

Elektrilised meditsiiniseadmed. Doospindalamõõtur

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

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EUROPEAN STANDARD

EN 60580

NORME EUROPÉENNE

EUROPÄISCHE NORM

May 2000

ICS 11.040.50

Supersedes HD 379 S1:1979

English version

**Medical electrical equipment
Dose area product meters
(IEC 60580:2000)**

Appareils électromédicaux
Radiamètres de produit exposition-surface
(CEI 60580:2000)

Medizinische elektrische Geräte
Dosisflächenprodukt-Messgeräte
(IEC 60580:2000)

This European Standard was approved by CENELEC on 2000-02-01. 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

Foreword

The text of document 62C/272/FDIS, future edition 1 of IEC 60580, prepared by IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60580 on 2000-02-01.

This European Standard supersedes HD 379 S1:1979.

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) 2000-11-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2003-02-01

Annexes designated "normative" are part of the body of the standard.
In this standard, annex ZA is normative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60580:2000 was approved by CENELEC as a European Standard without any modification.

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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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60417	Series	Graphical symbols for use on equipment	EN 60417	Series
IEC 60601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July + A13	1990 1994 1996
NOTE: Amendments A11 and A12 are superseded by EN 60601-1/A2:1995.				
IEC 60601-1-1	1992	Medical electrical equipment Part 1: General requirements for safety 1. Collateral standard: Safety requirements for medical electrical systems	EN 60601-1-1	1993
IEC 60601-1-2	1993	2. Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. December	1993 1997
IEC 60731	1997	Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy	EN 60731	1997
IEC 60788	1984	Medical radiology - Terminology	HD 501 S1	1988
IEC 60950 (mod) + corr. February 2000	1999	Safety of information technology equipment	EN 60950	2000
IEC 61000-4-2	1995	Electromagnetic compatibility (EMC) Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	EN 61000-4-2	1995
IEC 61000-4-3 (mod)	1995	Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	1996
IEC 61000-4-4	1995	Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test	EN 61000-4-4	1995

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 61000-4-5	1995	Part 4-5: Testing and measurement techniques - Surge immunity test	EN 61000-4-5	1995
IEC 61000-4-6	1996	Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6	1996
IEC 61000-4-11	1994	Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests	EN 61000-4-11	1994
IEC 61187 (mod)	1993	Electrical and electronic measuring equipment - Documentation	EN 61187 + corr. March	1994 1995
ICRU 60	1998	International Commission on Radiation Units and Measurements, Fundamental Quantities and Units for Ionizing Radiation, Report 60	-	-
ISO	1993	International Vocabulary of basic and general terms in metrology	-	-
ISO Guide	1993	Guide to the expression of uncertainty in measurement	-	-

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**MEDICAL ELECTRICAL EQUIPMENT –
DOSE AREA PRODUCT METERS**

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 60580 has been prepared by sub-committee 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 1977, and constitutes a technical revision.

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

FDIS	Report on voting
62C/272/FDIS	62C/275/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.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

A bilingual version of this publication may be issued at a later date.

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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 publication will remain unchanged until 2004. At this date, the publication 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. 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 International Standard 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.

The object of this International Standard 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.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, 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. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60417 (all parts), *Graphical symbols for use on equipment*

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

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 safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60731:1997, *Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy*

IEC 60788:1984, *Medical radiology – Terminology*

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⁾

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

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*

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 Terminology 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*; 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:

3.1

ACCOMPANYING DOCUMENTS

documents provided with an installation, equipment, associated equipment or accessory, containing important information for the assembler, installer and user, particularly regarding safety