

INTERNATIONAL STANDARD

IEC
60580

Second edition
2000-01

Medical electrical equipment – Dose area product meters

Appareils électromédicaux –

Radiamètres de produit exposition-surface



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For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams*.

* See web site address on title page.

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International Electrotechnical Commission
Telefax: +41 22 919 0300

3, rue de Varembé Geneva, Switzerland
e-mail: inmail@iec.ch IEC web site: <http://www.iec.ch>



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CONTENTS

	Page
FOREWORD	4
INTRODUCTION	6
Clause	
1 Scope and object	7
2 Normative references	7
3 Terminology and definitions	8
4 General requirements	13
4.1 Performance requirements	13
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	14
4.5.1 STANDARD TEST CONDITIONS	14
4.5.2 Test of components	14
4.5.3 STABILIZATION TIME	14
4.5.4 Adjustments during test	15
4.5.5 Uniformity of radiation field	15
4.6 Statistical fluctuations	15
4.7 Uncertainty of measurement	15
4.8 Constructional requirements as related to performance	15
4.8.1 Display	15
4.8.2 Indication of polarizing voltage failure	16
4.8.3 Over-ranging	16
4.8.4 Indication of reset or other inactive condition	16
4.8.5 IONIZATION CHAMBER	16
4.9 STABILITY CHECK DEVICE	17
4.10 Adjustment	17
4.11 Electrical safety	17
5 Limits of PERFORMANCE CHARACTERISTICS under STANDARD TEST CONDITIONS	18
5.1 RELATIVE INTRINSIC ERROR	18
5.2 Warning function	18
5.3 Repeatability	19
5.4 RESOLUTION of reading	19
5.5 STABILIZATION TIME	19
5.6 Reset on DOSE AREA PRODUCT ranges	19
5.7 Drift of INDICATED VALUES	19
5.8 Long term stability	20
5.9 RESPONSE TIME	20
5.10 Spatial uniformity of RESPONSE	20

Clause	Page
6 LIMITS OF VARIATION for effects of INFLUENCE QUANTITIES	21
6.1 Energy dependence of RESPONSE	21
6.2 DOSE AREA PRODUCT RATE dependence of DOSE AREA PRODUCT measurements	21
6.2.1 MEASURING ASSEMBLY	21
6.2.2 IONIZATION CHAMBER – Recombination losses	21
6.3 IRRADIATION TIME	22
6.4 Field size	22
6.5 Operating voltage	22
6.6 Air pressure	22
6.7 Temperature and humidity	22
6.8 Air density fluctuation in the IONIZATION CHAMBER	23
6.9 Electromagnetic compatibility	23
6.9.1 General	23
6.9.2 Electrostatic discharge	23
6.9.3 Radiated electromagnetic fields	24
6.9.4 Conducted disturbances induced by bursts and high frequencies	24
6.9.5 Surges	24
6.9.6 Voltage dips, short interruptions and voltage VARIATIONS	24
6.10 COMBINED STANDARD UNCERTAINTY	25
7 Marking	25
7.1 MEASURING ASSEMBLY	25
7.2 IONIZATION CHAMBER	25
8 ACCOMPANYING DOCUMENTS	25
Table 1 – Minimum EFFECTIVE RANGES	27
Table 2 – REFERENCE VALUES and STANDARD TEST CONDITIONS	27
Table 3 – Number of readings required to detect true differences Δ (95 % confidence level) between two sets of instrument readings	28
Table 4 – RELATIVE INSTRINSIC ERROR, I	28
Table 5 – Maximum values for the COEFFICIENT OF VARIATION, V_{\max}	28
Table 6 – LIMITS OF VARIATION for the effects of INFLUENCE QUANTITIES	29
Table 7 – Example for assessment of the COMBINED STANDARD UNCERTAINTY	30
Bibliography	31
Index of defined terms	32

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT – DOSE AREA PRODUCT METERS

FOREWORD

- 1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The 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 the 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 National Committees.
- 3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.
- 4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
- 5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
- 6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60580 has been prepared by sub-committee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1977, and constitutes a technical revision.

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

FDIS	Report on voting
62C/272/FDIS	62C/275/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

A bilingual version of this publication may be issued at a later date.

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 publication will remain unchanged until 2004. At this date, the publication 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. 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 International Standard 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.

The object of this International Standard 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.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60417 (all parts), *Graphical symbols for use on equipment*

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*

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 safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*

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

IEC 60788:1984, *Medical radiology – Terminology*

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⁾

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

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*

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)

3 Terminology and definitions

In this International Standard the auxiliary verb

- "shall" implies that compliance with a requirement is mandatory for compliance with the standard;
- "may" implies that compliance with a requirement is permitted to be accomplished in a particular manner for compliance with the standard.

The definitions given in this International Standard are generally in agreement with those in IEC 60788 and ISO: *International vocabulary of basic and general terms in metrology*; uncertainties are evaluated in accordance with ISO: *Guide to the expression of uncertainty in measurement*.

Terms not defined in this subclause or listed in the index of defined terms have the meanings defined in the above publications or are assumed to be terms of general scientific usage. An alphabetical list of defined terms is given in the index.

For the purposes of this International Standard the following definitions apply:

3.1

ACCOMPANYING DOCUMENTS

documents provided with an installation, equipment, associated equipment or accessory, containing important information for the assembler, installer and user, particularly regarding safety