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colour inside

Medical electrical equipment – Dose area product meters

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT – DOSE AREA PRODUCT METERS

FOREWORD

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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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)~~

3 Terms 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*;~~

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

~~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:~~

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC TR 60788:2004 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE 1 An index of defined terms is to be found at the end of the document.

NOTE 2 A searchable IEC Glossary can be found at std.iec.ch.

3.1
ACCOMPANYING DOCUMENT
document 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
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

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

Note 1 to entry: Unit: J kg^{-1}.

Note 2 to entry: The special name for the unit of AIR KERMA is gray (Gy) (ICRU ~~60~~ 85A).

3.3
AIR KERMA RATE
$\dot{K}$
quotient of dK by dt, where dK is the increment of AIR KERMA in the time interval dt, thus

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

Note 1 to entry: Unit: J kg^{-1} s^{-1}.

Note 2 to entry: ~~If~~ The special name ~~gray is used,~~ for the unit of AIR KERMA rate is gray per second (Gy s^{-1}) (ICRU ~~60~~ 85A).

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.~~

3.5
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

[SOURCE: IEC 60731:2011, 3.6]

3.6
DOSE AREA PRODUCT
$K \cdot A$
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

Note 1 to entry: The unit of DOSE AREA PRODUCT is Gym^2.

3.7
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

Note 1 to entry: A DOSE AREA PRODUCT METER contains the following components:

~~– IONIZATION CHAMBER~~
– RADIATION DETECTOR;
– MEASURING ASSEMBLY;
– STABILITY CHECK DEVICE.

3.8
DOSE AREA PRODUCT RATE
$\dot{K} \cdot A$
quotient of an increment of DOSE AREA PRODUCT by the corresponding increment of time

Note 1 to entry: The unit of DOSE AREA PRODUCT RATE is Gym^2/s.

3.9
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

Note 1 to entry: The concept of EFFECTIVE RANGE ~~may~~ can, 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)~~. Its limits are the maximum and MINIMUM RATED VALUES.

Note 2 to entry: The EFFECTIVE RANGE of INDICATED VALUES is referred to as EFFECTIVE RANGE in this document.

3.10
FIELD-CLASS DOSE AREA PRODUCT METER
DOSE AREA PRODUCT METER whose performance and stability are sufficient for it to be used to make routine measurements

Note 1 to entry: DOSE AREA PRODUCT METERS built in or permanently connected to the diagnostic X-ray unit are normally field-class instruments, but can also be reference-class instruments.

~~**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)~~

3.11
FILTRATION
modification of characteristics of ionizing RADIATION on passing through matter

Note 1 to entry: 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.

3.12
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

3.13
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

[SOURCE: IEC 60731:2011, 3.2]

3.14
INFLUENCE QUANTITY
any external quantity that may affect the performance of an instrument (e.g. ambient temperature, RADIATION QUALITY etc.)

[SOURCE: IEC 60731:2011, 3.7, modified – addition of the parenthesis]

3.15
INSTRUMENT PARAMETER
any internal property of an instrument that may affect the performance of this instrument

[SOURCE: IEC 60731:2011, 3.8]

~~**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)~~

3.16
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.~~

3.17
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~~

3.18
LIMITS OF VARIATION
maximum VARIATION of a PERFORMANCE CHARACTERISTIC, y, permitted by this document

Note 1 to entry: 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 $+L$ %.

[SOURCE: IEC 60731:2011, 3.13, modified – addition of " y, permitted by this document".]

3.19
LINEARITY
maximum VARIATION of the RESPONSE of an instrument within the EFFECTIVE RANGE of measurement quantity, permitted by this document

3.20
MANUFACTURER
organization or individual who produces an equipment

3.21
MEASURED VALUE
value of a physical quantity derived by applying all relevant corrections to an INDICATED VALUE

3.22
MEASURING ASSEMBLY
device to convert the output from the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR into a form suitable for the display of the value(s) of DOSE AREA PRODUCT or DOSE AREA PRODUCT RATE

3.23
MEDICAL RADIOLOGICAL EXAMINATION
medical examination using ~~effects of~~ ionizing RADIATION

3.24
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 document

[SOURCE: IEC 60731:2011, 3.15.1, modified – addition of "in order to comply with this document".]

3.25
PATIENT
living being (person or animal) undergoing medical investigation or treatment

[SOURCE: IEC 60601-1:2005, 3.76, modified – replacement of "a medical, surgical or dental procedure" by "medical investigation or treatment"]