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

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

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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- withdrawn,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.

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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*

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*