SLOVENSKI STANDARD
SIST EN 60580:2002

01-februar-2002

Nadomešča:
SIST HD 379 S1:1998

Medicinska električna oprema - Merilniki produkta površina-doza (IEC 60580:2000)

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

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

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

Ta slovenski standard je istoveten z: EN 60580:2000

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
17.240	Merjenje sevanja	Radiation measurements

SIST EN 60580:2002 **en**

EUROPEAN STANDARD **EN 60580**

NORME EUROPÉENNE

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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

Ref. No. EN 60580:2000 E

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.

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	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	1999 2000	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

Publication	Year	Title	EN/HD	Year
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	-	-

INTERNATIONAL STANDARD

IEC 60580

Second edition
2000-01

Medical electrical equipment –

Dose area product meters

Appareils électromédicaux –

Radiamètres de produit exposition-surface

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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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.
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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.

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.