

© Copyright SEK Svensk Elstandard. Reproduction in any form without permission is prohibited.

Röntgenmateriel – Mätare för produkten av area och exposition

*Medical electrical equipment –
Dose area product meters*

Som svensk standard gäller europastandarden EN IEC 60580:2020. Den svenska standarden innehåller den officiella engelska språkversionen av EN IEC 60580:2020.

Nationellt förord

Europastandarden EN IEC 60580:2020

består av:

- **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
- **IEC 60580, Third edition, 2019 - Medical electrical equipment - Dose area product meters**

utarbetad inom International Electrotechnical Commission, IEC.

Tidigare fastställd svensk standard SS-EN 60580, utgåva 1, 2000, gäller ej fr o m 2023-04-03.

Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a mätning, säkerhet och provning och för utförande, skötsel och dokumentation av elprodukter och elanläggningar.

Genom att utforma sådana standarder blir säkerhetsfordringar tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

SEK är Sveriges röst i standardiseringsarbetet inom elområdet

SEK Svensk Elstandard svarar för standardiseringen inom elområdet i Sverige och samordnar svensk medverkan i internationell och europeisk standardisering. SEK är en ideell organisation med frivilligt deltagande från svenska myndigheter, företag och organisationer som vill medverka till och påverka utformningen av tekniska regler inom elektrotekniken.

SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

Stora delar av arbetet sker internationellt

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

Var med och påverka!

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

SEK Svensk Elstandard

Box 1284
164 29 Kista
Tel 08-444 14 00
www.elstandard.se

English Version

**Medical electrical equipment - Dose area product meters
(IEC 60580:2019)**

Appareils électromédicaux - Radiamètres de produit
exposition-surface
(IEC 60580:2019)

Medizinische elektrische Geräte - Dosisflächenprodukt-
Messgeräte
(IEC 60580:2019)

This European Standard was approved by CENELEC on 2019-12-17. 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.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



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

European foreword

The text of document 62C/744/FDIS, future edition 3 of IEC 60580, 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 60580:2020.

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) 2020-10-03
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-04-03

This document supersedes EN 60580:2000 and all of its amendments and corrigenda (if any).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association.

Endorsement notice

The text of the International Standard IEC 60580:2019 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 60731:2011 NOTE Harmonized as EN 60731:2012 (not modified)

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.cenelec.eu.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60417-1	-	Graphical symbols for use on equipment -- Part 1: Overview and application		-
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
			+A12	2014
			+EN 60601-1:2006/corrigendum Mar. 2010	
			+AC	2014
			+A11	2011
IEC 60601-1-2	-	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	-
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 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	-

EN IEC 60580:2020 (E)

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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 61185	-	Ferrite cores (ETD-cores) intended for use in power supply applications - Dimensions	EN 61185	-
IEC 61267	-	Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics	EN 61267	-
IEC 62368-1	-	Audio/video, information and communication technology equipment - Part 1: Safety requirements	EN IEC 62368-1	-
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	+prAB	-

CONTENTS

FOREWORD	4
INTRODUCTION	6
1 Scope	7
2 Normative references	7
3 Terms and definitions	8
4 General requirements	14
4.1 Performance requirements	14
4.2 Minimum EFFECTIVE RANGES of DOSE AREA PRODUCT and DOSE AREA PRODUCT RATE	14
4.3 Plane of measurement	14
4.4 REFERENCE VALUES and STANDARD TEST CONDITIONS	14
4.5 General test conditions	15
4.5.1 STANDARD TEST CONDITIONS	15
4.5.2 Test of components	15
4.5.3 STABILIZATION TIME	15
4.5.4 Adjustments during test	16
4.5.5 Uniformity of RADIATION field	16
4.6 Statistical fluctuations	16
4.7 Uncertainty of measurement	17
4.8 Constructional requirements as related to performance	17
4.8.1 Display	17
4.8.2 Indication of polarizing voltage failure	17
4.8.3 Over-ranging	17
4.8.4 Indication of reset or other inactive condition	18
4.8.5 RADIATION DETECTOR	18
4.9 STABILITY CHECK DEVICE	18
4.10 Adjustment	19
4.11 Electrical safety	20
5 Limits of PERFORMANCE CHARACTERISTICS under STANDARD TEST CONDITIONS	20
5.1 Classification of DOSE AREA PRODUCT METERS according to LIMITS OF VARIATION	20
5.1.1 REFERENCE-CLASS DOSE AREA PRODUCT METERS	20
5.1.2 FIELD-CLASS DOSE AREA PRODUCT METERS	20
5.2 LINEARITY	20
5.3 Warning function	20
5.4 Repeatability	21
5.5 RESOLUTION of reading	21
5.6 STABILIZATION TIME	21
5.7 Reset on DOSE AREA PRODUCT ranges	21
5.8 Drift of INDICATED VALUES	21
5.9 Long term stability	22
5.10 RESPONSE TIME	22
5.11 Spatial uniformity of RESPONSE	23
6 LIMITS OF VARIATION for effects of INFLUENCE QUANTITIES	23
6.1 General	23
6.2 Energy dependence of RESPONSE	23

6.3	DOSE AREA PRODUCT RATE dependence of DOSE AREA PRODUCT measurements.....	23
6.3.1	MEASURING ASSEMBLY	23
6.3.2	IONIZATION CHAMBER – Recombination losses	24
6.4	IRRADIATION TIME	24
6.5	Field size	24
6.6	Operating voltage	24
6.7	Air pressure	25
6.8	Temperature and humidity	25
6.9	Air density fluctuation in the IONIZATION CHAMBER	25
6.10	Electromagnetic compatibility	25
6.10.1	General	25
6.10.2	Electrostatic discharge	26
6.10.3	Radiated electromagnetic fields	26
6.10.4	Conducted disturbances induced by bursts and high frequencies.....	26
6.10.5	Surges	27
6.10.6	Voltage dips, short interruptions and voltage VARIATIONS	27
6.11	COMBINED STANDARD UNCERTAINTY	27
7	Marking	29
7.1	MEASURING ASSEMBLY	29
7.2	RADIATION DETECTOR	30
8	ACCOMPANYING DOCUMENTS	30
	Bibliography.....	32
	INDEX OF DEFINED TERMS.....	33
	Table 1 – Minimum EFFECTIVE RANGES – DOSE AREA PRODUCT	14
	Table 2 – Minimum EFFECTIVE RANGES – DOSE AREA PRODUCT RATE	14
	Table 3 – REFERENCE VALUES and STANDARD TEST CONDITIONS.....	15
	Table 4 – Number of readings required to detect true differences Δ (95 % confidence level) between two sets of instrument readings	16
	Table 5 – LIMITS OF VARIATION for the effects of INFLUENCE QUANTITIES	19
	Table 6 – Maximum values for the COEFFICIENT OF VARIATION, $V_{\max}$	21
	Table 7 – Climatic conditions	25
	Table 8 – Example for assessment of the COMBINED STANDARD UNCERTAINTY – FIELD-CLASS DOSE AREA PRODUCT METER	28
	Table 9 – Example for assessment of the COMBINED STANDARD UNCERTAINTY – REFERENCE-CLASS DOSE AREA PRODUCT METER	29

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**MEDICAL ELECTRICAL EQUIPMENT –
DOSE AREA PRODUCT METERS****FOREWORD**

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60850 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published 2000, and constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- a) a second class of devices is introduced with tighter uncertainty tolerances;
- b) this document has been expanded to include detectors other than ionization chambers;
- c) radiation qualities have been updated to the new definitions according to IEC 61267;
- d) a requirement on the linearity of the dose area product rate measurement was added;
- e) changed chamber light transmission requirement from 70 % to 60 %.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
62C/744/FDIS	62C/751/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: in roman type;
- explanations, advice, general statements, exceptions and references: small roman type;
- *test specifications: italic type*;
- TERMS USED THROUGHOUT THIS STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 3 OR LISTED IN THE INDEX: 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 "<http://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.

INTRODUCTION

Diagnostic radiology is the largest contributor to man-made ionizing radiation to which the public is exposed. The reduction in the exposure received by PATIENTS undergoing MEDICAL RADIOLOGICAL EXAMINATIONS or procedures has therefore become a central issue in recent years. The purpose of routine measurement of DOSE AREA PRODUCT is to help in achieving an overall reduction in the radiation received by PATIENTS undergoing MEDICAL RADIOLOGICAL EXAMINATIONS. Provided adequate records are kept, it is possible to determine PATIENT doses, to compare different examination techniques, to establish a technique giving minimum RADIATION to a PATIENT, and to ensure a maintenance of that technique; in this respect, such measurements have a place of particular importance in training establishments. Examination of records may also indicate a deterioration in the efficiency of the image-production system.

MEDICAL ELECTRICAL EQUIPMENT – DOSE AREA PRODUCT METERS

1 Scope

This document specifies the performance and testing of DOSE AREA PRODUCT METERS intended to measure DOSE AREA PRODUCT and/or DOSE AREA PRODUCT RATE to which the PATIENT is exposed during MEDICAL RADIOLOGICAL EXAMINATIONS.

This document is applicable to the following types of DOSE AREA PRODUCT METERS:

- a) FIELD-CLASS DOSE AREA PRODUCT METERS normally used for the measurement of DOSE AREA PRODUCTS during MEDICAL RADIOLOGICAL EXAMINATIONS;
- b) REFERENCE-CLASS DOSE AREA PRODUCT METERS normally used for the CALIBRATION of FIELD-CLASS DOSIMETERS.

NOTE REFERENCE-CLASS DOSE AREA PRODUCT METERS can be used as FIELD-CLASS DOSE AREA PRODUCT METERS.

The object of this document is

- 1) to establish requirements for a satisfactory level of performance for DOSE AREA PRODUCT METERS, and
- 2) to standardize the methods for the determination of compliance with this level of performance.

Two levels of performance are specified:

- a lower level of performance applying to FIELD-CLASS DOSE AREA PRODUCT METERS;
- a higher level of performance applying to REFERENCE-CLASS DOSE AREA PRODUCT METERS.

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 60601-1-2, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 62368-1, *Audio/video, information and communication technology equipment – Part 1: Safety requirements*

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*

IEC 61187, *Electrical and electronic measuring equipment – Documentation*

IEC 61267, *Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics*

–