

Dose area product meters

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British Standard

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**Medical electrical equipment
Dose area product meters
(IEC 60580:2000)**

Appareils électromédicaux
Radiamètres de produit exposition-surface
(CEI 60580:2000)

Medizinische elektrische Geräte
Dosisflächenprodukt-Messgeräte
(IEC 60580:2000)

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European Committee for Electrotechnical Standardization
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Foreword

The text of document 62C/272/FDIS, future edition 1 of IEC 60580, prepared by IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60580 on 2000-02-01.

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The following dates were fixed:

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- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2003-02-01

Annexes designated "normative" are part of the body of the standard.
In this standard, annex ZA is normative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60580:2000 was approved by CENELEC as a European Standard without any modification.

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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 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 test¹⁾*

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

3.2

AIR KERMA (Letter symbol K)

quotient of dE_{tr} by dm , where dE_{tr} is the sum of the initial kinetic energies of all the charged particles in a mass dm of air, thus

$$K = \frac{dE_{tr}}{dm}$$

Unit: J kg⁻¹

The special name for the unit of AIR KERMA is gray (Gy) (ICRU 60)

3.3

AIR KERMA RATE (Letter symbol $\dot{K}$)

quotient of dK by dt , where dK is the increment of AIR KERMA in the time interval dt , thus

$$\dot{K} = \frac{dK}{dt}$$

Unit: J kg⁻¹ s⁻¹

If the special name gray is used, the unit of AIR KERMA rate is gray per second (Gy s⁻¹) (ICRU 60)

3.4

COEFFICIENT OF VARIATION

standard deviation of a set of readings expressed as a percentage of the mean value of these readings

3.5

CONVENTIONAL TRUE VALUE

value used instead of the TRUE VALUE when calibrating or determining the performance of an instrument, since in practice the TRUE VALUE is unknown and unknowable (IEC 60731)

NOTE The CONVENTIONAL TRUE VALUE will usually be the value determined by the STANDARD with which the instrument under test is compared.

3.6

CORRECTION FACTOR

dimensionless multiplier which corrects the INDICATED VALUE of an instrument from its value when operated under particular conditions to its value when operated under stated REFERENCE CONDITIONS (IEC 60731)

3.7

DOSE AREA PRODUCT (Letter symbol $K \cdot A$)

product of the area of the USEFUL BEAM and the AIR KERMA over the cross-section of the USEFUL BEAM, both quantities being measured at the same distance from the FOCAL SPOT. The unit of DOSE AREA PRODUCT is Gy m².

3.8

DOSE AREA PRODUCT METER

equipment which uses IONIZATION CHAMBERS for the measurement of DOSE AREA PRODUCT or DOSE AREA PRODUCT RATE in the beam of an X-ray machine used for diagnostic MEDICAL RADIOLOGICAL EXAMINATIONS

A DOSE AREA PRODUCT METER contains the following components:

- IONIZATION CHAMBER
- MEASURING ASSEMBLY
- STABILITY CHECK DEVICE

3.9

DOSE AREA PRODUCT RATE (Letter symbol $\dot{K} \cdot A$)

quotient of an increment of DOSE AREA PRODUCT by the corresponding increment of time. The unit of DOSE AREA PRODUCT RATE is $\text{Gy m}^2/\text{s}$

3.10

EFFECTIVE RANGE (of INDICATED VALUES)

range of INDICATED VALUES for which an instrument complies with a stated performance; the maximum (minimum) EFFECTIVE INDICATED VALUE is the highest (lowest) in this range

The concept of EFFECTIVE RANGE may, for example, also be applied to scale readings and to related quantities that are not directly indicated by the instrument, e.g. input current (IEC 60731)

NOTE The EFFECTIVE RANGE of INDICATED VALUES is referred to as EFFECTIVE RANGE in this standard.

3.11

EXPANDED UNCERTAINTY

quantity defining the interval about the result of a measurement within which the values that could reasonably be attributed to the measurand may be expected to lie with a higher degree of confidence (IEC 60731)

3.12

FILTRATION

modification of characteristics of ionizing radiation on passing through matter

NOTE FILTRATION includes:

- modification of the energy spectrum of ionizing radiation by preferential absorption of components;
- modification of the spatial distribution of radiation intensity over the cross section of a radiation beam, by differential ATTENUATION.

3.13

HALF-VALUE LAYER

thickness of a specified material which under NARROW BEAM CONDITIONS attenuates photon radiation according to its energy spectrum to an extent such that the AIR KERMA RATE is reduced to one half of the value that is measured without the material

3.14

INDICATED VALUE

value of a quantity derived from the scale reading of an instrument together with any scale factors indicated on the control panel of the instrument (IEC 60731)

3.15

INFLUENCE QUANTITY

any external quantity that may affect the performance of an instrument (e.g. ambient temperature, RADIATION QUALITY etc.) (IEC 60731)

3.16

INSTRUMENT PARAMETER

any internal property of an instrument that may affect the performance of this instrument (IEC 60731)

3.17

INTRINSIC ERROR

deviation of the MEASURED VALUE (i.e. the INDICATED VALUE, corrected to REFERENCE CONDITIONS) from the CONVENTIONAL TRUE VALUE under STANDARD TEST CONDITIONS (IEC 60731)

3.18

IONIZATION CHAMBER

detector consisting of a chamber filled with a suitable medium, usually gaseous, in which an electric field, insufficient to induce charge multiplication, is provided for the collection at the electrodes of charges associated with ions and the electrons produced in the SENSITIVE VOLUME of the detector by ionizing radiation

NOTE For use with DOSE AREA PRODUCT METERS, IONIZATION CHAMBERS are constructed in such a way as to allow the air inside the measuring volume to communicate freely with the atmosphere. Sealed chambers are not suitable for use with DOSE AREA PRODUCT METERS, because the necessary wall thickness of a sealed chamber may cause an unacceptable energy dependence of the RESPONSE and because the long term stability of sealed chambers is not guaranteed.

3.19

IRRADIATION TIME

duration of irradiation determined according to specific methods, usually the time during which the rate of a RADIATION quantity exceeds a specified level

3.20

LEAKAGE CURRENT

any current in the signal path arising in the detector and/or MEASURING ASSEMBLY which is not produced by ionization in the IONIZATION CHAMBER

3.21

LIMITS OF VARIATION

maximum VARIATION of a PERFORMANCE CHARACTERISTIC, y , permitted by this standard. If LIMITS OF VARIATION are stated as $\pm L$ %, the VARIATION, $\Delta y/y$, expressed as a percentage, shall remain in the range from $-L$ % to $+L$ % (IEC 60731)

3.22

MANUFACTURER

organization or individual who produces an equipment

3.23

MEASURED VALUE

value of a physical quantity derived by applying all relevant corrections to an INDICATED VALUE

3.24

MEASURING ASSEMBLY

device to convert the output from the IONIZATION CHAMBER into a form suitable for the display of the value(s) of DOSE AREA PRODUCT or DOSE AREA PRODUCT RATE

3.25

MEDICAL RADIOLOGICAL EXAMINATION

medical examination using effects of ionizing radiation

3.26

MINIMUM RATED RANGE

least range of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER within which the instrument shall operate within the specified LIMITS OF VARIATION in order to comply with this standard (IEC 60731)

3.27

PATIENT

living being (person or animal) undergoing medical investigation or treatment (IEC 60601-1)