

Medical electrical equipment — Dosimeters with ionization chambers and/or semi-conductor detectors as used in X-ray diagnosis imaging

The European Standard EN 61674:1997, with the incorporation of amendment A1:2002, has the status of a British Standard

ICS 11.040.50

National foreword

This British Standard is the English language version of EN 61674:1997, including amendment A1:2002. It is identical with IEC 61674:1997, including amendment 1:2002.

The UK participation in its preparation was entrusted to Technical Committee CH/83, Dosimeters (Medical), which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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English version

Medical electrical equipment — Dosimeters with ionization chambers and/or semi-conductor detectors as used in x-ray diagnosis imaging

(includes amendment A1:2002)

(IEC 61674:1997 + A1:2002)

Appareils électromédicaux —
Dosimètres à chambres d'ionisation et/ou à
détecteurs à semi-conducteurs utilisés en
imagerie de diagnostic à rayonnement X
(inclut l'amendement A1:2002)
(CEI 61674:1997 + A1:2002)

Medizinische elektrische Geräte —
Dosimeter mit Ionisationskammern und/oder
Halbleiterdetektoren für den Einsatz an
diagnostischen Röntgeneinrichtungen
(enthält Änderung A1:2002)
(IEC 61674:1997 + A1:2002)

This European Standard was approved by CENELEC on 1997-10-01; amendment A1 was approved by CENELEC on 2002-09-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

The European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B-1050 Brussels

Foreword

The text of document 62C/195/FDIS, future edition 1 of IEC 61674, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61674 on 1997-10-01.

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Annexes designated “normative” are part of the body of the standard.

Annexes designated “informative” are given for information only.

In this standard, Annex ZA is normative and Annex A and Annex B are informative. Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61674:1997 was approved by CENELEC as a European Standard without any modification.

In the official version, for Annex A, Bibliography, the following notes have to be added for the standards indicated:

IEC 60580	NOTE Harmonized as HD 379 S1:1979 (not modified).
IEC 60601-1	NOTE Harmonized as EN 60601-1:1990 (not modified).
IEC 60601-1-2	NOTE Harmonized as EN 60601-1-2:1993 (not modified).
IEC 60601-2-9	NOTE Harmonized as EN 60601-2-9:1996 (not modified).
IEC 60731	NOTE Harmonized as EN 60731:1997 (not modified).
IEC 61010-1	NOTE Harmonized, together with its amendment 1:1992, as EN 61010-1:1993 (modified).

Foreword to amendment A1

The text of document 62C/333/FDIS, future amendment 1 to IEC 61674, prepared by IEC SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as amendment A1 to EN 61674:1997 on 2002-09-01.

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Endorsement notice

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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 PATIENT dose will be minimized when the X-ray producing equipment is correctly adjusted for image quality and radiation output. These adjustments require that the routine measurement of AIR KERMA, AIR KERMA LENGTH and/or AIR KERMA RATE be made accurately. The equipment covered by this standard plays an essential part in achieving the required accuracy. The DOSIMETERS used for adjustment and control measurements must be of satisfactory quality and must therefore fulfil the special requirements laid down in this standard.

1 Scope and object

1.1 Scope

This International Standard specifies the performance and some related constructional requirements of DIAGNOSTIC DOSIMETERS, as defined in 3.1, intended for the measurement of AIR KERMA, AIR KERMA LENGTH or AIR KERMA RATE, in photon radiation fields used in RADIOGRAPHY, including MAMMOGRAPHY, RADIOSCOPY and COMPUTED TOMOGRAPHY (CT), for X-rays with generating potentials not greater than 150 kV.

This International Standard is applicable to the performance of DOSIMETERS with IONIZATION CHAMBERS and/or SEMI-CONDUCTOR DETECTORS as used in X-ray diagnostic imaging.

1.2 Object

The object of this standard is:

- 1) to establish requirements for a satisfactory level of performance for DIAGNOSTIC DOSIMETERS; and
- 2) to standardize the methods for the determination of compliance with this level of performance.

This standard is not concerned with the safety aspects of DOSIMETERS. The DIAGNOSTIC DOSIMETERS covered by this standard are not intended for use in physical contact with the PATIENT and therefore, the requirements for electrical safety applying to them are contained in IEC 61010-1.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and 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. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60417:1973, *Graphical symbols for use on equipment — Index, survey and compilation of the single sheets.*

IEC 60788:1984, *Medical radiology — Terminology.*

IEC 61000-4-1:1992, *Electromagnetic compatibility (EMC) — Part 4: Testing and measurement techniques — Section 1: Overview of immunity tests — Basic EMC publication.*

IEC 61000-4-2:1995, *Electromagnetic compatibility (EMC) — Part 4: Testing and measurement techniques — Section 2: Electrostatic discharge immunity test — Basic EMC publication.*

IEC 61000-4-3:1995, *Electromagnetic compatibility (EMC) — Part 4: Testing and measurement techniques — Section 3: Radiated, radio-frequency, electromagnetic field immunity test.*

IEC 61000-4-4:1995, *Electromagnetic compatibility (EMC) — Part 4: Testing and measurement techniques — Section 4: Electrical fast transient/burst immunity test — Basic EMC publication.*

IEC 61000-4-5:1995, *Electromagnetic compatibility (EMC) — Part 4: Testing and measurement techniques — Section 5: Surge immunity tests.*

IEC 61000-4-6:1996, *Electromagnetic compatibility (EMC) — Part 4: Testing and measurement techniques — Section 6: Immunity to conducted disturbances induced by radio frequency fields.*

IEC 61000-4-11:1994, *Electromagnetic compatibility (EMC) — Part 4: Testing and measurement techniques — Section 11: Voltage dips, short interruptions and voltage variations immunity test — Basic EMC publication*.

IEC 61187:1993, *Electrical and electronic measuring equipment — Documentation*.

IEC 61267:1994, *Medical diagnostic X-ray equipment — Radiation conditions for use in the determination of characteristics*.

3 Terminology and definitions

In this 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 60788:1984, *Medical radiology — Terminology*;
- ISO:1993, *International vocabulary of basic and general terms in metrology*, 2nd ed.;

but some definitions have been given a more restricted meaning. Such special definitions shall be regarded as applying only to this standard.

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

For the purpose of this International Standard the following definitions apply.

3.1

(DIAGNOSTIC) DOSIMETER

equipment which uses IONIZATION CHAMBERS and/or SEMI-CONDUCTOR DETECTORS for the measurement of AIR KERMA, AIR KERMA LENGTH and/or AIR KERMA RATE in the beam of an X-ray machine used for diagnostic medical radiological examinations

a DIAGNOSTIC DOSIMETER contains the following components:

- one or more DETECTOR ASSEMBLIES which may or may not be an integral part of the MEASURING ASSEMBLY;
- a MEASURING ASSEMBLY;
- one or more STABILITY CHECK DEVICES (optional).

3.1.1

DETECTOR ASSEMBLY

RADIATION DETECTOR and all other parts to which the RADIATION DETECTOR is permanently attached, except the MEASURING ASSEMBLY

NOTE The DETECTOR ASSEMBLY normally includes:

- the RADIATION DETECTOR and the stem (or body) on which the RADIATION DETECTOR is permanently mounted (or embedded);
- the electrical fitting and any permanently attached cable or pre-amplifier.

3.1.1.1**RADIATION DETECTOR**

element which transduces AIR KERMA, AIR KERMA LENGTH or AIR KERMA RATE into a measurable electrical signal. It may be either an IONIZATION CHAMBER or a SEMI-CONDUCTOR DETECTOR.

1) IONIZATION CHAMBER: Ionization detector consisting of a chamber filled with air, in which an electric field insufficient to induce gas multiplication is provided for the collection, at the electrodes, of charges associated with the ions and electrons produced in the sensitive volume of the detector by ionizing radiation. The chamber is constructed in such a way as to allow the air inside the measuring volume to communicate freely with the atmosphere so that corrections to the RESPONSE for changes in air density need to be made.

2) VENTED CHAMBER: An IONIZATION CHAMBER constructed in such a way as to allow the air inside the measuring volume to communicate freely with the atmosphere so that corrections to the RESPONSE for changes in air density need to be made.

NOTE Sealed chambers are not suitable, 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) SEMI-CONDUCTOR DETECTOR: Either a) and/or b):

a) semi-conductor device operating in the shorted junction mode that utilizes the production and motion of excess free charge carriers in the semi-conductor for the detection and measurement of incident ionizing radiation;

b) scintillator material optically coupled to a semi-conductor photodiode operating in the shorted junction mode, in which assembly incident ionizing radiation is first converted to light and then to an electrical signal.

3.1.2**MEASURING ASSEMBLY**

device to convert the output from the DETECTOR ASSEMBLY into a form suitable for the display of the value(s) of AIR KERMA, AIR KERMA LENGTH or AIR KERMA RATE

3.1.3**STABILITY CHECK DEVICE**

device, either separate or integral part of the DIAGNOSTIC DOSIMETER, which enables the stability of the RESPONSE of the RADIATION DETECTOR and/or MEASURING ASSEMBLY to be checked

NOTE The STABILITY CHECK DEVICE may be a purely electrical device, or a radiation source, or it may include both.

3.1.4**CT DOSIMETER**

DIAGNOSTIC DOSIMETER which uses long narrow IONIZATION CHAMBERS and/or SEMI-CONDUCTOR DETECTORS for the measurement of AIR KERMA integrated along the length of the DETECTOR when the DETECTOR is exposed to a cross-sectional X-ray scan of a computed tomographic machine

a CT DOSIMETER contains the following components:

- one or more DETECTOR ASSEMBLIES;
- a MEASURING ASSEMBLY.

3.1.5**CT DETECTOR**

RADIATION DETECTOR which is used for CT dosimetry

3.2**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

3.3**TRUE VALUE**

value of the physical quantity to be measured by an instrument

3.4

CONVENTIONAL TRUE VALUE

the 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

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

3.4.1

STANDARD

instrument which defines, represents physically, maintains or reproduces the unit of measurement of a quantity (or a multiple or sub-multiple of that unit) in order to transfer it to other instruments by comparison

3.5

MEASURED VALUE

best estimate of the TRUE VALUE of a quantity, derived from the INDICATED VALUE of an instrument together with the application of all relevant CORRECTION FACTORS

3.5.1

ERROR OF MEASUREMENT

difference between the MEASURED VALUE of a quantity and the TRUE VALUE of that quantity

3.5.2

OVERALL UNCERTAINTY

uncertainty associated with the MEASURED VALUE, i.e. representing the bounds within which the ERROR OF MEASUREMENT is estimated to lie (see also 4.5)

3.5.3

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

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

3.7

INFLUENCE QUANTITY

any external quantity that may affect the performance of an instrument (e.g. ambient temperature, radiation quality, etc.)

3.8

INSTRUMENT PARAMETER

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

3.9

REFERENCE VALUE

particular value of an INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) chosen for the purpose of reference, 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

3.9.1

REFERENCE CONDITIONS

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

3.10**STANDARD TEST VALUES**

value(s), 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

3.10.1**STANDARD TEST CONDITIONS**

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

3.11**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

3.11.1**RELATIVE INTRINSIC ERROR**

ratio of the INTRINSIC ERROR to the CONVENTIONAL TRUE VALUE

3.12**PERFORMANCE CHARACTERISTIC**

one of the quantities used to define the performance of an instrument (e.g. RESPONSE, LEAKAGE CURRENT)

3.12.1**RESPONSE**

quotient of the INDICATED VALUE by the CONVENTIONAL TRUE VALUE

3.12.2**RESOLUTION OF THE DISPLAY**

smallest change of scale reading to which a numerical value can be assigned without further interpolation:

- for an analogue display, the RESOLUTION is the smallest fraction of a scale interval that can be determined by an observer under specified conditions;
- for a digital display, the RESOLUTION is the smallest significant increment of the reading.

3.12.3**EQUILIBRATION TIME**

time taken for a scale reading to reach and remain within a specified deviation from its final steady value, after a sudden change in an INFLUENCE QUANTITY has been applied to the instrument

3.12.4**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

3.12.5**STABILIZATION TIME**

time taken for a stated PERFORMANCE CHARACTERISTIC to reach and remain within a specified deviation from its final steady value, after the DOSIMETER has been switched on (and, if the RADIATION DETECTOR is an IONIZATION CHAMBER, after the polarizing voltage has been applied)

3.12.6**LEAKAGE CURRENT**

any current in the signal path arising in the DETECTOR and/or MEASURING ASSEMBLY which is not produced by ionization in the RADIATION DETECTOR

3.13**VARIATION**

relative difference, $\Delta y/y$, between the values of a PERFORMANCE CHARACTERISTIC, y , when one INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) successively assumes two specified values, the other INFLUENCE QUANTITIES (and INSTRUMENT PARAMETERS) being kept constant at the STANDARD TEST VALUES (unless other values are specified)