# 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)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch


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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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# MEDICAL ELECTRICAL EQUIPMENT – DOSE AREA PRODUCT METERS

## FOREWORD

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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

- 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.

# MEDICAL ELECTRICAL EQUIPMENT – DOSE AREA PRODUCT METERS

## 1 Scope

This document specifies the performance and testing of DOSE AREA PRODUCT METERS 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 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

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

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

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

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

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

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

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

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

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

IEC 61187, *Electrical and electronic measuring equipment – Documentation*

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



## 3 Terms and definitions

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 85A).

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

$$\dot{K} = \frac{\mathrm{d}K}{\mathrm{d}t}$$

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

Note 2 to entry: The special name for the unit of AIR KERMA rate is gray per second (Gy s$^{-1}$) (ICRU 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**
**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 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:

– 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 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. 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**
**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]

**3.16**
**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

**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

**3.18**
**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, 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 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 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"]

**3.26**
**PERFORMANCE CHARACTERISTIC**
one of the quantities used to define the performance of an instrument (e.g. RESPONSE, RADIATION DETECTOR LEAKAGE CURRENT)

[SOURCE: IEC 60731:2011, 3.11, modified – modification of the example]

**3.27**
**QUALITY EQUIVALENT FILTRATION**
quantitative indication of the FILTRATION effected by one or several layer(s) of reference material(s) which, if substituted in a beam of specified RADIATION QUALITY under NARROW BEAM CONDITION for the material or an object under consideration, give(s) the same RADIATION QUALITY as for the material under consideration

**3.28**
**RADIATION DETECTOR**
equipment, generally sub-assembly, or substance which, in the presence of RADIATION, provides by either direct or indirect means a signal or other indication suitable for use in measuring one or more quantities of the incident RADIATION

**3.29**
**RADIATION DETECTOR LEAKAGE CURRENT**
any current in the signal path arising in the RADIATION DETECTOR system which is not produced by ionizing RADIATION in the measuring volume

**3.30**
**RADIATION QUALITY**
for a specific type of RADIATION, the description of any characteristic that depends on its energy spectrum

Note 1 to entry: For the purposes of this document, a practical approximation of RADIATION QUALITY is expressed as the quotient of the first HALF-VALUE LAYER and the second HALF-VALUE LAYER.

**3.31**
**RATED FIELD SIZE**
size of the USEFUL BEAM at the RADIATION DETECTOR within which the RADIATION DETECTOR performs to its specification

**3.32**
**RATED RANGE (of use)**
range of values of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER within which the instrument will operate within the LIMITS OF VARIATION



Note 1 to entry: Its limits are the maximum and MINIMUM RATED VALUES.



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

[SOURCE: IEC 60731:2011, 3.15, modified – Addition of the Note 2 to entry.]

**3.33**
**REFERENCE CONDITIONS**
conditions under which all INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS have their REFERENCE VALUES

[SOURCE: IEC 60731:2011, 3.9.1]

**3.34**
**REFERENCE-CLASS DOSE AREA PRODUCT METER**
DOSE AREA PRODUCT METER whose performance and stability are sufficient for it to be used to calibrate other DOSE AREA PRODUCT METERS or for higher-precision field use requirements

**3.35**
**REFERENCE VALUE**
particular value of an INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) chosen for the purpose of reference

Note 1 to entry: I.e. the value of an INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) at which the CORRECTION FACTOR for dependence on that INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) is unity.

[SOURCE: IEC 60731:2011, 3.9]

**3.36**
**RESPONSE**
quotient of the INDICATED VALUE divided by the CONVENTIONAL TRUE VALUE

[SOURCE: IEC 60731:2011, 3.11.1, modified – "ionization charge or current" was replaced by "indicated value".]

**3.37**
**RESPONSE TIME**
the time taken for a scale reading to reach and remain within a specified deviation from its final steady value, after a sudden change in the quantity being measured

[SOURCE: IEC 60731:2011, 3.11.4, modified – "scale" was added to the definition.]

**3.38**
**RESOLUTION OF THE DISPLAY**
smallest change of scale reading to which a numerical value can be assigned without further interpolation

Note 1 to entry: For an analogue display, the RESOLUTION is the smallest fraction of a scale interval that can be determined by an observer under specified conditions.

Note 2 to entry: For a digital display, the RESOLUTION is the smallest significant increment of the reading.

[SOURCE: IEC 60731:2011, 3.11.2, modified – Addition of new notes to entry.]

**3.39**
**STABILITY CHECK DEVICE**
device, either separate or integral part of the DOSE AREA PRODUCT METER, which enables the stability of the RESPONSE of the RADIATION DETECTOR and/or MEASURING ASSEMBLY to be checked



Note 1 to entry: The STABILITY CHECK DEVICE can be a purely electrical device.



**3.40**
**STABILIZATION TIME**
time taken for a stated PERFORMANCE CHARACTERISTIC to reach and remain within a specified deviation from its final steady value, after the DOSE AREA PRODUCT METER has been switched on and after the polarizing voltage, if needed, has been applied to the RADIATION DETECTOR

**3.41**
**STANDARD TEST CONDITIONS**
conditions under which all INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS have their STANDARD TEST VALUES

[SOURCE: IEC 60731:2011, 3.10.1]

**3.42**
**STANDARD TEST VALUES**
value, values or range of values of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER which are permitted when carrying out calibrations or tests on another INFLUENCE QUANTITY or INSTRUMENT PARAMETER

[SOURCE: IEC 60731:2011, 3.10]

**3.43**
**USEFUL BEAM**
all X-rays which emerge through a cone defined by the focus point and the specified aperture of its PROTECTIVE SHIELDING or of its BEAM-LIMITING DEVICE