SLOVENSKI STANDARD
SIST HD 583 S1:1998

01-oktober-1998

Medical electrical equipment - Medical electron accelerators - Functional performance characteristics (IEC 60976:1989)

Medical electrical equipment - Medical electron accelerators - Functional performance characteristics

Medizinische elektrische Geräte - Medizinische Elektronenbeschleuniger - Apparative Qualitätsmerkmale

Appareils électromédicaux - Accélérateurs médicaux d'électrons - Caractéristiques fonctionnelles

Ta slovenski standard je istoveten z: **HD 583 S1:1991**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
11.040.60	Terapevtska oprema	Therapy equipment

SIST HD 583 S1:1998 **en**

HARMONIZATION DOCUMENT

DOCUMENT D'HARMONISATION

HARMONISIERUNGSDOKUMENT

HD 583 S1

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Descriptors: Medical electrical equipment, electron accelerators, X-ray and electronic therapy, functional characteristics, tests, test conditions

ENGLISH VERSION

MEDICAL ELECTRICAL EQUIPMENT
MEDICAL ELECTRON ACCELERATORS
FUNCTIONAL PERFORMANCE CHARACTERISTICS
(IEC 976:1989)

Appareils électromédicaux
Accélérateurs médicaux d'électrons
Caractéristiques fonctionnelles
(CEI 976:1989)

Medizinische elektrische Geräte
Medizinische Elektronenbeschleuniger-Anlagen
Apparative Qualitätsmerkmale
(IEC 976:1989)

This Harmonization Document was approved by CENELEC on 1991-03-15. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for implementation of this Harmonization Document on a national level.

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

This Harmonization Document exists in three official versions (English, French, German).

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

Ref. No. HD 583 S1:1991 E
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FOREWORD

The CENELEC questionnaire procedure, performed for finding out whether or not the International Standard IEC 976:1989 could be accepted without textual changes, has shown that no CENELEC common modifications were necessary for the acceptance as Harmonization Document.

The reference document was submitted to the CENELEC members for formal vote and was approved by CENELEC as HD 583 S1 on 15 March 1991.

The following dates were fixed:

- latest date of announcement of the HD at national level	(doa)	1991-09-01
- latest date of publication of a harmonized national standard	(dop)	1992-03-01
- latest date of withdrawal of conflicting national standards	(dow)	1992-03-01

For products which have complied with the relevant national standard before 1992-03-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 1997-03-01.

Annexes designated "normative" are part of the body of the standard. In this standard, annex ZA is normative.

ENDORSEMENT NOTICE

The text of the International Standard IEC 976:1989 was approved by CENELEC as a Harmonization Document without any modification.

ANNEX ZA (normative)

OTHER INTERNATIONAL PUBLICATIONS QUOTED IN THIS STANDARD WITH THE REFERENCES OF THE RELEVANT EUROPEAN PUBLICATIONS

IEC Publication	Date	Title	EN/HD	Date
601-1*	1977	Safety of electrical medical equipment Part 1: General requirements	HD 395.1 S1	1979
601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1	1990
601-2-1	1981	Safety of medical electrical equipment Part 2: Particular requirements for medical electron accelerators in the range 1 MeV to 50 MeV Section One: General Section Two: Radiation safety for equipment Amendment No.1 (1984): Section Three	-	-
788	1984	Medical radiology - Terminology	HD 501 S1	1988
977	1989	Medical electrical equipment Medical electron accelerators in the range 1 MeV to 50 MeV - Guidelines for functional performance characteristics	-	-

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* Superseded by the second edition 1988, remained valid until 1990-12-31.

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
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Première édition
First edition
1989-10

Appareils électromédicaux

Accélérateurs médicaux d'électrons –
Caractéristiques fonctionnelles

Medical electrical equipment

Medical electron accelerators –
Functional performance characteristics

Numéro de référence
Reference number
CEI/IEC 976: 1989

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT
Medical electron accelerators — Functional performance characteristics

FOREWORD

1) The formal decisions or agreements of the IEC on technical matters, prepared by Technical Committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

2) They have the form of recommendations for international use and they are accepted by the National Committees in that sense.

3) In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules in so far as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.

PREFACE

This standard has been prepared by Sub-Committee 62C: High-Energy Radiation Equipment and Equipment for Nuclear Medicine, of IEC Technical Committee No. 62: Electrical Equipment in Medical Practice.

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

Six Months' Rule	Report on Voting
62C(CO)35	62C(CO)45

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

The following IEC publications are quoted in this standard:

Publications Nos. 601-1 (1977): Safety of electrical medical equipment. Part 1: General requirements.
601-1 (1988): Medical electrical equipment. Part 1: General requirements for safety.
601-2-1 (1981): Safety of medical electrical equipment. Part 2: Particular requirements for medical electron accelerators in the range 1 MeV to 50 MeV. Section One: General. Section Two: Radiation safety for equipment.
Amendment No. 1 (1984): Section Three.
788 (1984): Medical radiology — Terminology.
977 (1989): Medical electrical equipment. Medical electron accelerators in the range 1 MeV to 50 MeV — Guidelines for functional performance characteristics.

MEDICAL ELECTRICAL EQUIPMENT
Medical electron accelerators — Functional performance characteristics

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INTRODUCTION

Standards containing safety requirements for MEDICAL ELECTRON ACCELERATORS have been published by the IEC, details of which will be found in the Preface.

The present standard specifies methods of test and methods of disclosure of functional performance of ELECTRON ACCELERATORS intended for RADIOTHERAPY. It permits a direct comparison between the performance data of equipment of different manufacture.

Since this standard does not contain safety requirements it has not been numbered in the IEC 601 publication series. It describes aspects of functional performance of ELECTRON ACCELERATORS and the way in which they should be presented. It also includes test methods and conditions suitable for type tests. These test methods are suggested test methods and alternative methods may be equally appropriate, but the specified functional performance characteristics of the MEDICAL ELECTRON ACCELERATORS shall be related to these test methods and conditions. Tests specified in this standard are not necessarily appropriate for ensuring that any individual ELECTRON ACCELERATOR conforms with the declared functional performance during the course of its working lifetime. Guidance on the values which may be expected are given in the Report, IEC Publication 977.

1 Scope and object

1.1 *Scope*

1.1.1 This standard applies to MEDICAL ELECTRON ACCELERATORS when used, for therapy purposes, in human medical practice.

1.1.2 This standard applies to ELECTRON ACCELERATORS which deliver a RADIATION BEAM of either X-RADIATION or ELECTRON RADIATION with NOMINAL ENERGIES in the range 1 MeV to 50 MeV at maximum ABSORBED DOSE RATES between 0,001 Gy s^{-1} and 1 Gy s^{-1} at 1 m from the RADIATION SOURCE and at NORMAL TREATMENT DISTANCES between 50 cm and 200 cm from the RADIATION SOURCE.

1.1.3 The present standard describes a set of measurements requiring two to three months' work to complete. It specifies test procedures to be performed by the manufacturer at the design and construction stage of a MEDICAL ELECTRON ACCELERATOR but does not specify acceptance tests to be performed after installation at the purchaser's site. The accompanying report, IEC Publication 977, however, does suggest that many of the test procedures are appropriate for acceptance tests.

1.1.4 The measurement conditions described in the present standard differ from those currently in use. This applies particularly to the PHANTOM position for measurements and the measurement of distances from the ISOCENTRE. These new conditions should be substituted for and not be added to present methods.

1.2 *Object*

This standard specifies test procedures for the determination and disclosure of functional performance characteristics, knowledge of which is deemed necessary for proper application

and use of an ELECTRON ACCELERATOR and which are to be declared in the ACCOMPANYING DOCUMENTS together with the greatest deviation or variation to be expected under specific conditions in NORMAL USE. A format for presentation of functional performance values is given in Appendix B.

It is recognized that inaccuracies in the test methods must be allowed for when assessing performance. However, it is not felt to be advisable to combine the errors into an overall performance tolerance but to keep them separate in the expectation that more accurate test methods will be evolved.

It is not intended that this standard should in any way inhibit the future development of new designs of equipment which may have operating modes and parameters different from those described herein, provided that such equipment achieves equivalent levels of performance for the treatment of PATIENTS.

Except where otherwise stated this standard assumes that the ELECTRON ACCELERATORS have an ISOCENTRIC GANTRY. Where the equipment is NON-ISOCENTRIC the description of performance and test methods may need to be suitably adapted.

Note. — A statement of compliance with this Standard does not necessarily imply that these tests will be or have been applied as type tests or as individual tests.

1.3 *Environmental conditions*

1.3.1 *General*

Except where other allowable environmental conditions are stated in the ACCOMPANYING DOCUMENTS this particular standard applies to equipment installed, used or kept in locations where the following environmental conditions prevail:

a) the ambient temperature falls within the range 15 °C to 35 °C;

b) the relative humidity falls within the range 30% to 75%;

c) the atmospheric pressure falls within the range 7×10^4 Pa to 11×10^4 Pa (700 mbar to 1100 mbar).

1.3.2 *Transport and storage*

The allowable enivronmental conditions for transport and storage shall be stated in the ACCOMPANYING DOCUMENTS.

1.3.3 *Power supply*

Sub-clause 1.4*b)*2) of IEC Publication 601-1, first edition, 1977, applies.*

A sufficiently low internal impedance is needed to prevent voltage fluctuations between on-load and off-load steady states exceeding ±5%.

2 Terminology

2.1 *Definitions*

In this standard terms printed in SMALL CAPITALS are used as defined in IEC Publication 788.

New additional terms are listed in Appendix A.

An index of the terms referring to the above-mentioned source is also given in Appendix A.

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* See also Sub-clause 10.2.2 in the second edition, 1988.

2.2 *Degree of requirements*

In this Standard the auxiliary verb

— "shall" implies that compliance with a requirement is mandatory for compliance with the standard.

— "should" implies that compliance with a requirement is strongly recommended but is not 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.

3 General information to the USER

The ACCOMPANYING DOCUMENTS shall state all functional performance characteristics contained in Clauses 5 to 13 and the information required in Sub-clauses 3.1 to 3.8.

3.1 *Available NOMINAL ENERGIES and ABSORBED DOSE RATES*

The ACCOMPANYING DOCUMENTS shall state the available NOMINAL ENERGIES and the available associated ABSORBED DOSE RATES at NORMAL TREATMENT DISTANCE under conditions of maximum BUILD-UP in a PHANTOM for the maximum and 10 cm × 10 cm RADIATION FIELDS for both X-RADIATION and ELECTRON RADIATION.

3.2 *Available RADIATION FIELDS*

The ACCOMPANYING DOCUMENTS shall list the available RADIATION FIELDS in centimetres by centimetres at NORMAL TREATMENT DISTANCE for both X-RADIATION and ELECTRON RADIATION.

3.3 *NORMAL TREATMENT DISTANCE*

The ACCOMPANYING DOCUMENTS shall state the NORMAL TREATMENT DISTANCE in centimetres.

3.4 *Available FILTERS*

The ACCOMPANYING DOCUMENTS shall state for X-RADIATION and ELECTRON RADIATION the designation, the NOMINAL ENERGY and the maximum square RADIATION FIELD (square corners) of the available FIELD FLATTENING FILTERS.

For each available WEDGE FILTER for X-RADIATION the ACCOMPANYING DOCUMENTS shall state the

— designation,

— NOMINAL ENERGY,

— maximum RADIATION FIELD (for which the WEDGE FILTER is designed),

— WEDGE FILTER ANGLE,

— isodose value used for the determination of WEDGE FILTER ANGLE for the specified X-RAY FIELD,

— WEDGE FILTER FACTOR.

The ACCOMPANYING DOCUMENTS shall contain examples of isodose charts measured with the surface of the PHANTOM as indicated in Sub-clause 4.2 obtained using WEDGE FILTERS and FIELD FLATTENING FILTERS of the same design on an ELECTRON ACCELERATOR of the same specification.

Together with each isodose chart a warning shall be given that the values shown are only typical values and must not be used for the planning of the treatment of the PATIENT unless they have been verified by measurements on the individual ELECTRON ACCELERATOR.

3.5 *Availability*

The ACCOMPANYING DOCUMENTS shall state the time necessary to reach the READY STATE from the STAND-BY STATE.

3.6 *Influencing quantities*

The ACCOMPANYING DOCUMENTS shall state any information necessary concerning environmental conditions and extreme conditions of use (for example a maximum period of continuous operation) possibly affecting the functional performance characteristics contained in this standard.

3.7 *Maintenance*

The ACCOMPANYING DOCUMENTS shall contain information about the procedure necessary to enable the functional performance of the ELECTRON ACCELERATOR to be maintained within the values stated in this standard.

3.8 *Presentation*

The information to the USER required by this standard should be provided in the format shown in Appendix B.

4 Standardized test conditions

In determining functional performance characteristics in accordance with this standard, standardized test conditions given in Sub-clauses 4.1 to 4.5 shall prevail unless otherwise required.

4.1 *Angle settings*

The angles of

- the roll of the RADIATION HEAD, Axis ②,
- the pitch of the RADIATION HEAD, Axis ③,
- rotation of the BEAM LIMITING SYSTEM, Axis ④,

are at zero unless otherwise required. See Figures 1 to 3.

If in this standard the test conditions call for measurements to be made at angular positions of the GANTRY, Axis ①, or of the BEAM LIMITING SYSTEM, Axis ④, of 90° only, it is equally acceptable to use the angular position of 270°.

4.2 *Properties and positioning of the PHANTOM*

Unless otherwise required, the PHANTOM is a water PHANTOM. If a PHANTOM made of any other material is used, appropriate corrections shall be made.

For any test involving the use of a PHANTOM the surface of the PHANTOM is normal to the RADIATION BEAM AXIS.

The PHANTOM extends at least 5 cm outside the RADIATION BEAM unless it can be shown that a smaller PHANTOM does not significantly affect the results of the measurement.

The depth of the PHANTOM is at least 10 cm greater than the depth of the measuring point.

4.3 *Positioning of measuring points*

Measurements are made unless otherwise required

- on the RADIATION BEAM AXIS, or

— in a plane normal to the RADIATION BEAM AXIS at STANDARD MEASUREMENT DEPTHS in a PHANTOM,

whichever is appropriate.

For measurements in the X-RAY BEAM in ISOCENTRIC ELECTRON ACCELERATORS the measurement plane contains the ISOCENTRE, unless otherwise required. The surface of the PHANTOM is 10 cm from the ISOCENTRE in the direction to the RADIATION SOURCE.

For measurements both in the ELECTRON BEAMS and in the X-RAY BEAMS in NON-ISOCENTRIC ELECTRON ACCELERATORS the surface of the PHANTOM is at the NORMAL TREATMENT DISTANCE, unless otherwise required.

4.4 *RADIATION DETECTORS*

Measurements are made with a RADIATION DETECTOR

— from whose SCALE READINGS relative ABSORBED DOSE can be determined when corrections for spatial changes of the RADIATION SPECTRUM are made, and

— that has adequate spatial resolution in regions of high dose gradients, for example at the edges of the RADIATION FIELD.

4.5 *STANDARD MEASUREMENT DEPTHS*

4.5.1 *X-RAY BEAMS*

The STANDARD MEASUREMENT DEPTH for measurements in the X-RAY BEAM is 10 cm.

4.5.2 *ELECTRON BEAMS*

The STANDARD MEASUREMENT DEPTH for measurements in the ELECTRON BEAM is half the specified PENETRATIVE QUALITY for a 10 cm × 10 cm RADIATION FIELD.

4.6 *RADIATION FIELDS*

Where in the test procedure RADIATION FIELDS of specified sizes are not available, the nearest available RADIATION FIELDS should be used. The sizes of RADIATION FIELDS are quoted for the NORMAL TREATMENT DISTANCE.

Maximum RADIATION FIELD refers to the maximum square RADIATION FIELD, unless otherwise indicated.

4.7 *Adjustments during test*

During the course of any test procedure only those adjustments of the ELECTRON ACCELERATOR are permissible that can be carried out using controls normally accessible to the OPERATOR and which are regarded as forming part of the normal operation of the ELECTRON ACCELERATOR.

5 DOSE MONITORING SYSTEM

The ACCOMPANYING DOCUMENTS shall state the information to the USER required in Clause 5

— in the case of a PRIMARY-SECONDARY DOSE MONITORING SYSTEM: for the PRIMARY DOSE MONITORING SYSTEM,

— in the case of a REDUNDANT DOSE MONITORING SYSTEM: for both systems.