SVENSK STANDARD

SS-EN IEC 61676, utg 2:2023

2023-12-13

REDLINE VERSION

Röntgenmateriel – Instrument för icke-invasiv mätning av rörspänningen hos diagnostisk röntgenutrustning

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

En så kallad ”Redline version” (RLV) innehåller både standarden som fastställts som SS och en ändringsmarkerad IEC-standard. Alla tillägg och borttagningar sedan den tidigare utgåvan av IEC-standarden är markerade med färg. Med en RLV sparar du mycket tid när du ska identifiera och bedöma aktuella ändringar i standarden. SEK Svensk Elstandard kan bara ge ut RLV i de fall den finns tillgänglig från IEC.

IEC 61676

Edition 2.0 2023-03
REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

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 978-2-8322-6703-5

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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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition IEC 61676:2002+AMD1:2008 CSV. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

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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.

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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 ~~may~~ 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 ~~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 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~~ 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 ~~required~~ applicable, and this value serves as a guide for the LIMITS OF VARIATION for the effects of INFLUENCE QUANTITIES.

~~[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 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:~~1984~~2004, ~~*Medical radiology – Terminology*~~ *Medical electrical equipment – Glossary of defined terms*

IEC 61000-4-2~~:1995~~, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – 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 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test*~~. Basic EMC Publication~~

IEC 61000-4-5~~:1995~~, *Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test*~~. Basic EMC Publication~~

IEC 61000-4-6~~:1996~~, *Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields*~~. Basic EMC Publication~~

IEC 61000-4-11~~:1994~~, *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~~. 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~~2019, *Graphical symbols for use on equipment –~~ Index and synopsis~~ Registered symbol*

SVENSK STANDARD

SS-EN IEC 61676, utg 2:2023

Fastställd	Sida	Ansvarig kommitté
2023-12-13	1 (37)	SEK TK 62BC

Röntgenmateriel – Instrument för icke-invasiv mätning av rörspänningen hos diagnostisk röntgenutrustning

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

Som svensk standard gäller europastandarden EN IEC 61676:2023. Den svenska standarden innehåller den officiella engelska språkversionen av EN IEC 61676:2023.

Nationellt förord

Europastandarden EN IEC 61676:2023

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 61676, Second edition, 2023 - Medical electrical equipment – Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology**

utarbetad inom International Electrotechnical Commission, IEC.

Tidigare fastställd svensk standard SS-EN 61676, utg 1:2003 med eventuella tillägg, ändringar och rättelser gäller ej fr o m 2026-04-25.

ICS 11.040.50; 11.040.55

Denna standard är fastställd av SEK Svensk Elstandard,
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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)

This European Standard was approved by CENELEC on 2023-04-25. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN IEC 61676:2023 E

SEK Svensk Elstandard

SS-EN IEC 61676, utg 2:2023

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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Endorsement notice

The text of the International Standard IEC 61676:2023 was approved by CENELEC as a European Standard without any modification.

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)

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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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	-
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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	-	-

IEC 61676

Edition 2.0 2023-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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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.

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*