



SLOVENSKI STANDARD
oSIST prEN IEC 61674:2023
01-april-2023

Medicinska električna oprema - Dozimetri z ionizacijskimi komorami oziroma polprevodniški detektorji, kot so uporabljeni pri rentgenskem diagnostičnem slikanju

Medical electrical equipment - Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging

Medizinische elektrische Geräte - Dosimeter mit Ionisationskammern und/oder Halbleiterdetektoren für den Einsatz an diagnostischen Röntgeneinrichtungen

Appareils électromédicaux - Dosimètres à chambres d'ionisation et/ou à détecteurs semiconducteurs utilisés en imagerie de diagnostic à rayonnement X

Ta slovenski standard je istoveten z: prEN IEC 61674:2023

ICS:

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17.240	Merjenje sevanja	Radiation measurements

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62C/865/CDV

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IEC SC 62C : EQUIPMENT FOR RADIOTHERAPY, NUCLEAR MEDICINE AND RADIATION DOSIMETRY	
SECRETARIAT: Germany	SECRETARY: Ms Regina Geierhofer
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: <input type="checkbox"/> Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED: <input type="checkbox"/> EMC <input type="checkbox"/> ENVIRONMENT <input checked="" type="checkbox"/> QUALITY ASSURANCE <input checked="" type="checkbox"/> SAFETY	
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TITLE:

Medical electrical equipment - Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging

PROPOSED STABILITY DATE: 2027

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83 INTERNATIONAL ELECTROTECHNICAL COMMISSION

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**MEDICAL ELECTRICAL EQUIPMENT –
DOSIMETERS WITH IONIZATION CHAMBERS AND/OR
SEMICONDUCTOR DETECTORS AS USED
IN X-RAY DIAGNOSTIC IMAGING**

FOREWORD

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126 International Standard IEC 61674 has been prepared by subcommittee 62C: Equipment for
127 radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62:
128 Electrical equipment in medical practice.

129 This second edition cancels and replaces the first edition of IEC 61674. This edition
130 constitutes a technical revision.

131 The text of this standard is based on the following documents:

FDIS	Report on voting
62C/551/FDIS	62C/555/RVD

132

133 Full information on the voting for the approval of this standard can be found in the report on
134 voting indicated in the above table.

- 135 This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.
- 136 In this standard, the following print types are used:
- 137 – Requirements and definitions: roman type.
 - 138 – *Test specifications: italic type.*
 - 139 – Informative material appearing outside of tables, such as notes, examples and references: in smaller type.
140 Normative text of tables is also in a smaller type.
 - 141 – TERMS DEFINED IN CLAUSE 3 OF IEC 60601-1, IN THIS PARTICULAR STANDARD OR AS NOTED:
142 SMALL CAPITALS.
- 143 The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC
144 Directives, Part 2. For the purposes of this standard, the auxiliary verb:
- 145 – “shall” means that compliance with a requirement or a test is mandatory for compliance
146 with this standard;
 - 147 – “should” means that compliance with a requirement or a test is recommended but is not
148 mandatory for compliance with this standard;
 - 149 – “may” is used to describe a permissible way to achieve compliance with a requirement or
150 test.
- 151 The committee has decided that the contents of this publication will remain unchanged until
152 the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data
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- 154 • reconfirmed,
 - 155 • withdrawn,
 - 156 • replaced by a revised edition, or
 - 157 • amended.
- 158 <https://standards.iteh.ai/catalog/standards/sist/9f3e8b55-af19-4ea3-bfeb-81c789fac877/osist-pren-iec-61674-2023>
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161

INTRODUCTION

162 Diagnostic radiology is the largest contributor to man-made IONIZING RADIATION to which the
163 public is exposed. The reduction in the exposure received by PATIENTS undergoing medical
164 radiological examinations or procedures has therefore become a central issue in recent years.
165 The PATIENT dose will be minimized when the X-ray producing equipment is correctly adjusted
166 for image quality and radiation output. These adjustments require that the routine
167 measurement of AIR KERMA, AIR KERMA LENGTH PRODUCT and/or AIR KERMA RATE be made
168 accurately. The equipment covered by this standard plays an essential part in achieving the
169 required accuracy. The DOSIMETERS used for adjustment and control measurements must be
170 of satisfactory quality and must therefore fulfil the special requirements laid down in this
171 standard.

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173 **MEDICAL ELECTRICAL EQUIPMENT –**
174 **DOSIMETERS WITH IONIZATION CHAMBERS AND/OR**
175 **SEMICONDUCTOR DETECTORS AS USED**
176 **IN X-RAY DIAGNOSTIC IMAGING**
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178
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180 **1 Scope and object**

181 **1.1 Scope**

182 This International Standard specifies the performance and some related constructional
183 requirements of DIAGNOSTIC DOSIMETERS intended for the measurement of AIR KERMA, AIR
184 KERMA LENGTH PRODUCT or AIR KERMA RATE, in photon radiation fields used in medical X-ray
185 imaging, such as RADIOGRAPHY, RADIOSCOPY and COMPUTED TOMOGRAPHY (CT), for X-radiation
186 with generating potentials in the range of 20 kV to 150 kV.

187 This International Standard is applicable to the performance of DOSIMETERS with VENTED
188 IONIZATION CHAMBERS and/or SEMICONDUCTOR DETECTORS as used in X-ray diagnostic imaging.

189 **1.2 Object**

190 The object of this standard is:

- 191 a) to establish requirements for a satisfactory level of performance for DIAGNOSTIC
192 DOSIMETERS, and
193 b) to standardize the methods for the determination of compliance with this level of
194 performance.

195 This standard is not concerned with the safety aspects of DOSIMETERS. The DIAGNOSTIC
196 DOSIMETERS covered by this standard are not intended for use in the PATIENT ENVIRONMENT
197 and, therefore, the requirements for electrical safety applying to them are contained in
198 IEC 61010-1.

199 **2 Normative references**

200 The following documents, in whole or in part, are normatively referenced in this document and
201 are indispensable for its application. For dated references, only the edition cited applies. For
202 undated references, the latest edition of the referenced document (including any
203 amendments) applies.

204 IEC 60050 (all parts), *International Electrotechnical Vocabulary* (available at
205 <<http://www.electropedia.org>>)

206 IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic
207 safety and essential performance*

208 IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic
209 safety and essential performance – Collateral standard: Radiation protection in diagnostic
210 X-ray equipment*

211 IEC 60417, *Graphical symbols for use on equipment* (Available at: <[http://www.graphical-
212 symbols.info/equipment](http://www.graphical-symbols.info/equipment)>)

213 IEC 60731:2011, *Medical electrical equipment – Dosimeters with ionization chambers as used
214 in radiotherapy*

- 215 IEC 60788:2004, *Medical electrical equipment – Glossary of defined terms*
- 216 IEC 61000-4 (all parts) *Electromagnetic compatibility (EMC) – Part 4: Testing and measuring*
217 *techniques*
- 218 IEC 61000-4-2, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement*
219 *techniques – Electrostatic discharge immunity test*
- 220 IEC 61000-4-3, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement*
221 *techniques – Radiated, radio-frequency, electromagnetic field immunity test*
- 222 IEC 61000-4-4, *Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement*
223 *techniques – Electrical fast transient/burst immunity test*
- 224 IEC 61000-4-6, *Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement*
225 *techniques – Immunity to conducted disturbances induced by radio-frequency fields*
- 226 IEC 61000-4-11, *Electromagnetic compatibility (EMC) – Part 4-11: Testing and measurement*
227 *techniques – Voltage dips, short interruptions and voltage variations immunity tests*
- 228 IEC 61187, *Electrical and electronic measuring equipment – Documentation*
- 229 IEC 61267:2005, *Medical diagnostic X-ray equipment – Radiation conditions for use in the*
230 *determination of characteristics*
- 231 ISO/IEC GUIDE 98-3:2008, *Uncertainty of measurement – Part 3: Guide to the expression of*
232 *uncertainty in measurement (GUM:1995)*
- 233 ISO/IEC Guide 99:2007, *International vocabulary of metrology – Basic and general concepts*
234 *and associated terms (VIM)*
- 235 ISO 3534-1:2006, *Statistics – Vocabulary and symbols – Part 1: General statistical terms and*
236 *terms used in probability*

237 **3 Terms and definitions**

238 For the purposes of this document, the terms and definitions given in IEC/TR 60788:2004 and
239 the following apply.

240 **3.1**

241 **DIAGNOSTIC DOSIMETER**

242 **DOSIMETER**

243 equipment which uses IONIZATION CHAMBERS and/or SEMICONDUCTOR DETECTORS for the
244 measurement of AIR KERMA, AIR KERMA LENGTH PRODUCT and/or AIR KERMA RATE in the beam of
245 an X-RAY EQUIPMENT used for diagnostic medical radiological examinations

246 Note 1 to entry: A DIAGNOSTIC DOSIMETER contains the following components:

- 247 – one or more DETECTOR ASSEMBLIES which may or may not be an integral part of the MEASURING ASSEMBLY;
- 248 – a MEASURING ASSEMBLY;
- 249 – one or more STABILITY CHECK DEVICES (optional).

250 **3.1.1**

251 **DETECTOR ASSEMBLY**

252 RADIATION DETECTOR and all other parts to which the RADIATION DETECTOR is permanently
253 attached, except the MEASURING ASSEMBLY

- 254 Note 1 to entry: The DETECTOR ASSEMBLY normally includes:
- 255 – the RADIATION DETECTOR and the stem (or body) on which the RADIATION DETECTOR is permanently mounted (or
256 embedded);
- 257 – the electrical fitting and any permanently attached cable or pre-amplifier.
- 258 **3.1.1.1**
- 259 **RADIATION DETECTOR**
- 260 element which transduces AIR KERMA, AIR KERMA LENGTH PRODUCT or AIR KERMA RATE into a
261 measurable electrical signal
- 262 Note 1 to entry: A radiation detector may be either an ionization chamber or a semiconductor detector.
- 263 **3.1.1.1.1**
- 264 **IONIZATION CHAMBER**
- 265 **CHAMBER**
- 266 ionizing RADIATION DETECTOR consisting of a CHAMBER filled with air, in which an electric field
267 insufficient to produce gas multiplication is provided for the collection at the electrodes of
268 charges associated with the ions and the ELECTRONS produced in the measuring volume of the
269 detector by IONIZING RADIATION
- 270 Note 1 to entry: An IONIZATION CHAMBER can be sealed or vented.
- 271 Note 2 to entry: Vented IONIZATION CHAMBERS are constructed in such a way as to allow the air inside the
272 measuring volume to communicate freely with the atmosphere, so that corrections to the RESPONSE for changes in
273 air density need to be made.
- 274 Note 3 to entry: Sealed IONIZATION CHAMBERS are not suitable, because the necessary wall thickness of a sealed
275 CHAMBER may cause an unacceptable energy dependence of the RESPONSE and because the long term stability of
276 sealed CHAMBERS is not guaranteed.
- 277 [SOURCE: IEC 60731:2011, 3.1.1.1, modified – three new notes to entry have replaced the
278 two original notes.]
- 279 **3.1.1.1.2**
- 280 **VENTED IONIZATION CHAMBER**
- 281 IONIZATION CHAMBER constructed in such a way as to allow the air inside the measuring volume
282 to communicate freely with the atmosphere such that corrections to the RESPONSE for changes
283 in air density need to be made
- 284 [SOURCE: IEC 60731:2011, 3.1.1.1.3, modified – the term has been changed from "vented
285 chamber" to "VENTED IONIZATION CHAMBER".]
- 286 **3.1.1.1.3**
- 287 **SEMICONDUCTOR DETECTOR**
- 288 semiconductor device that utilises the production and motion of electron-hole pairs in a
289 charge carrier depleted region of the semiconductor for the detection and measurement of
290 IONIZING RADIATION
- 291 Note 1 to entry: The production of electron-hole pairs is caused either
- 292 – directly by interaction of the IONIZING RADIATION with the semiconductor material, or
- 293 – indirectly by first converting the incident radiation energy to light in a scintillator material directly in front of and
294 optically coupled to a semiconductor photodiode, which then produces the electrical signal.
- 295 **3.1.2**
- 296 **MEASURING ASSEMBLY**
- 297 device to measure the electrical signal from the RADIATION DETECTOR and convert it into a form
298 suitable for displaying the values of DOSE or KERMA or their corresponding rates
- 299 [SOURCE: IEC 60731:2011, 3.1.2. modified – the term IONIZATION CHAMBER in the original
300 definition has been replaced by the term RADIATION DETECTOR]