IEC 60580

Edition 3.0 2019-11
REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

Medical electrical equipment – Dose area product meters

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.50

ISBN 978-2-8322-7605-1

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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.
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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

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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. ~~DOSE AREA PRODUCT METERS must be of satisfactory quality and must therefore fulfil the special requirements laid down in this International Standard.~~

MEDICAL ELECTRICAL EQUIPMENT – DOSE AREA PRODUCT METERS

1 Scope ~~and object~~

This document specifies the performance and testing of DOSE AREA PRODUCT METERS ~~with IONIZATION CHAMBERS~~ 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:~~1988~~2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

~~IEC 60601-1-1:1992, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems*~~

IEC 60601-1-2~~:1993~~, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic ~~compatibility~~ disturbances – Requirements and tests*

~~IEC 60731:1997, *Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy*~~

IEC TR 60788:~~1984~~2004, ~~*Medical radiology – Terminology*~~ *Medical electrical equipment – Glossary of defined terms*

~~IEC 60950:1999, *Safety of information technology equipment*~~

IEC 61000-4-2~~:1995~~, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

IEC 61000-4-3~~:1995~~, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test* ~~1)~~

IEC 61000-4-4~~:1995~~, *Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test*

IEC 61000-4-5~~:1995~~, *Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test*

IEC 61000-4-6~~:1996~~, *Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances induced by radio-frequency fields*

IEC 61000-4-11~~:1994~~, *Electromagnetic compatibility (EMC) – Part 4-11: Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests*

IEC 61187~~:1993~~, *Electrical and electronic measuring equipment – Documentation*

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

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

~~ICRU 60:1998, *International Commission on Radiation Units and Measurements, Fundamental Quantities and Units for Ionizing Radiation*, Report 60, ICRU Publications, Bethesda MD (1998)~~

~~ISO, *International Organization for Standardization, International vocabulary of basic and general terms in metrology*, 2nd edition, Geneva (1993)~~

~~ISO, *International Organization for Standardization, Guide to the expression of uncertainty in measurement*, 1st edition, Geneva (1993)~~

~~1) There exists a consolidated edition 1.1 (1998) that includes IEC 61000-4-3 (1995) and its amendment 1 (1998).~~

IEC 60580

Edition 3.0 2019-11

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment – Dose area product meters

Appareils électromédicaux – Radiamètres de produit exposition-surface

IEC 60580:2019-11(en-fr)

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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APPAREILS ÉLECTROMÉDICAUX – RADIAMÈTRES DE PRODUIT EXPOSITION-SURFACE

AVANT-PROPOS

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La Norme internationale IEC 60850 a été établie par le sous-comité 62C: Appareils de radiothérapie, de médecine nucléaire et de dosimétrie du rayonnement, du comité d'études 62 de l'IEC: Équipements électriques dans la pratique médicale.

Cette troisième édition annule et remplace la deuxième édition parue en 2000, et constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

a) une deuxième classe de dispositifs a été introduite, avec des tolérances d'incertitude plus strictes;
b) la présente norme a été étendue pour inclure les détecteurs autres que les chambres d'ionisation;

c) les qualités de rayonnement ont été mises à jour en fonction des nouvelles définitions de l'IEC 61267;

d) une exigence relative à la linéarité du mesurage du débit de produit exposition-surface a été ajoutée;

e) l'exigence relative à la transmission lumineuse de la chambre a été modifiée, passant de 70 % à 60 %.

Le texte de cette Norme internationale est issu des documents suivants:

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

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de la présente Norme internationale.

Ce document a été rédigé selon les directives ISO/IEC, Partie 2.

Dans la présente norme, les caractères d'imprimerie suivants sont utilisés:

– exigences dont la conformité peut être vérifiée par un essai et définitions: caractères romains;

– explications, conseils, énoncés de portée générale, exceptions et références: petits caractères romains;

– *modalités d'essai: caractères italiques*;

– TERMES EMPLOYES DANS CETTE NORME ET QUI SONT DEFINIS A L'ARTICLE 3 OU REPERTORIES DANS L'INDEX: PETITES MAJUSCULES.

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- amendé.

INTRODUCTION

Le radiodiagnostic est la plus importante source de rayonnements ionisants produits par l'homme à laquelle le public est exposé. Par conséquent, la réduction de l'exposition reçue par les PATIENTS soumis à des procédures ou EXAMENS RADIOLOGIQUES MEDICAUX est devenue un problème central au cours de ces dernières années. L'objectif du mesurage de routine du PRODUIT EXPOSITION-SURFACE est de contribuer à une réduction globale des rayonnements reçus par les PATIENTS qui sont soumis à des EXAMENS RADIOLOGIQUES MEDICAUX. Il est possible de déterminer les doses reçues par le PATIENT, de comparer les différentes techniques d'examen, d'établir une technique exposant le PATIENT à un minimum de rayonnements, et d'assurer le suivi de cette technique, à condition de tenir des dossiers appropriés; à ce sujet, de tels mesurages occupent une place particulièrement importante dans les établissements de formation. L'examen des dossiers peut aussi indiquer une baisse de l'efficacité du système de production d'image.

APPAREILS ÉLECTROMÉDICAUX – RADIAMÈTRES DE PRODUIT EXPOSITION-SURFACE

1 Domaine d'application

Le présent document spécifie la performance et l'essai des RADIAMETRES DE PRODUIT EXPOSITION-SURFACE destinés au mesurage du PRODUIT EXPOSITION-SURFACE et/ou du DEBIT DE PRODUIT EXPOSITION-SURFACE auquel le PATIENT est exposé au cours des EXAMENS RADIOLOGIQUES MEDICAUX.

Le présent document est applicable aux types suivants de RADIAMETRES DE PRODUIT EXPOSITION-SURFACE:

a) les RADIAMETRES DE PRODUIT EXPOSITION-SURFACE DE CLASSE DE ROUTINE normalement utilisés pour le mesurage des PRODUITS EXPOSITION-SURFACE au cours des EXAMENS RADIOLOGIQUES MEDICAUX;

b) les RADIAMETRES DE PRODUIT EXPOSITION-SURFACE DE CLASSE DE REFERENCE normalement utilisés pour l'ÉTALONNAGE des DOSIMETRES DE CLASSE DE ROUTINE.

NOTE Les RADIAMETRES DE PRODUIT EXPOSITION-SURFACE DE CLASSE DE REFERENCE peuvent être utilisés en tant que RADIAMETRES DE PRODUIT EXPOSITION-SURFACE DE CLASSE DE ROUTINE.

L'objet du présent document est

1) d'établir les exigences pour assurer un niveau de performance satisfaisant des RADIAMETRES DE PRODUIT EXPOSITION-SURFACE, et
2) de normaliser les méthodes pour déterminer la conformité à ce niveau de performance.

Deux niveaux de performance sont spécifiés:

– un niveau inférieur de performance applicable aux RADIAMETRES DE PRODUIT EXPOSITION-SURFACE DE CLASSE DE ROUTINE;
– un niveau supérieur de performance applicable aux RADIAMETRES DE PRODUIT EXPOSITION-SURFACE DE CLASSE DE REFERENCE.

2 Références normatives

Les documents suivants cités dans le texte constituent, pour tout ou partie de leur contenu, des exigences du présent document. Pour les références datées, seule l'édition citée s'applique. Pour les références non datées, la dernière édition du document de référence s'applique (y compris les éventuels amendements).

IEC 60417, *Symboles graphiques utilisables sur le matériel* (disponible à l'adresse http://www.graphical-symbols.info/equipment)

IEC 60601-1:2005, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*

IEC 60601-1-2, *Appareils électromédicaux – Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Perturbations électromagnétiques – Exigences et essais*

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IEC 61000-4-2, *Compatibilité électromagnétique (CEM) – Partie 4-2: Techniques d'essai et de mesure – Essai d'immunité aux décharges électrostatiques*

IEC 61000-4-3, *Compatibilité électromagnétique (CEM) – Partie 4-3: Techniques d'essai et de mesure – Essai d'immunité aux champs électromagnétiques rayonnés aux fréquences radioélectriques*

IEC 61000-4-4, *Compatibilité électromagnétique (CEM) – Partie 4-4: Techniques d'essai et de mesure – Essai d'immunité aux transitoires électriques rapides en salves*

IEC 61000-4-5, *Compatibilité électromagnétique (CEM) – Partie 4-5: Techniques d'essai et de mesure – Essai d'immunité aux ondes de choc*

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IEC 61187, *Équipement de mesures électriques et électroniques – Documentation*

IEC 61267, *Équipement de diagnostic médical à rayonnement X – Conditions de rayonnement pour utilisation dans la détermination des caractéristiques*