

# 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**



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## CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
1 Scope.....	7
2 Normative references .....	7
3 Terms and definitions .....	8
4 General performance requirements for measurement of PRACTICAL PEAK VOLTAGE measurements.....	11
4.1 Quantity to be measured.....	11
4.2 Limits of PERFORMANCE CHARACTERISTICS .....	11
4.2.1 Limits .....	11
4.2.2 Maximum error .....	11
4.2.3 Over and under range indications .....	12
4.2.4 Repeatability .....	13
4.2.5 Long term stability .....	13
4.3 LIMITS OF VARIATION for effects of INFLUENCE QUANTITIES .....	13
4.3.1 INFLUENCE QUANTITIES .....	13
4.3.2 MINIMUM RATED RANGE of use .....	13
4.3.3 REFERENCE CONDITIONS .....	14
4.3.4 STANDARD TEST CONDITIONS.....	14
4.3.5 LIMITS OF VARIATION.....	14
4.4 Performance test procedures .....	15
4.4.1 General remarks.....	15
4.4.2 Dependence of instrument RESPONSE on voltage waveform and frequency .....	16
4.4.3 Dependence of instrument RESPONSE on ANODE ANGLE.....	17
4.4.4 Dependence of instrument RESPONSE on FILTRATION.....	17
4.4.5 Dependence of instrument RESPONSE on dose rate .....	17
4.4.6 Dependence of instrument RESPONSE on IRRADIATION TIME .....	18
4.4.7 Dependence of instrument RESPONSE on field size .....	18
4.4.8 Dependence of instrument RESPONSE on focus-to-detector distance.....	18
4.4.9 Dependence of instrument RESPONSE on angle of incidence of RADIATION.....	19
4.4.10 Dependence of instrument RESPONSE on angle of detector rotation with respect to the X-RAY TUBE axis.....	19
4.4.11 Dependence of instrument RESPONSE on temperature and humidity .....	19
4.4.12 Dependence of instrument RESPONSE on operating voltage .....	20
4.4.13 Dependence of instrument RESPONSE on electromagnetic compatibility .....	21
4.4.14 Additional tungsten filtration (tube aging).....	22
5 Special instrumental requirements and marking.....	23
5.1 Requirements for the complete instruments .....	23
5.2 General.....	23
5.3 Display .....	23
5.4 Range of measurement.....	23
5.5 Connectors and cables .....	23
6 ACCOMPANYING DOCUMENTS .....	24
6.1 General.....	24
6.2 Information provided .....	24
6.3 Instrument description.....	24

6.4	Detector .....	24
6.5	Delay time .....	24
6.6	Measurement window .....	24
6.7	Data outlet .....	24
6.8	Transport and storage .....	24
Annex A (informative) COMBINED STANDARD UNCERTAINTY .....		25
Annex B (informative) Additional information on PRACTICAL PEAK VOLTAGE .....		26
B.1	Overview .....	26
B.2	Simplified formalism for the determination of the PRACTICAL PEAK VOLTAGE $\hat{U}$ .....	26
Bibliography .....		32
Index of defined terms .....		33
Figure B.1 – Example of a waveform of a two-pulse generator .....		28
Figure B.2 – Example of a waveform of a constant-voltage generator .....		28
Figure B.3 – Example of falling load waveform .....		29
Table 1 – Minimum effective ranges .....		11
Table 2 – Minimum RATED RANGE OF USE, REFERENCE CONDITIONS, STANDARD TEST CONDITIONS, LIMITS OF VARIATION ( $\pm L$ ) and INTRINSIC ERROR ( $E$ ) for the EFFECTIVE RANGE of use, for the pertaining INFLUENCE QUANTITY .....		14
Table 3 – Minimum test points and test values of PRACTICAL PEAK VOLTAGE for INFLUENCE QUANTITIES .....		16
Table 4 – Maximum HALF-VALUE LAYER (HVL) depending on anode angle .....		23
Table A.1 – Example for assessment of the COMBINED STANDARD UNCERTAINTY – Instruments used for NON-INVASIVE MEASUREMENT of X-RAY TUBE VOLTAGE .....		25
Table B.1 – Values of 20 samples of the falling load waveform in Figure B.3 .....		29
Table B.2 – Voltage bins, probability and weighting factors for the 20 samples of the falling load waveform in Figure B.3 .....		30
Table B.3 – Weighting factors for the 20 equally spaced samples of the falling load waveform in Figure B.3 .....		31

## 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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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](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/standardsdev/publications](http://www.iec.ch/standardsdev/publications).

In this document the following print types are used:

- requirements, compliance with which can be tested, and definitions: in normal 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 CAPS.

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- 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  $\pm 5\%$  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*