SLOVENSKI STANDARD
oSIST prEN IEC 61676:2022

01-marec-2022

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: prEN IEC 61676:2022

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
11.040.55	Diagnostična oprema	Diagnostic equipment
17.240	Merjenje sevanja	Radiation measurements

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62C/830/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 61676 ED2**	
DATE OF CIRCULATION: **2022-01-21**	CLOSING DATE FOR VOTING: **2022-04-15**
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IEC SC 62C : EQUIPMENT FOR RADIOTHERAPY, NUCLEAR MEDICINE AND RADIATION DOSIMETRY	
SECRETARIAT: Germany	SECRETARY: Ms Regina Geierhofer
OF INTEREST TO THE FOLLOWING COMMITTEES: SC 62B	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.

FUNCTIONS CONCERNED:

☒ EMC ☐ ENVIRONMENT ☒ QUALITY ASSURANCE ☒ SAFETY

☒ SUBMITTED FOR CENELEC PARALLEL VOTING ☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

Attention IEC-CENELEC parallel voting

The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting.

The CENELEC members are invited to vote through the CENELEC online voting system.

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

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

PROPOSED STABILITY DATE: 2026

NOTE FROM TC/SC OFFICERS:

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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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.

This second edition of IEC 61676 cancels and replaces the edition 1.1, published in 2009. It includes an assessment of the COMBINED STANDARD UNCERTAINTY for the performance of a hypothetical instrument for the non-invasive measurement of the tube high voltage (in Annex A) which replaces Annex A of the edition 1.1 titled "Recommended performance criteria for the invasive divider".

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 the base publication and its amendments 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.

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

NOTE The committee knows this second edition of the standard does still not address all problems associated with non-invasive high voltage measurements. For mammography only molybdenum filtration is considered in conjunction with a molybdenum anode although in addition tungsten and rhodium anodes with other filtrations are in use like rhodium, aluminium, copper, silver or titanium. At the time when this document was drafted there were not enough data available in the literature to define realistic limits of variation for these types of INFLUENCE QUANTITIES. On the other hand, the committee was informed that several international projects were started to examine the general behaviour of non-invasive X-ray multimeters of the main manufacturers. Results from these studies were to be expected within about 5 years. Therefore, the committee decided to set a short stability time for the second edition and update the standard as soon as the results from these new examinations will be 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 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.

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.

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 documents are referred to in the text in such a way that some or all of their content constitutes requirements 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, *Graphical symbols for use on equipment* (available at http://www.graphical-symbols.info/equipment)

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

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

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

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

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

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

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

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

IEC 61187, *Electrical and electronic measuring equipment – Documentation*

ISO 7000:1989, *Graphical symbols for use on equipment – Index and synopsis*

3 Terminology and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC TR 60788:2004 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE 1 An index of defined terms is to be found at the end of the document.

NOTE 2 A searchable IEC Glossary can be found at std.iec.ch

3.1
CORRECTION FACTOR
dimensionless multiplier which corrects the INDICATED VALUE of an instrument from its value when operated under particular conditions to its value when operated under stated REFERENCE CONDITIONS

3.2
EFFECTIVE RANGE
range of INDICATED VALUES for which an instrument complies with a stated performance. The maximum (minimum) effective INDICATED VALUE is the highest (lowest) in this range

3.3
INDICATED VALUE
value of quantity derived from the scale reading of an instrument together with any scale factors indicated on the control panel of the instrument

3.4
INFLUENCE QUANTITY
any external quantity that may affect the performance of an instrument (e.g., ambient temperature etc.) and any property of the X-RAY EQUIPMENT under test that needs to be taken into account in using the instrument for NON-INVASIVE MEASUREMENT of X-RAY TUBE VOLTAGE (e.g., range of X-RAY TUBE VOLTAGE, ANODE ANGLE, anode material, TOTAL FILTRATION etc.)

3.5
INSTRUMENT PARAMETER
any internal property of an instrument that may affect the performance of the instrument

3.6
INTRINSIC ERROR
deviation of the MEASURED VALUE (i.e., the INDICATED VALUE, corrected to REFERENCE CONDITIONS) from the CONVENTIONAL TRUE VALUE under STANDARD TEST CONDITIONS

3.7
INVASIVE MEASUREMENT
measurement of the X-RAY TUBE VOLTAGE by external connection of a suitable meter or a high resistance divider

3.8
LIMITS OF VARIATION
maximum VARIATION of a PERFORMANCE CHARACTERISTIC y, permitted by this standard. If the LIMITS OF VARIATION are stated as $\pm L$ % the VARIATION $\Delta y / y$, expressed as a percentage, shall remain in the range from $-L$ % to $+L$ %

3.9
MAXIMUM PEAK VOLTAGE
maximum value of the X-RAY TUBE VOLTAGE in a specified time interval. The unit of this quantity is the volt (V)

3.10
MEAN PEAK VOLTAGE
mean value of all X-RAY TUBE VOLTAGE peaks during a specified time interval. The unit of this quantity is the volt (V)

3.11
MEASURED VALUE
best estimate of the CONVENTIONAL TRUE VALUE of a quantity, being derived from the INDICATED VALUE of an instrument together with the application of all relevant CORRECTION FACTORS

NOTE The CONVENTIONAL TRUE VALUE will usually be the value determined by the working standard with which the instrument under test is being compared.

3.12
MINIMUM EFFECTIVE RANGE
smallest permitted range of INDICATED VALUES for which an instrument complies with a stated performance

3.13
NON-INVASIVE MEASUREMENT
measurement of X-RAY TUBE VOLTAGE by analysis of the emitted RADIATION

3.14
PERFORMANCE CHARACTERISTIC
one of the quantities used to define the performance of an instrument (e.g., RESPONSE)

3.15
VOLTAGE RIPPLE
VOLTAGE RIPPLE at the X-RAY TUBE, *r*, is expressed as a percentage of the peak voltage, U_{max}, over a specified time interval. This is expressed by the formula:

$$r = \frac{U_{max} - U_{min}}{U_{max}} \cdot 100\%$$

where U_{max} is the highest voltage in the interval, and U_{min} is the lowest voltage in the interval

3.16
PRACTICAL PEAK VOLTAGE (PPV)
PRACTICAL PEAK VOLTAGE $\hat{U}$ is defined as:

$$\hat{U} = \frac{\int_{U_{min}}^{U_{max}} p(U) \cdot w(U) \cdot U \, dU}{\int_{U_{min}}^{U_{max}} p(U) \cdot w(U) \, dU} \quad \text{with} \quad \int_{U_{min}}^{U_{max}} p(U) \, dU = 1$$

where $p(U)$ is the distribution function for the voltage U and $w(U)$ is a weighting function. U_{max} is the highest voltage in the interval, and U_{min} is the lowest voltage in the interval. The unit of the quantity PRACTICAL PEAK VOLTAGE is the volt (V)

NOTE Additional information on the PRACTICAL PEAK VOLTAGE, the weighting function *w(U)* and the distribution function *p(U)* is provided in Annex C. Using this weighting function *w(U)* the PRACTICAL PEAK VOLTAGE will be defined as the constant potential which produces the same AIR KERMA contrast behind a specified PHANTOM as the non-dc voltage under test.