IEC 61676

Edition 2.0 2023-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Appareils électromédicaux – Appareils de dosimétrie pour le mesurage non invasif de la tension du tube radiogène dans la radiologie de diagnostic

IEC 61676:2023-03(en-fr)

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.50; 11.040.55

ISBN 978-2-8322-6698-4

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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

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IEC 61676 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This second edition of IEC 61676 cancels and replaces first edition published in 2002, Amendment 1:2008. This edition constitutes a technical revision.

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".

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

Draft	Report on voting
62C/830/CDV	62C/866/RVC

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

In this document 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 DOCUMENT 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 document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

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- withdrawn,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

NOTE The committee knows this second edition of the document 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 document 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 can 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 document 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 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 used 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 applicable, 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

This document 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 document 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 document 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 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

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 for equipment with input current up to 16 A per phase*

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 7000:2019, *Graphical symbols for use on equipment – Registered symbol*

3 Terms 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

Note 1 to entry: 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 can affect the performance of an instrument (e.g., ambient temperature etc.) and any property of the X-RAY EQUIPMENT under test that shall 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 can 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 document

Note 1 to entry: If the LIMITS OF VARIATION are stated as $\pm L$ % the VARIATION Δy / 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

Note 1 to entry: 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

Note 1 to entry: 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 1 to entry: The CONVENTIONAL TRUE VALUE is usually 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 at the X-RAY TUBE, r, expressed as a percentage of the peak voltage, U_{max}, over a specified time interval

Note 1 to entry: The VOLTAGE RIPPLE is expressed by the formula:

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

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

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

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

Note 1 to entry: The unit of the quantity PRACTICAL PEAK VOLTAGE is the volt (V).

Note 2 to entry: 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 is 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
RATED RANGE OF USE
range of values of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER within which the instrument will operate within the LIMITS OF VARIATION

Note 1 to entry: The limits of rated range are the maximum and minimum RATED values.

Note 2 to entry: 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 document.

3.18
REFERENCE CONDITION
condition 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
ratio of the INTRINSIC ERROR to the CONVENTIONAL TRUE VALUE

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

3.22
STANDARD TEST CONDITION
condition under which all INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS have their STANDARD TEST VALUES

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

3.24
VARIATION
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

Note 1 to entry: 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 can 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 70 kV to 150 kV	W	80 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, l, 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 formula:

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

where $\hat{U}_{\text{meas}}$ is the MEASURED VALUE of PRACTICAL PEAK VOLTAGE and $\hat{U}_{\text{true}}$ is the TRUE VALUE of the PRACTICAL PEAK VOLTAGE. The voltages for the MINIMUM EFFECTIVE RANGE are listed in Table 1.

The compliance test for performance requirement for this subclause is listed under 4.2.2.2.

4.2.2.2 Maximum INTRINSIC ERROR for voltages below 50 kV

The maximum INTRINSIC ERROR, E, of PRACTICAL PEAK VOLTAGE, $\hat{U}$, measurements made under STANDARD TEST CONDITIONS shall not be greater than ±1 kV over the EFFECTIVE RANGE of voltages. This is expressed by the formula:

$$|E| = \left| \hat{U}_{\text{meas}} - \hat{U}_{\text{true}} \right| \leq 1{,}0 \text{ kV}$$

where $\hat{U}_{\text{meas}}$ is the MEASURED VALUE of PRACTICAL PEAK VOLTAGE and $\hat{U}_{\text{true}}$ is the CONVENTIONAL TRUE VALUE of the PRACTICAL PEAK VOLTAGE. The voltages for the MINIMUM EFFECTIVE RANGE are listed in Table 1.

Compliance with performance requirements 4.2.2.1 and 4.2.2.2 shall be checked by measuring the RELATIVE INTRINSIC ERROR above 50 kV or the INTRINSIC ERROR below 50 kV over the EFFECTIVE RANGE of voltages for each application claimed. STANDARD TEST CONDITIONS are listed in Table 2 for each application. The end points of the EFFECTIVE RANGE shall be checked. For mammography, the nominal step between measurements shall be no greater than 2 kV. For all other applications the nominal step between measurements shall be no greater than 5 kV for voltages below 100 kV, and no greater than 10 kV for voltages above 100 kV.

If more than one instrument configuration can be utilised to measure a span of voltages, then that span of voltages shall be measured utilising all relevant instrument configurations. As a minimum the end points and enough interim points shall be measured to meet the minimum step requirements given above. An example could be the use of different absorber pairs to provide overlapping voltage spans. In the case of different absorber pairs, if the first measured from 40 kV to 80 kV, and the second from 60 kV to 120 kV, then the overlapping span would be from 60 kV to 80 kV. At a minimum, measurements would be made utilising each absorber pair at 60 kV, 65 kV, 70 kV, 75 kV, and 80 kV.

4.2.3 Over and under range indications

The instrument shall clearly indicate when it is displaying a reading outside its EFFECTIVE RANGE of PRACTICAL PEAK VOLTAGE.

Conditions above and below the EFFECTIVE RANGE of PRACTICAL PEAK VOLTAGE shall be tested and it shall be demonstrated that if the instrument displays a reading it will be clearly indicated to the user that the reading might not meet the accuracy of the instrument.

If more than one instrument configuration can be utilised to measure a span of voltages, then over and under range conditions shall be checked for all relevant instrument configurations. An example could be the use of different absorber pairs to provide overlapping voltage spans. In the case of different absorber pairs, if the first measured from 40 kV to 80 kV, and the second from 60 kV to 120 kV, then over and under range indications would be checked below 40 kV and above 80 kV for the first absorber pair, and below 60 kV and above 120 kV for the second absorber pair. (The instrument's refusal to make a reading under these conditions is an acceptable result.)

Compliance with performance requirement of this subclause shall be verified at the lowest limit of the RATED RANGE of dose rates. All other INFLUENCE QUANTITIES shall be at STANDARD TEST CONDITIONS as listed in Table 2.

4.2.4 Repeatability

When a measurement is repeated with the same instrument under unaltered conditions, the COEFFICIENT OF VARIATION shall not exceed ±0,5 % or the standard deviation shall not exceed 0,5 kV, whichever is greater.

Compliance with performance requirement of this subclause shall be checked by determining the COEFFICIENT OF VARIATION of ten consecutive measurements taken at the lowest limit of the RATED RANGE of dose rates. All other INFLUENCE QUANTITIES shall be at STANDARD TEST CONDITIONS as listed in Table 2 for each application. The end points of the EFFECTIVE RANGE and one point near the middle of the EFFECTIVE RANGE shall be checked. The test shall be conducted a second time with the dose rate also within STANDARD TEST CONDITIONS.

If more than one instrument configuration can be utilised to measure a span of voltages, then the end points of that span of voltages shall be measured utilising all relevant instrument configurations. An example could be the use of different absorber pairs to provide overlapping voltage spans. In the case of different absorber pairs, if the first measured from 40 kV to 80 kV, and the second from 60 kV to 120 kV, then the overlapping span would be from 60 kV to 80 kV. At a minimum, measurements would be made utilising each absorber pair at 60 kV and 80 kV.

4.2.5 Long term stability

The design and construction shall be such that the instrument RESPONSE does not change by more than ±2,0 % for voltages above 50 kV over a period of one year. For voltages below 50 kV, the difference between the INDICATED VALUE and CONVENTIONAL TRUE VALUE shall not change by more than ±1,0 kV over a period of one year.

Compliance with this performance requirement shall be checked by retaining a representative instrument, stored under STANDARD TEST CONDITIONS of temperature and relative humidity and by measuring the RELATIVE INTRINSIC ERROR above 50 kV or the INTRINSIC ERROR below 50 kV at a minimum of two voltages, one near the top and one near the bottom of the EFFECTIVE RANGE.

If more than one instrument configuration can be utilised to measure a span of voltages, then the end points of that span of voltages shall be measured utilising all relevant instrument configurations. An example could be the use of different absorber pairs to provide overlapping voltage spans. In the case of different absorber pairs, if the first measured from 40 kV to 80 kV, and the second from 60 kV to 120 kV, then the overlapping span would be from 60 kV to 80 kV. At a minimum, measurements would be made utilising each absorber pair at 60 kV and 80 kV.

These measurements shall be made at a minimum of one-month intervals over a period of not less than six months. Linear regression analysis shall be used to extrapolate these readings to obtain the change in RESPONSE over one full year.

4.3 LIMITS OF VARIATION for effects of INFLUENCE QUANTITIES

4.3.1 INFLUENCE QUANTITIES

Quantities which can influence the performance of the instrument are given in Table 2.

4.3.2 MINIMUM RATED RANGE of use

The MINIMUM RATED RANGE of use for each of the INFLUENCE QUANTITIES involved is given in Table 2.