SLOVENSKI STANDARD
SIST EN 60731:1998

01-september-1998

Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy (IEC 60731:1997)

Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy

Medizinische elektrische Geräte - Dosimeter mit Ionisationskammern zur Anwendung in der Strahlentherapie

Appareils électromédicaux - Dosimètres à chambre d'ionisation utilisés en radiothérapie

Ta slovenski standard je istoveten z: **EN 60731:1997**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
17.240	Merjenje sevanja	Radiation measurements

SIST EN 60731:1998 **en**

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English version

Medical electrical equipment
Dosimeters with ionization chambers as used in radiotherapy
(IEC 60731:1997)

Appareils électromédicaux
Dosimètres à chambre d'ionisation
utilisés en radiothérapie
(CEI 60731:1997)

Elektromedizinische Geräte
Dosimeter mit Ionisationskammern zur
Verwendung in der Strahlentherapie
(IEC 60731:1997)

This European Standard was approved by CENELEC on 1997-10-01. 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.

This 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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

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Foreword

The text of document 62C/170/FDIS, future edition 2 of IEC 60731, 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 60731 on 1997-10-01.

This European Standard supersedes HD 534 S1:1989.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1998-07-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1998-07-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annexes A and ZA are normative and annexes B and C are informative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60731:1997 was approved by CENELEC as a European Standard without any modification.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE: When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60051	series	Direct acting indicating analogue electrical-measuring instruments and their accessories	EN 60051	series
IEC 60417	1973	Graphical symbols for use on equipment - Index, survey and compilation of the single sheets	HD 243 S12[1)]	1995
IEC 60601-1	1988	Medical electrical equipment Part 1: General requirements for safety NOTE: Amendments A11 and A12 are superseded by EN 60601-1/A2:1995.	EN 60601-1 + corr. July + A13	1990 1994 1996
IEC 60601-2-9	1987	Part 2: Particular requirements for the safety of dosimeters used in radiotherapy with electrically-connected radiation detectors	HD 395.2.9 S1[2)]	1989
IEC 60788	1984	Medical radiology - Terminology	HD 501 S1	1988
IEC 61000-4-1	1992	Electromagnetic compatibility (EMC) Part 4: Testing and measurement techniques Section 1: Overview of immunity tests Basic EMC publication	EN 61000-4-1	1994
IEC 61000-4-2	1995	Section 2: Electrostatic discharge immunity test - Basic EMC publication	EN 61000-4-2	1995
IEC 61000-4-3 (mod)	1995	Section 3: Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	1996

1) HD 243 S12 includes supplements A:1974 to M:1994 to IEC 60417.

2) HD 395.2.9 S1 is superseded by EN 60601-2-9:1996 and its corrigendum December 1996, which are based on IEC 60601-2-9:1996.

Publication	Year	Title	EN/HD	Year
IEC 61000-4-4	1995	Section 4: Electrical fast transient/burst immunity test - Basic EMC publication	EN 61000-4-4	1995
IEC 61000-4-5	1995	Section 5: Surge immunity test	EN 61000-4-5	1995
IEC 61000-4-6	1996	Section 6: Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6	1996
IEC 61000-4-11	1994	Section 11: Voltage dips, short interruptions and voltage variations immunity tests	EN 61000-4-11	1994
IEC 61010-1 (mod)	1990	Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements	EN 61010-1[3)]	1993
IEC 61187 (mod)	1993	Electrical and electronic measuring equipment - Documentation	EN 61187 + corr. March	1994 1995
ISO	1993	International Vocabulary of basic and general terms in metrology	-	-
ISO 3534-1	1993	Statistics - Vocabulary and symbols Part 1: Probability and general statistical terms	-	-
ICRU	1980	Radiation quantities and units		

3) EN 61010-1:1993 includes A1:1992 to IEC 61010-1.

NORME INTERNATIONALE

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Deuxième édition
Second edition
1997-07

Appareils électromédicaux –

Dosimètres à chambres d'ionisation utilisés en radiothérapie

Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

DOSIMETERS WITH IONIZATION CHAMBERS AS USED IN RADIOTHERAPY

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 60731 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 second edition cancels and replaces the first edition published in 1982 and its amendment 1 (1987) and constitutes a technical revision.

The text of this standard is based on the following documents:

FDIS	Report on voting
62C/170/FDIS	62C/197/RVD

Full information on the voting for the approval of this standard can be found in the report of voting indicated in the above table.

Annex A forms an integral part of this standard.

Annexes B and C are for information only.

INTRODUCTION

This International Standard is applicable to the performance of DOSIMETERS with IONIZATION CHAMBERS as used in radiotherapy.

The effectiveness of treatment of PATIENTS receiving radiotherapy depends on the accuracy of the dose of radiation received; an excessive dose can lead to excessive tissue damage, while an insufficient dose will not provide the therapeutic benefit sought. The equipment covered by this standard plays an essential part in achieving the required accuracy.

This standard is not concerned with the safety aspects of DOSIMETERS. The relevant IEC standards covering safety depend upon the way in which the DOSIMETER is used:

– if it is used in physical contact with a PATIENT the particular requirements for safety applying to DOSIMETERS with IONIZATION CHAMBERS as used in radiotherapy are contained in IEC 60601-2-9. These requirements supplement the General requirements for safety of MEDICAL ELECTRICAL EQUIPMENT given in IEC 60601-1 (1988), amendment 1 (1991) and amendment 2 (1995);

– if it is not used in physical contact with a PATIENT, then the safety requirements for DOSIMETERS with IONIZATION CHAMBERS as used in radiotherapy are contained in IEC 61010-1 (1990).

DOSIMETERS which comply with this standard should nevertheless be used in accordance with the relevant national or international dosimetry protocol (code of practice). In particular, measurements should be made to determine the ion collection efficiency and polarity effect of the CHAMBER under the exact conditions of use.

MEDICAL ELECTRICAL EQUIPMENT –

DOSIMETERS WITH IONIZATION CHAMBERS AS USED IN RADIOTHERAPY

1 Scope and object

1.1 *Scope*

1.1.1 This International Standard specifies the performance requirements of RADIOTHERAPY DOSIMETERS, as defined in 3.1, intended for the measurement of ABSORBED DOSE TO WATER or AIR KERMA (and their RATES) in photon or electron radiation fields as used in radiotherapy.

NOTE – Throughout this standard:

– if no material is specified, the term "ABSORBED DOSE" or "DOSE" means "ABSORBED DOSE TO WATER (in water)" and the term "KERMA" means "AIR KERMA (in air)";

– when the quantity "AIR KERMA (in air)" in units "Gy" is used, the quantity "EXPOSURE" in units "C/kg" is also allowable.

1.1.2 The dose-monitoring systems incorporated in radiotherapy treatment machines are not covered by this standard, neither are the re-entrant ion chambers used for brachytherapy source calibration.

1.1.3 This standard is applicable to the following types of DOSIMETER:

a) FIELD-CLASS DOSIMETERS normally used for

1) the measurement of KERMA or DOSE in a radiation beam, either in air or in a PHANTOM;

2) *in vivo* skin surface or intracavitary measurements of DOSE on PATIENTS.

b) REFERENCE-CLASS DOSIMETERS normally used for the calibration of FIELD-CLASS DOSIMETERS.

NOTE – REFERENCE-CLASS DOSIMETERS may be used as FIELD-CLASS DOSIMETERS.

1.2 *Object*

1.2.1 The object of this standard is:

a) to establish requirements for a satisfactory level of performance for RADIOTHERAPY DOSIMETERS;

b) to standardize methods for the determination of compliance with this level of performance.

1.2.2 Two levels of performance are specified:

– a lower level of performance applying to FIELD-CLASS DOSIMETERS;

– a higher level of performance applying to REFERENCE-CLASS DOSIMETERS.

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 60051, *Direct acting indicating analogue electrical measuring instruments and their accessories*

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

IEC 60601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*

IEC 60601-2-9: 1987, *Medical electrical equipment – Part 2: Particular requirements for the safety, of dosimeters used in radiotherapy with electrically-connected radiation detectors*

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 requirements – Basic EMC Publication*

IEC 61000-4-3: 1995, *Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 3: Radiated electromagnetic field requirements*

IEC 61000-4-4: 1995, *Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 4: Electrical fast transient /burst requirements – Basic EMC Publication*

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

IEC 61000-4-6: 1996, *Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 6: Conducted disturbances induced by radio frequency fields above 9 kHz*

IEC 61000-4-11: 1994, *Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 11: Voltage dips, short interruptions and voltage variation immunity tests*

IEC 61010-1: 1990, *Safety requirements for electrical equipment for measurement control, and laboratory use – Part 1: General requirements*

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

ISO, 1993, *International Vocabulary of basic and general terms in metrology*

ISO 3534-1: 1993, *Statistics – Vocabulary and symbols – Part 1: Probability and general statistical terms*

ICRU 33: 1980, *Radiation Quantities and Units*