

SLOVENSKI STANDARD

SIST EN 60976:2002

01-februar-2002

BUXca Yý U
SIST HD 583 S1:1998

Medical electrical equipment - Medical electron accelerators - Functional performance characteristics

Medical electrical equipment - Medical electron accelerators - Functional performance characteristics

Medizinische elektrische Geräte - Medizinische Elektronenbeschleuniger - Apparative Qualitätsmerkmale

Appareils électromédicaux - Accélérateurs médicaux d'électrons - Caractéristiques fonctionnelles

<https://standards.iteh.ai/catalog/standards/sist/19d75396-fe7c-41b6-8136-62ae27caa066/sist-en-60976-2002>

Ta slovenski standard je istoveten z: **EN 60976:1999**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
13.280	Varstvo pred sevanjem	Radiation protection

SIST EN 60976:2002

en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN 60976:2002

<https://standards.iteh.ai/catalog/standards/sist/19d75396-fe7c-41b6-8136-62ae27caa066/sist-en-60976-2002>

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60976

May 1999

ICS 11.040.50

Supersedes HD 583 S1:1991

English version

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

Appareils électromédicaux
Accélérateurs médicaux d'électrons
Caractéristiques fonctionnelles
(CEI 60976:1989)

Medizinische elektrische Geräte
Medizinische Elektronenbeschleuniger
Apparative Qualitätsmerkmale
(IEC 60976:1989)

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN 60976:2002

<https://standards.iteh.ai/catalog/standards/sist/19d75396-fe7c-41b6-8136-62ae27caa066/sist-en-60976-2002>

This European Standard was approved by CENELEC on 1999-04-01. 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 the International Standard IEC 60976:1989, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was approved by CENELEC as HD 583 S1 on 1991-03-15.

This Harmonization Document was submitted to the formal vote for conversion into a European Standard and was approved by CENELEC as EN 60976 on 1999-04-01.

The following date was 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) 2000-04-01

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 60976:1989 was approved by CENELEC as a European Standard without any modification.

SIST EN 60976:2002

<https://standards.iteh.ai/catalog/standards/sist/19d75396-fe7c-41b6-8136-62ae27caa066/sist-en-60976-2002>

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 60601-1	1977	Safety of medical electrical equipment Part 1: General requirements	HD 395.1 S2 ¹⁾	1988
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 60601-2-1	1981	Part 2: Particular requirements for medical electron accelerators in the range 1 MeV to 50 MeV	-	-
A1	1984 ²⁾	Section 1: General Section 2: Radiation safety for equipment	-	-
IEC 60788	1984	Medical radiology - Terminology	HD 501 S1	1988
IEC 60977	1989	Medical electrical equipment - Medical electron accelerators in the range of 1 MeV to 50 MeV - Guidelines for functional performance characteristics	-	-

1) HD 395.1 S2 includes A1:1984 to IEC 60601-1.

2) IEC 60601-2-1:1998 is harmonized as EN 60601-2-1:1998.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN 60976:2002

<https://standards.iteh.ai/catalog/standards/sist/19d75396-fe7c-41b6-8136-62ae27caa066/sist-en-60976-2002>

**NORME
INTERNATIONALE
INTERNATIONAL
STANDARD**

**CEI
IEC
976**

Première édition
First edition
1989-10

Appareils électromédicaux

**Accélérateurs médicaux d'électrons –
Caractéristiques fonctionnelles**

iTeh STANDARD PREVIEW
Medical electrical equipment
(standards.iteh.ai)

**Medical electron accelerators –
Functional performance characteristics**

<https://standards.iteh.ai/catalog/standards/sist/19d75396-fe7c-41b6-8136-62ae27caa066/sist-en-60976-2002>

© CEI 1989 Droits de reproduction réservés — Copyright - all rights reserved

Aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'éditeur.

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher

Bureau central de la Commission Electrotechnique Internationale 3, rue de Varembé Genève Suisse



Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE

XB

Pour prix, voir catalogue en vigueur
For price, see current catalogue

CONTENTS

	Page
FOREWORD	7
PREFACE	7
INTRODUCTION	9
Clause	
1 Scope and object	9
1.1 Scope	9
1.2 Object	9
1.3 Environmental conditions	11
2 Terminology	11
2.1 Definitions	11
2.2 Degree of requirements	13
3 General information to the USER	13
3.1 Available NOMINAL ENERGIES and ABSORBED DOSE RATES	13
3.2 Available RADIATION FIELDS	13
3.3 NORMAL TREATMENT DISTANCE	13
3.4 Available FILTERS	13
3.5 Availability	15
3.6 Influencing quantities	15
3.7 Maintenance	15
3.8 Presentation	15
4 Standardized test conditions	15
4.1 Angle settings	15
4.2 Properties and positioning of the PHANTOM	15
4.3 Positioning of measuring points	15
4.4 RADIATION DETECTORS	17
4.5 STANDARD MEASUREMENT DEPTHS	17
4.6 RADIATION FIELDS	17
4.7 Adjustments during test	17
5 DOSE MONITORING SYSTEM	17
5.1 Reproducibility	19
5.2 Proportionality	21
5.3 Dependence on angular positions	21
5.4 Dependence on GANTRY rotation	25
5.5 Dependence on the shape of the RADIATION FIELD	25
5.6 Stability of calibration	27
5.7 Stability in MOVING BEAM RADIOTHERAPY	31
6 Depth ABSORBED DOSE characteristics	33
6.1 X-RADIATION	33
6.2 ELECTRON RADIATION	37
7 Uniformity of RADIATION FIELDS	41
7.1 X-RADIATION	41
7.2 ELECTRON RADIATION	51
7.3 Penumbra of RADIATION FIELDS	55
8 Indication of RADIATION FIELDS	57
8.1 X-RADIATION	57
8.2 ELECTRON RADIATION	63
8.3 Geometry of the BEAM LIMITING SYSTEM for X-RADIATION	67
8.4 Illuminance and penumbra of the LIGHT FIELD	67
9 Indication of the RADIATION BEAM AXIS	69
9.1 Indication on entry to the PATIENT	69
9.2 Indication on exit from the PATIENT	73

Clause	Page
10 ISOCENTRE	73
10.1 Displacement of the RADIATION BEAM AXIS from the ISOCENTRE	73
10.2 Indication of the ISOCENTRE	77
11 Indication of distance along the RADIATION BEAM AXIS	77
11.1 Indicating device	77
11.2 Additional indicating device for equipment with variable distance between RADIATION SOURCE and ISOCENTRE and for NON-ISOCENTRIC equipment	79
12 Zero position of rotational scales	79
12.1 Information to the USER	81
12.2 Tests	81
13 Congruence of opposed RADIATION FIELDS	83
13.1 Information to the USER	83
13.2 Test	83
14 Movements of the PATIENT table	83
14.1 Vertical movement of the table	87
14.2 ISOCENTRIC rotation of the table	87
14.3 Parallelism of table rotational axes	87
14.4 Rigidity of the table	89
FIGURES 1 to 9	93
APPENDIX A — Terminology	111
APPENDIX B — Format for presentation of functional performance values	123

iTeh STANDARD PREVIEW

(standards.iteh.ai)

SIST EN 60976:2002

<https://standards.iteh.ai/catalog/standards/sist/19d75396-fe7c-41b6-8136-62ae27caa066/sist-en-60976-2002>

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:

SIST EN 60976:2002

<https://standards.iteh.ai/catalog/standards/sist/19d75396-67a-41b6-8136-62ae27eaa066/sist-en-60976-2002>

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

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

1 Scope and object

1.1 Scope

SIST EN 60976:2002

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 environmental conditions for transport and storage shall be stated in the ACCOMPANYING DOCUMENTS.

1.3.3 *Power supply*

Sub-clause 1.4b)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 $\pm 5\%$.

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.

* 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.

iTeh STANDARD PREVIEW

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.

[SIST EN 60976:2002](https://standards.iteh.ai/catalog/standards/sist/19d75396-fe7c-41b6-8136-62ae27caa066/sist-en-60976-2002)

[https://standards.iteh.ai/catalog/standards/sist/19d75396-fe7c-41b6-8136-](https://standards.iteh.ai/catalog/standards/sist/19d75396-fe7c-41b6-8136-62ae27caa066/sist-en-60976-2002)

[62ae27caa066/sist-en-60976-2002](https://standards.iteh.ai/catalog/standards/sist/19d75396-fe7c-41b6-8136-62ae27caa066/sist-en-60976-2002)

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.