SLOVENSKI STANDARD
SIST EN 61674:1998

01-september-1998

Medical electrical equipment - Dosimeters with ionization chambers and/or semi-conductor detectors as used in x-ray diagnosis imaging (IEC 61674:1997)

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

Medizinische elektrische Geräte - Dosimeter mit Ionisationskammern und/oder Halbleiterdetektoren für den Einsatz an diagnostischen Röntgeneinrichtungen

Appareils électromédicaux - Dosimètres à chambres d'ionisation et/ou à détecteurs à semi-conducteurs utilisés en imagerie de diagnostic à rayonnement X

Ta slovenski standard je istoveten z: **EN 61674:1997**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
17.240	Merjenje sevanja	Radiation measurements

SIST EN 61674:1998 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61674

November 1997

ICS 11.040.50; 17.240

English version

Medical electrical equipment - Dosimeters with ionization chambers and/or semi-conductor detectors as used in x-ray diagnosis imaging
(IEC 61674:1997)

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

Medizinische elektrische Geräte
Dosimeter mit Ionisationskammern
und/oder Halbleiterdetektoren für
den Einsatz an diagnostischen
Röntgeneinrichtungen
(IEC 61674:1997)

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, Czech Republic, 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

Ref. No. EN 61674:1997 E

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.

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, annex ZA is normative and annexes A and 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).

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 60417	1973	Graphical symbols for use on equipment Index, survey and compilation of the single sheets	HD 243 S12[1)]	1995
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
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 - Basic EMC publication	EN 61000-4-11	1994
IEC 61187 (mod)	1993	Electrical and electronic measuring equipment - Documentation	EN 61187 + corr. March	1994 1995

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

Publication	Year	Title	EN/HD	Year
IEC 61267	1994	Medical diagnostic X-ray equipment Radiation conditions for use in the determination of characteristics	EN 61267	1994

NORME INTERNATIONALE

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Appareils électromédicaux –

Dosimètres à chambres d'ionisation et/ou à détecteurs à semi-conducteurs utilisés en imagerie de diagnostic à rayonnement X

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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 61674 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice. The text of this standard is based on the following documents:

FDIS	Report on voting
62C/195/FDIS	62C/207/RVD

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

Annexes A and B are for information only.

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.

MEDICAL ELECTRICAL EQUIPMENT –

DOSIMETERS WITH IONIZATION CHAMBERS AND/OR SEMI-CONDUCTOR DETECTORS AS USED IN X-RAY DIAGNOSTIC IMAGING

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).