SLOVENSKI STANDARD
SIST EN 60976:2002/A1:2002

01-februar-2002

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

Ta slovenski standard je istoveten z: **EN 60976:1999/A1:2000**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
13.280	Varstvo pred sevanjem	Radiation protection

SIST EN 60976:2002/A1:2002 **en**

EUROPEAN STANDARD **EN 60976/A1**

NORME EUROPÉENNE

EUROPÄISCHE NORM December 2000

ICS 11.040.50;13.280

English version

Medical electrical equipment - Medical electron accelerators - Functional performance characteristics
(IEC 60976:1989/A1:2000)

Appareils électromédicaux - Accélérateurs médicaux d'électrons - Caractéristiques fonctionnelles (CEI 60976:1989/A1:2000)

Medizinische elektrische Geräte - Medizinische Elektronenbeschleuniger - Apparative Qualitätsmerkmale (IEC 60976:1989/A1:2000)

This amendment A1 modifies the European Standard EN 60976:1999; it was approved by CENELEC on 2000-11-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 amendment 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/276/FDIS, future amendment 1 to 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 submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as amendment A1 to EN 60976:1999 on 2000-11-01.

The following dates were fixed:

- latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2001-08-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 2003-11-01

This European Standard is to be read in conjunction with EN 60601-2-1.

Endorsement notice

The text of amendment 1:2000 to the International Standard IEC 60976:1989 was approved by CENELEC as an amendment to the European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

Publication	Year	Title	EN/HD	Year
Add:				
IEC 61217	1996	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	1996

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
60976

1989

AMENDEMENT 1
AMENDMENT 1
2000-07

Amendement 1

Appareils électromédicaux –

Accélérateurs médicaux d'électrons – Caractéristiques fonctionnelles

Amendment 1

Medical electrical equipment –

Medical electron accelerators – Functional performance characteristics

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Международная Электротехническая Комиссия

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FOREWORD

This amendment 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 amendment is based on the following documents:

FDIS	Report on voting
62C/276/FDIS	62C/278/RVD

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

Introduction to this amendment

Since this International Standard was first published in 1989, multi-element BEAM LIMITING DEVICES (BLDs) have been introduced and are now widely used for determining the shape of the RADIATION FIELD, with or without the use of back-up BLDs. A multi-element BLD may produce rectangular, symmetrical or asymmetrical and irregular RADIATION FIELDS. In some cases, the multi-element BLD takes the place of one or more of the standard BLD pairs of jaws, in other cases, the multi-element BLD may serve as a tertiary device, in addition to the standard BLDs. In addition to the shaping of X-RAY FIELDS, multi-element BLDs may, in some cases, be used for shaping ELECTRON FIELDS, with or without ELECTRON BEAM APPLICATORS.

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PREFACE

Add, to the existing preface and before the list of IEC publications, the following new text:

This standard, together with IEC 60977, should be read in conjunction with IEC 60601-2-1.

Add to the list of publications, the following new standard:

IEC 61217:1996; *Radiotherapy equipment – Coordinates, movements and scales*

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3.2 Available RADIATION FIELDS

Add, at the end of this subclause, the following new text:

For a multi-element BLD, the ACCOMPANYING DOCUMENTS shall state:

- the number of elements;
- their dimensions projected to the NORMAL TREATMENT DISTANCE;
- the dimensions of their minimum and maximum RADIATION FIELD sizes, with coordinates stated along axes Xb and Yb (see IEC 61217); and
- the location of these RADIATION FIELDS in relation to the REFERENCE AXIS.

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Add, after 3.8, the following new subclause 3.9:

3.9 Dimensions, shapes, clearances, within the RADIATION HEAD, and in the region RADIATION HEAD to ISOCENTRE, of BEAM LIMITING DEVICES

For multi-element BLDs, the ACCOMPANYING DOCUMENTS shall include an EQUIPMENT layout drawing with all dimensions indicated in centimetres, in which is detailed the following information:

- the NORMAL TREATMENT DISTANCE;
- the distances from the X-RADIATION SOURCE (front surface of the X-RADIATION TARGET), or ELECTRON RADIATION window, if applicable, to the proximal or distal surfaces of all BLDs, including any of the multi-element type;
- the thicknesses of all BLDs; and
- the dimensions, and location, relative to the NORMAL TREATMENT DISTANCE or to the X-RADIATION source, of
  - the fixed RADIATION HEAD surface, proximal to the NORMAL TREATMENT DISTANCE, to which demountable ACCESSORIES may be attached, and
  - any combinations of demountable or fixed RADIATION HEAD ACCESSORY structures, and RADIATION FIELD shaping devices such as ELECTRON BEAM APPLICATORS, WEDGE FILTERS, RADIATION FIELD shaping blocks or jaws, including those used in conjunction with multi-element BLDs.

See figure 10 which provides an example of the layout of a RADIATION HEAD, with multi-element BLD (in this case a tertiary type) and several X-RADIATION ACCESSORIES. Where a multi-element BLD is used with ELECTRON RADIATION, a similar layout diagram, with multi-element BLD and/or ELECTRON BEAM APPLICATOR, and any other ELECTRON RADIATION ACCESSORIES included, shall also be provided.