IEC 61676

Edition 1.1 2009-01

INTERNATIONAL STANDARD

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

IEC 61676:2002+A1:2008

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

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Email: csc@iec.ch
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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.50; 11.040.55

ISBN 978-2-88910-552-6

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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 International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

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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 consolidated version of IEC 61676 consists of the first edition (2002) [documents 62C/340/FDIS and 62C/344/RVD] and its amendment 1 (2008) [documents 62C/445/CDV and 62C/452/RVC].

The technical content is therefore identical to the base edition and its amendment and has been prepared for user convenience.

It bears the edition number 1.1.

A vertical line in the margin shows where the base publication has been modified by amendment 1.

NOTE In the amendment, a new influence quantity "Additional tungsten filtration (tube aging)" has been introduced.

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 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 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.

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*

IEC 61187:1993, *Electrical and electronic measuring equipment – Documentation*

ISO:1993, *International vocabulary of basic and general terms in metrology* (ISBN 92-67-01075-1)

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

3 Terminology and definitions

For the purposes of this standard the following definitions apply.

The definitions given in this standard are generally in agreement with those in IEC 60788 and the ISO *International vocabulary of basic and general terms in metrology*. Any terms not defined in this subclause have the meanings defined in the above publications or are assumed to be in general scientific usage.

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
the 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
the 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
the 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
the MINIMUM EFFECTIVE RANGE is the 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
the 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 equation:

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

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)
The 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 B. 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.

3.17
RATED RANGE (of use)
the range of values of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER within which the instrument will operate within the LIMITS OF VARIATION. Its limits are the maximum and minimum RATED values.

The MINIMUM RATED RANGE is the least range of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER within which the instrument shall operate within the specified LIMITS OF VARIATION in order to comply with this standard

3.18
REFERENCE CONDITIONS
conditions under which all INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS have their REFERENCE VALUES

3.19
REFERENCE VALUE
particular value of an INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) chosen for the purposes of reference i.e. the value of an INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) at which the CORRECTION FACTOR for dependence on that INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) is unity

3.20
RELATIVE INTRINSIC ERROR
the ratio of the INTRINSIC ERROR to the CONVENTIONAL TRUE VALUE

3.21
RESPONSE
the quotient of the INDICATED VALUE divided by the CONVENTIONAL TRUE VALUE

3.22
STANDARD TEST CONDITIONS
conditions under which all INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS have their STANDARD TEST VALUES

3.23
STANDARD TEST VALUES
a value, values, or a range of values of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER, which is/are permitted when carrying out calibrations or tests on another INFLUENCE QUANTITY or INSTRUMENT PARAMETER

3.24
VARIATION
The relative difference $\Delta y / y$, between the values of a PERFORMANCE CHARACTERISTIC y, when one INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) assumes successively two specified values, the other INFLUENCE QUANTITIES (and INSTRUMENT PARAMETERS) being kept constant at the STANDARD TEST VALUES (unless other values are specified)

3.25
X-RAY TUBE VOLTAGE
potential difference applied to an X-RAY TUBE between the anode and the cathode . The unit of this quantity is the volt (V)

4 General performance requirements for measurement of PRACTICAL PEAK VOLTAGE measurements

4.1 Quantity to be measured

The quantity to be measured is the PRACTICAL PEAK VOLTAGE.

NOTE Additional quantities may be displayed.

The MINIMUM EFFECTIVE RANGES of PRACTICAL PEAK VOLTAGE shall be as listed in table 1 for the relevant X-RAY applications.

Table 1 – MINIMUM EFFECTIVE RANGES

Application	Nominal Anode Material	MINIMUM EFFECTIVE RANGE
Mammography (20 kV to 50 kV)	Mo a)	24 kV to 35 kV
Diagnostic (40 kV to 150 kV)	W	60 kV to 120 kV
CT (80 kV to 150 kV)	W	100 kV to 140 kV
Dental (40 kV to 110 kV)	W	60 kV to 90 kV
Fluoroscopic (40 kV to 130 kV)	W	60 kV to 120 kV

a) For mammography anode materials other than Mo, the MINIMUM EFFECTIVE RANGE of PPV shall be at least 10 kV.

4.2 Limits of PERFORMANCE CHARACTERISTICS

4.2.1 Limits

All values of the limits of PERFORMANCE CHARACTERISTICS stated in this subclause do not contain the uncertainty of the test equipment.

4.2.2 Maximum error

4.2.2.1 Maximum RELATIVE INTRINSIC ERROR for voltages above 50 kV

The RELATIVE INTRINSIC ERROR, I, of PRACTICAL PEAK VOLTAGE, $\hat{U}$, measurements made under STANDARD TEST CONDITIONS, shall not be greater than ±2 % over the EFFECTIVE RANGE of voltages. This is expressed by the equation:

$$|I| = \left| \frac{\hat{U}_{\text{meas}} - \hat{U}_{\text{true}}}{\hat{U}_{\text{true}}} \right| \leq 0{,}02$$