ELEKTRILISED MEDITSIINISEADMED. DOOSPINDALAMÕÕTUR

Medical electrical equipment - Dose area product meters

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN IEC 60580:2020 sisaldab Euroopa standardi EN IEC 60580:2020 ingliskeelset teksti.	This Estonian standard EVS-EN IEC 60580:2020 consists of the English text of the European standard EN IEC 60580:2020.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 03.04.2020.	Date of Availability of the European standard is 03.04.2020.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.50

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60580

April 2020

ICS 11.040.50

Supersedes EN 60580:2000 and all of its amendments and corrigenda (if any)

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.

Publication	Year	Title	EN/HD	Year
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	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	-

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 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 +prAB	-
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

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.