

# INTERNATIONAL STANDARD

# IEC 60580

Second edition  
2000-01

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## Medical electrical equipment – Dose area product meters

*Appareils électromédicaux –  
Radiamètres de produit exposition-surface*

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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 $\Delta$ (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*<sup>1)</sup>

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<sup>1)</sup> 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*, 2<sup>nd</sup> edition, Geneva (1993)

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