	1995	Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test	EN 61000-4-4	1995
IEC 61000-4-5	1995	Part 4-5: Testing and measurement techniques - Surge immunity test	EN 61000-4-5	1995
IEC 61000-4-6	1996	Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6	1996
IEC 61000-4-11	1994	Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests	EN 61000-4-11	1994
IEC 61010-1	2001	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements	EN 61010-1 + corr. June	2001 2002
IEC 61187 (mod)	1993	Electrical and electronic measuring equipment - Documentation	EN 61187 + corr. March	1994 1995

Publication	Year	Title	EN/HD	Year
ISO	1993	International vocabulary of basic and general terms in metrology	-	-
ISO 7000	1989	Graphical symbols for use on equipment - Index and synopsis	-	-

INTERNATIONAL STANDARD

IEC 61676

First edition
2002-09

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

Appareils électromédicaux – Instruments de dosimétrie pour la mesure non invasive de la tension du tube radiogène dans la radiologie de diagnostic

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 61676 has been prepared by subcommittee SC 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, 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
62C/340/FDIS	62C/344/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 3.

Annexes A, B and C are for information only.

In this standard the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type;
– notes, explanations, advice, general statements and exceptions: in small roman type;
– *test specifications: in italic type;*
– TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3 OR IN IEC 60601-1 AND ITS COLLATERAL STANDARDS: IN SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2004. At this date, the publication will be

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

A bilingual version of this publication may be issued at a later date.

NOTE The committee is aware of the fact that this standard does not address all problems associated with non-invasive high voltage measurements. In particular one influence quantity concerning the target condition is not dealt with at all. Before this can be done, a substantial amount of measurements is still necessary to improve the physical understanding of this influence quantity. On the other hand, for the reasons described in the introduction there is an urgent need to publish this standard in order to assure that non-invasive measurements are comparable to each other within tolerable uncertainties, regardless of differences in X-RAY GENERATOR, waveform or other influence quantities (except target condition), which is not the case for the time being. The committee has decided to revise this standard as soon as sufficient knowledge on the outstanding items is available.

INTRODUCTION

The result of a measurement of the X-RAY TUBE VOLTAGE by means of invasive or non-invasive instruments is normally expressed in the form of one single number for the value of the tube voltage, irrespective of whether the tube voltage is constant potential or shows a time dependent waveform. Non-invasive instruments for the measurement of the X-RAY TUBE VOLTAGE on the market usually indicate the 'mean peak voltage'. But the quantity 'mean peak voltage' is not unambiguously defined and may be any mean of all voltage peaks. It is impossible to establish test procedures for the performance requirements of non-invasive instruments for the measurement of the X-RAY TUBE VOLTAGE without the definition of the quantity under consideration. Therefore, this Standard is based on a quantity recently proposed in the literature[1] to be called "PRACTICAL PEAK VOLTAGE". The PRACTICAL PEAK VOLTAGE is unambiguously defined and applicable to any waveform. This quantity is related to the spectral distribution of the emitted X-RADIATION and the image properties. X-RAY GENERATORS operating at the same value of the PRACTICAL PEAK VOLTAGE will produce the same low level contrast in the RADIOGRAMS, even when the waveforms of the tube voltages are different. Detailed information on this concept is provided in Annex B. An example for the calculation of the PRACTICAL PEAK VOLTAGE in the case of a "falling load" waveform is also given in Annex B.

As a result of introducing a new quantity, the problem arises that this standard has been written for instruments which were not explicitly designed for the measurement of the PRACTICAL PEAK VOLTAGE. However, from preliminary results of a trial type test of a non-invasive instrument currently on the market, it can be expected that future instruments and most instruments on the market will be able to fulfil the requirements stated in this standard without insurmountable difficulties. For the most critical requirements on voltage waveform and frequency dependence of the RESPONSE, it turned out from these investigations that it is even easier to comply with the standard by using the PRACTICAL PEAK VOLTAGE as the measurement quantity.

The calibration and adjustment of the X-RAY TUBE VOLTAGE of an X-RAY GENERATOR is generally performed by the MANUFACTURER using a direct INVASIVE MEASUREMENT. Instruments utilising NON-INVASIVE MEASUREMENTS can also be used to check the calibration or to adjust THE X-RAY TUBE VOLTAGE. These instruments are required to have uncertainties of the voltage measurement comparable with the INVASIVE MEASUREMENT. One of the most important parameters of diagnostic X-RAY EQUIPMENT is the voltage applied to the X-RAY TUBE, because both the image quality in diagnostic radiology and the DOSE received by the PATIENT undergoing radiological examinations are dependent on the X-RAY TUBE VOLTAGE. An overall uncertainty below ±5 % is required, and this value serves as a guide for the LIMITS OF VARIATION for the effects of INFLUENCE QUANTITIES.

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[1] See annex B.

MEDICAL ELECTRICAL EQUIPMENT –

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

1 Scope and object

This International Standard specifies the performance requirements of instruments as used in the NON-INVASIVE MEASUREMENT of X-RAY TUBE VOLTAGE up to 150 kV and the relevant compliance tests. This standard also describes the method for calibration and gives guidance for estimating the uncertainty in measurements performed under conditions different from those during calibration.

Applications for such measurement are found in diagnostic RADIOLOGY including mammography, COMPUTED TOMOGRAPHY (CT), dental radiology and RADIOSCOPY. This standard is not concerned with the safety aspect of such instruments. The requirements for electrical safety applying to them are contained in IEC 61010-1.

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 60417 (all parts), *Graphical symbols for use on equipment*

IEC 60788:1984, *Medical radiology – Terminology*

IEC 61000-4-2:1995, *Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 2: Electrostatic discharge immunity test.* Basic EMC Publication

IEC 61000-4-3:2000, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test.* Basic EMC Publication

IEC 61000-4-4:1995, *Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 4: Electrical fast transient/burst immunity test.* Basic EMC Publication

IEC 61000-4-5:1995, *Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 5: Surge immunity test.* Basic EMC Publication

IEC 61000-4-6:1996, *Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 6: Immunity to conducted disturbances, induced by radio frequency fields.* Basic EMC Publication

IEC 61000-4-11:1994, *Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 11: Voltage dips, short interruptions and voltage variations immunity tests.* Basic EMC Publication

IEC 61010-1:2001, *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1:General Requirements*