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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN IEC 61676:2023 sisaldab Euroopa standardi EN IEC 61676:2023 ingliskeelset teksti.	This Estonian standard EVS-EN IEC 61676:2023 consists of the English text of the European standard EN IEC 61676:2023.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 12.05.2023.	Date of Availability of the European standard is 12.05.2023.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

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ICS 11.040.50, 11.040.55

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 61676

May 2023

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English Version

Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology (IEC 61676:2023)

Appareils électromédicaux - Appareils de dosimétrie pour le mesurage non invasif de la tension du tube radiogène dans la radiologie de diagnostic (IEC 61676:2023)

Medizinische elektrische Geräte - Geräte für die nicht-invasive Messung der Röntgenröhrenspannung in der diagnostischen Radiologie (IEC 61676:2023)

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European foreword

The text of document 62C/830/CDV, future edition 2 of IEC 61676, prepared by SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 61676:2023.

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- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2024-01-25
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In the official version, for Bibliography, the following notes have to be added for the standard indicated:

IEC 60580:2019	NOTE	Approved as EN IEC 60580:2020 (not modified)
IEC 60731:2011	NOTE	Approved as EN 60731:2012 (not modified)

IEC 61676

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INTERNATIONAL STANDARD

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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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CONTENTS

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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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