BS EN IEC 61676:2023
Incorporating corrigendum January 2024

BSI Standards Publication

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

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National foreword

This British Standard is the UK implementation of EN IEC 61676:2023. It is identical to IEC 61676:2023, incorporating corrigendum January 2024. It supersedes BS EN 61676:2002+A1:2009, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/62/3, Equipment for radiotherapy, nuclear medicine and radiation dosimetry.

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Date	Text affected
29 February 2024	Implementation of IEC corrigendum January 2024: Subclause 3.16 equation corrected

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 61676

May 2023

ICS 11.040.50; 11.040.55

Supersedes EN 61676:2002; EN 61676:2002/A1:2009

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.

The following dates are fixed:

- 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
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2026-04-25

This document supersedes EN 61676:2002 and all of its amendments and corrigenda (if any).

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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)

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cencenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60417	-	Graphical symbols for use on equipment. Index, survey and compilation of the single sheets.	-	-
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
+ A2	2020		+ A2	2021
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	EN 61000-4-2	-
IEC 61000-4-3	-	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN IEC 61000-4-3	-
IEC 61000-4-4	-	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test	EN 61000-4-4	-
IEC 61000-4-5	-	Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test	EN 61000-4-5	-
IEC 61000-4-6	-	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6	-

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Publication	Year	Title	EN/HD	Year
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	EN IEC 61000-4-11	-
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	EN 61187	-
ISO 7000	2019	Graphical symbols for use on equipment_- Registered symbols	-	-

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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".

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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.

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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.

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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*

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