



BSI Standards Publication

Medical electrical equipment — Dose area product meters

National foreword

This British Standard is the UK implementation of EN IEC 60580:2020. It is identical to IEC 60580:2019. It supersedes BS EN 60580:2000, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/62/3, Equipment for radiotherapy, nuclear medicine and radiation dosimetry.

A list of organizations represented on this committee can be obtained on request to its secretary.

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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)

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Comité Européen de Normalisation Electrotechnique
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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.

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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)

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**

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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*