

SLOVENSKI STANDARD oSIST prEN IEC 61676:2022

01-marec-2022

Medicinska električna oprema - Dozimetrijska oprema za posredno merjenje napetosti rentgenske elektronke v diagnostični radiologiji

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

Medizinische elektrische Geräte Geräte für die nicht-invasive Messung der Röntgenröhrenspannung in der diagnostischen Radiologie

Appareils électromédicaux - instruments de dosimétrie pour la mesure non invasive de la tension du tube radiogène dans la radiologie de diagnostic

Ta slovenski standard je istoveten z: ai/cat prEN IEC 61676:2022

75eb-4fd7-bc5f-736f9b14fd42/osist-pren-iec-61676-

2022

ICS:

11.040.50	Radiografska oprema
11.040.55	Diagnostična oprema
17.240	Merjenje sevanja

Radiographic equipment Diagnostic equipment Radiation measurements

oSIST prEN IEC 61676:2022

en

iTeh STANDARD PREVIEW (standards.iteh.ai)

oSIST prEN IEC 61676:2022 https://standards.iteh.ai/catalog/standards/sist/7b1814aa-75eb-4fd7-bc5f-736f9b14fd42/osist-pren-iec-61676-2022



COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: IEC 61676 ED2 DATE OF CIRCULATION: 2022-01-21 SUPERSEDES DOCUMENTS: 62C/796A/CD, 62C/808A/CC

IEC SC 62C : EQUIPMENT FOR RADIOTHERAPY, NUCLEAR MEDICINE AND RADIATION DOSIMETRY			
Secretariat:	Secretary:		
Germany	Ms Regina Geierhofer		
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD:		
SC 62B			
iTeh STA	Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.		
FUNCTIONS CONCERNED:			
	QUALITY ASSURANCE SAFETY		
Submitted for CENELEC PARALLEL VOTING	Not submitted for CENELEC parallel voting		
Attention IEC-CENELEC parallel voting			
The attention of IEC National Committees, Smembers of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. 75eb-4fd7-bc5f-736f9b14	<u>C 61676:2022</u> og/standards/sist/7b1814aa- d42/osist-pren-iec-61676-		
The CENELEC members are invited to vote through the CENELEC online voting system.	22		

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

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

PROPOSED STABILITY DATE: 2026

NOTE FROM TC/SC OFFICERS:

Copyright © 2021 International Electrotechnical Commission, IEC. All rights reserved. It is permitted to download this electronic file, to make a copy and to print out the content for the sole purpose of preparing National Committee positions. You may not copy or "mirror" the file or printed version of the document, or any part of it, for any other purpose without permission in writing from IEC.

iTeh STANDARD PREVIEW (standards.iteh.ai)

oSIST prEN IEC 61676:2022 https://standards.iteh.ai/catalog/standards/sist/7b1814aa-75eb-4fd7-bc5f-736f9b14fd42/osist-pren-iec-61676-2022 1

CONTENTS

2	FO	REW	ORD	4
3	INT	rrod	UCTION	6
4	1	Scop	be and object	7
5	2	Norn	native references	7
6	3	Term	ninology and definitions	8
7	4	Gen	eral performance requirements for measurement of PRACTICAL PEAK VOLTAGE	
8		mea	surements	10
9		4.1	Quantity to be measured	10
10		4.2	Limits of PERFORMANCE CHARACTERISTICS	11
11		4.3	LIMITS OF VARIATION for effects of INFLUENCE QUANTITIES	13
12		4.4	Performance test procedures	15
13	5	Spec	cial instrumental requirements and marking	22
14		5.1	Requirements for the complete instruments	22
15		5.2	General	22
16		5.3	Display	22
17		5.4	Range of measurement	22
18		5.5	Connectors and cables CII. SIANDAND	22
19	6	Acco	OMPANYING DOCUMENTS DDFVTFVV	22
20		6.1	General	22
21		6.2	Information provided	22
22		6.3	Instrument description	22
23		6.4	Detector	23
24		6.5	Delay time <u>OSIST prEN IEC 616/6:2022</u>	23
25		6.6	Measurement windowards.iten.al/catalog/standards/sist/01814aa-	23
26		6.7	Data outlet	23
27		6.8	Transport and storage	23
28	An	nex A	(Informative) COMBINED STANDARD UNCERTAINTY	24
29	An	nex B	(informative) Additional information on PRACTICAL PEAK VOLTAGE	25
30	INE	DEX C	OF DEFINED TERMS	31
31				
32	Fig	ure B	1 – Example of a waveform of a two-pulse generator	27
33	Fig	ure B	2 – Example of a waveform of a constant-voltage generator	27
31 31	Fig		3 – Example of falling load waveform	<u>2</u> 7 28
04 0 <i>5</i>	i iy			20
35				
36	Ia	ble 1 -	- MINIMUM EFFECTIVE RANGES	11
37 20	Tal	ble 2 -	- Minimum RATED RANGE OF USE, REFERENCE CONDITIONS, STANDARD TEST	
30 39	RAI	NGE O	f use, for the pertaining INFLUENCE QUANTITY	14
40	Tal	hle 3 -	- Minimum test points and test values of PRACTICAL PEAK VOLTAGE for	
40 41	INF	LUENC	CE QUANTITIES	15
42	Tal	ble 4 -	- Maximum HALF-VALUE LAYER (HVL) depending on anode angle	21
43	Tal	ble B	1 – Values of 20 samples of the falling load waveform in figure B.3	28
44	Tal	ble R	2 - Voltage bins probability and weighting factors for the 20 samples of the	
45	fall	ing lo	ad waveform in figure B.3	29

62C/830/CDV - 3 -	IEC CDV 61676 © IEC 2021
-------------------	--------------------------

46	Table B.3 – Weighting factors for the 20 equally spaced samples of the falling load	
47	waveform in figure B.3	30

48

iTeh STANDARD PREVIEW (standards.iteh.ai)

oSIST prEN IEC 61676:2022 https://standards.iteh.ai/catalog/standards/sist/7b1814aa-75eb-4fd7-bc5f-736f9b14fd42/osist-pren-iec-61676-2022 oSIST prEN IEC 61676:2022

	620	C/830/CDV	- 4 -	IEC CDV 61676 © IEC 2021
49	IN	TERNATIONAL ELECTROTECHN	IICAL COMMISSIC)N
50		-		
51		MEDICAL ELEC	TRICAL EQUIPME	ENT –
52 53		Dosimetric instruments us	ed for non-invasi	ve measurement
54		of X-ray tube voltag	ge in diagnostic r	adiology
55 56				
50 57		FO	REWORD	
58 59 60 61 62 63 64 65 66 67	1)	The International Electrotechnical Commission (I all national electrotechnical committees (IEC international co-operation on all questions conce this end and in addition to other activities, IEC Technical Reports, Publicly Available Specifi Publication(s)"). Their preparation is entrusted to in the subject dealt with may participate in t governmental organizations liaising with the IEC with the International Organization for Standar agreement between the two organizations.	EC) is a worldwide organiz National Committees). T erning standardization in th D publishes International S cations (PAS) and Guide D technical committees; any his preparatory work. Int D also participate in this p dization (ISO) in accorda	cation for standardization comprising The object of IEC is to promote e electrical and electronic fields. To Standards, Technical Specifications, es (hereafter referred to as "IEC y IEC National Committee interested ernational, governmental and non- reparation. IEC collaborates closely nce with conditions determined by
68 69 70	2)	The formal decisions or agreements of IEC on te consensus of opinion on the relevant subjects interested IEC National Committees.	chnical matters express, as since each technical con	s nearly as possible, an international nmittee has representation from all
71 72 73 74	3)	IEC Publications have the form of recommenda Committees in that sense. While all reasonable Publications is accurate, IEC cannot be held misinterpretation by any end user.	tions for international use efforts are made to ensu responsible for the way i	and are accepted by IEC National re that the technical content of IEC n which they are used or for any
75 76 77 78	4)	In order to promote international uniformity, IE transparently to the maximum extent possible between any IEC Publication and the correspond the latter.	C National Committees u in their national and reg ling national or regional pu	ndertake to apply IEC Publications ional publications. Any divergence blication shall be clearly indicated in
79 80	5)	IEC provides no marking procedure to indicat equipment declared to be in conformity with an IB	e its approval and canno conclusion dards/sist/	t be rendered responsible for any 7b1814aa-
81 82	6) 7)	All users should ensure that they have the latest	edition of this publication.	C-010/0-
83 84 85 86	7)	members of its technical committees and IEC Na other damage of any nature whatsoever, whet expenses arising out of the publication, use of Publications.	ational Committees for any her direct or indirect, or f of, or reliance upon, this	personal injury, property damage or for costs (including legal fees) and IEC Publication or any other IEC
87 88	8)	Attention is drawn to the Normative references indispensable for the correct application of this p	cited in this publication. U ublication.	se of the referenced publications is
89 90	9)	Attention is drawn to the possibility that some of patent rights. IEC shall not be held responsible for	of the elements of this IEC or identifying any or all suc	C Publication may be the subject of h patent rights.
91 92 93	Inte for Ele	ernational Standard IEC 61676 has been radiotherapy, nuclear medicine and ra actrical equipment in medical practice.	en prepared by subco diation dosimetry, of	ommittee SC 62C: Equipment IEC Technical Committee 62:
94 95 96 97 98	This second edition of IEC 61676 cancels and replaces the edition 1.1, published in 2009. 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".			tion 1.1, published in 2009. It ITY for the performance of a f the tube high voltage (in nmended performance criteria
99 100				

- 101 In this standard the following print types are used:
- 102 requirements, compliance with which can be tested, and definitions: in roman type;
- 103 notes, explanations, advice, general statements and exceptions: in small roman type;
- 104 test specifications: in italic type;
- 105 TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3 OR IN IEC 60601-1 AND ITS COLLATERAL STANDARDS: IN SMALL CAPITALS.

107 The committee has decided that the contents of the base publication and its amendments will 108 remain unchanged until the maintenance result date indicated on the IEC web site under 109 "http://webstore.iec.ch" in the data related to the specific publication. At this date, 110 the publication will be

- 111 reconfirmed,
- 112 withdrawn,
- 113 replaced by a revised edition, or
- 114 amended.
- 115 A bilingual version of this publication may be issued at a later date.

NOTE The committee knows this second edition of the standard 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 standard as soon as the results from these new examinations will be available.

125oSIST prEN IEC 61676:2022126https://standards.iteh.ai/catalog/standards/sist/7b1814aa-
75eb-4fd7-bc5f-736f9b14fd42/osist-pren-iec-61676-
2022

IEC CDV 61676 © IEC 2021

INTRODUCTION

128 The result of a measurement of the X-RAY TUBE VOLTAGE by means of invasive or non-invasive 129 instruments is normally expressed in the form of one single number for the value of the tube 130 voltage, irrespective of whether the tube voltage is constant potential or shows a time 131 dependent waveform. Non-invasive instruments for the measurement of the X-RAY TUBE 132 VOLTAGE on the market usually indicate the "mean peak voltage". But the quantity "mean peak 133 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 134 instruments for the measurement of the X-RAY TUBE VOLTAGE without the definition of the 135 136 quantity under consideration. Therefore, this standard is based on a quantity called 137 "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 138 139 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 140 when the waveforms of the tube voltages are different. Detailed information on this concept is 141 142 provided in Annex B. An example for the calculation of the PRACTICAL PEAK VOLTAGE in the 143 case of a "falling load" waveform is also given in Annex B.

144 The calibration and adjustment of the X-RAY TUBE VOLTAGE of an X-RAY GENERATOR is 145 generally performed by the MANUFACTURER using a direct INVASIVE MEASUREMENT. Instruments 146 utilising NON-INVASIVE MEASUREMENTS can also be used to check the calibration or to adjust 147 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 148 149 parameters of diagnostic X-RAY EQUIPMENT is the voltage applied to the X-RAY TUBE, because 150 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 151 uncertainty below ± 5 % is required, and this value serves as a guide for the LIMITS OF VARIATION for the effects of INFLUENCE QUANTITIES. 152 153

> oSIST prEN IEC 61676:2022 https://standards.iteh.ai/catalog/standards/sist/7b1814aa-75eb-4fd7-bc5f-736f9b14fd42/osist-pren-iec-61676-2022

127

154

MEDICAL ELECTRICAL EQUIPMENT -

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

159

155 156

157

158

- 160
- 161

Scope and object 162 1

This International Standard specifies the performance requirements of instruments as used in 163 the NON-INVASIVE MEASUREMENT of X-RAY TUBE VOLTAGE up to 150 kV and the relevant 164 165 compliance tests. This standard also describes the method for calibration and gives guidance for estimating the uncertainty in measurements performed under conditions different from 166 167 those during calibration.

168 Applications for such measurement are found in diagnostic RADIOLOGY including 169 mammography, COMPUTED TOMOGRAPHY (CT), dental radiology and RADIOSCOPY. This standard is not concerned with the safety aspect of such instruments. The requirements for electrical 170 171 safety applying to them are contained in IEC 61010-1.

2 Normative references 172

PREVIE W

Teh STANDARD

The following documents are referred to in the text in such a way that some or all of their 173 174 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 175 176 any amendments) applies.

- IEC 60417, Graphical symbols for use on equipment (available status) statuards it is in the symbols for use on equipment (available status) statuards it is in the symbols 177 symbols.info/equipment) /Seb-4fd7-bc5f-736f9b14fd42/osist-pren-iec-61676-178
- 179 IEC TR 60788:2004, Medical electrical equipment – Glossary of defined terms
- 180 IEC 61000-4-2, Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test 181
- IEC 61000-4-3, Electromagnetic compatibility (EMC) Part 4-3: Testing and measurement 182 183 techniques – Radiated, radio-frequency, electromagnetic field immunity test
- 184 IEC 61000-4-4, Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test 185
- IEC 61000-4-5, Electromagnetic compatibility (EMC) Part 4-5: Testing and measurement 186 187 techniques – Surge immunity test
- 188 IEC 61000-4-6, Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances induced by radio-frequency fields 189
- 190 IEC 61000-4-11, Electromagnetic compatibility (EMC) – Part 4-11: Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests 191
- 192 IEC 61010-1, Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements 193
- 194 IEC 61187, Electrical and electronic measuring equipment – Documentation

000/000/0DV/	0
620/830/CDV	- 8 -

195 ISO 7000:1989, Graphical symbols for use on equipment – Index and synopsis

196 **3 Terminology 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.
- 199 ISO and IEC maintain terminological databases for use in standardization at the following200 addresses:
- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp
- 203 NOTE 1 An index of defined terms is to be found at the end of the document.
- 204 NOTE 2 A searchable IEC Glossary can be found at std.iec.ch

205 **3.1**

206 **CORRECTION FACTOR**

- 207 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

iTeh STANDARD

210 **3.2**211 EFFECTIVE RANGE

- range of INDICATED VALUES for which an instrument complies with a stated performance. The
- 213 maximum (minimum) effective INDICATED VALUE is the highest (lowest) in this range

(standards.iteh.ai)

214 **3.3**

215 INDICATED VALUE

value of quantity derived from the scale reading of an2instrument together with any scale factors indicated on the control panel of the instrument dards/sist/7b1814aa-

75eb-4fd7-bc5f-736f9b14fd42/osist-pren-iec-61676-

218 **3.4**

219 INFLUENCE QUANTITY

- any external quantity that may affect the performance of an instrument (e.g., ambient temperature etc.) and any property of the X-RAY EQUIPMENT under test that needs to be taken into account in using the instrument for NON-INVASIVE MEASUREMENT of X-RAY TUBE VOLTAGE
- 223 (e.g., range of X-RAY TUBE VOLTAGE, ANODE ANGLE, anode material, TOTAL FILTRATION etc.)

224 **3.5**

225 INSTRUMENT PARAMETER

any internal property of an instrument that may affect the performance of the instrument

227 **3.6**

- 228 INTRINSIC ERROR
- 229 deviation of the MEASURED VALUE (i.e., the INDICATED VALUE, corrected to REFERENCE 230 CONDITIONS) from the CONVENTIONAL TRUE VALUE under STANDARD TEST CONDITIONS

231 **3.7**

232 INVASIVE MEASUREMENT

measurement of the X-RAY TUBE VOLTAGE by external connection of a suitable meter or a high
 resistance divider

235 **3.8**

236 LIMITS OF VARIATION

- maximum VARIATION of a PERFORMANCE CHARACTERISTIC y, permitted by this standard. If the LIMITS OF VARIATION are stated as $\pm L$ % the VARIATION $\Delta y / y$, expressed as a percentage, shall
- 239 remain in the range from -L % to +L %

2022

62C/830/CDV

- 9 -

240 **3.9**

241 MAXIMUM PEAK VOLTAGE

242 maximum value of the X-RAY TUBE VOLTAGE in a specified time interval. The unit of this 243 quantity is the volt (V)

244 **3.10**

245 MEAN PEAK VOLTAGE

- 246 mean value of all X-RAY TUBE VOLTAGE peaks during a specified time interval. The unit of this 247 quantity is the volt (V)
- 248 **3.11**

249 MEASURED VALUE

- best estimate of the CONVENTIONAL TRUE VALUE of a quantity, being derived from the INDICATED
 VALUE of an instrument together with the application of all relevant CORRECTION FACTORS
- NOTE The CONVENTIONAL TRUE VALUE will usually be the value determined by the working standard with which the instrument under test is being compared.

254 **3.12**

255 MINIMUM EFFECTIVE RANGE

smallest permitted range of INDICATED VALUES for which an instrument complies with a statedperformance

iTeh STANDARD

- 259 NON-INVASIVE MEASUREMENT
- 260 measurement of X-RAY TUBE VOLTAGE by analysis of the emitted RADIATION

261 3.14

3.13

258

3.14 (standards.iteh.ai)

- 262 PERFORMANCE CHARACTERISTIC
 263 one of the quantities used to define the performance of an instrument (e.g., RESPONSE)
- oSIST prEN IEC 61676:2022
- **3.15** https://standards.iteh.ai/catalog/standards/sist/7b1814aa-
- 265 VOLTAGE RIPPLE 75eb-4fd7-bc5f-736f9b14fd42/osist-pren-iec-61676-
- 266 VOLTAGE RIPPLE at the X-RAY TUBE, r, is expressed as a percentage of the peak voltage, U_{max} , 267 over a specified time interval. This is expressed by the formula:

$$268 r = \frac{U_{\max} - U_{\min}}{U_{\max}} \cdot 100\%$$

269 where U_{max} is the highest voltage in the interval, and U_{min} is the lowest voltage in the interval

270 **3.16**

271 PRACTICAL PEAK VOLTAGE (PPV)

272 PRACTICAL PEAK VOLTAGE U is defined as:

273
$$\hat{U} = \frac{\bigcup_{\text{max}} \int p(U) \cdot w(U) \cdot U \, dU}{\bigcup_{\text{max}} U_{\text{max}}} \quad \text{with} \quad \int p(U) \, dU = 1$$
$$\bigcup_{U_{\text{min}}} p(U) \cdot w(U) \, dU$$

where p(U) is the distribution function for the voltage U and w(U) is a weighting function. U_{max} is the highest voltage in the interval, and U_{min} is the lowest voltage in the interval. The unit of the quantity PRACTICAL PEAK VOLTAGE is the volt (V)

277 NOTE Additional information on the PRACTICAL PEAK VOLTAGE, the weighting function w(U) and the distribution 278 function p(U) is provided in Annex C. Using this weighting function w(U) the PRACTICAL PEAK VOLTAGE will be 279 defined as the constant potential which produces the same AIR KERMA contrast behind a specified PHANTOM as the 280 non-dc voltage under test.